Cemiplimab (LIBTAYO®)

Regeneron GmbH

Anhang 4-G zu Modul 4 A

Monotherapie zur adjuvanten Behandlung von erwachsenen Patienten mit kutanem Plattenepithelkarzinom (cSCC) und hohem Rezidivrisiko nach Operation und Bestrahlung

Stand: 12.12.2025

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1 Ergänzende Analysen Hauptteil

1.1 EORTC QLQ-C30

1.1.1 1. Datenschnitt

Table 2.1.1: Completion rate at instrument level-EORTC QLQ-C30
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

[a] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADQS. Extract date: 04Oct2024.
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Table 2.1.2: Completion rate at scale level-EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.3: Completion rate at scale level-EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.4: Completion rate at scale level-EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.5: Completion rate at scale level-EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.6: Completion rate at scale level-EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.7: Completion rate at scale level-EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.8: Completion rate at scale level-EORTC QLQ-C30 Fatigue scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.9: Completion rate at scale level-EORTC QLQ-C30 Pain scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.10: Completion rate at scale level-EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	189 (93.1%)	189 (91.7%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.11: Completion rate at scale level-EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.12: Completion rate at scale level-EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.13: Completion rate at scale level-EORTC QLQ-C30 Insomnia scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.14: Completion rate at scale level-EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.15: Completion rate at scale level-EORTC QLQ-C30 Constipation scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table 2.1.16: Completion rate at scale level-EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	175	156 (89.1%)	156 (74.6%)
Cycle 3 - Day 1	155	140 (90.3%)	140 (67.0%)
Cycle 4 - Day 1	138	125 (90.6%)	125 (59.8%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	179	159 (88.8%)	159 (77.2%)
Cycle 3 - Day 1	146	132 (90.4%)	132 (64.1%)
Cycle 4 - Day 1	123	116 (94.3%)	116 (56.3%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 04Oct2024.

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Table A2.1.1: Completion rate at instrument level-EORTC QLQ-C30
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

[a] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:23.

Table A2.1.2: Completion rate at scale level-EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	142 (82.6%)	142 (67.9%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:29.

Table A2.1.3: Completion rate at scale level-EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	113 (79.0%)	113 (54.1%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:34.

Table A2.1.4: Completion rate at scale level-EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:39.

Table A2.1.5: Completion rate at scale level-EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:44.

Table A2.1.6: Completion rate at scale level-EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:49.

Table A2.1.7: Completion rate at scale level-EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	141 (82.0%)	141 (67.5%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:32:55.

Table A2.1.8: Completion rate at scale level-EORTC QLQ-C30 Fatigue scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:00.

Table A2.1.9: Completion rate at scale level-EORTC QLQ-C30 Pain scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:05.

Table A2.1.10: Completion rate at scale level-EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	142 (82.6%)	142 (67.9%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:10.

Table A2.1.11: Completion rate at scale level-EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:15.

Table A2.1.12: Completion rate at scale level-EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:20.

Table A2.1.13: Completion rate at scale level-EORTC QLQ-C30 Insomnia scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:26.

Table A2.1.14: Completion rate at scale level-EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:31.

Table A2.1.15: Completion rate at scale level-EORTC QLQ-C30 Constipation scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:36.

Table A2.1.16: Completion rate at scale level-EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	143 (83.1%)	143 (68.4%)
FOLLOW-UP VISIT 1	143	114 (79.7%)	114 (54.5%)
FOLLOW-UP VISIT 2	131	107 (81.7%)	107 (51.2%)
FOLLOW-UP VISIT 3	117	87 (74.4%)	87 (41.6%)
FOLLOW-UP VISIT 4	97	72 (74.2%)	72 (34.4%)
FOLLOW-UP VISIT 5	79	56 (70.9%)	56 (26.8%)
FOLLOW-UP VISIT 6	57	41 (71.9%)	41 (19.6%)
FOLLOW-UP VISIT 7	40	26 (65.0%)	26 (12.4%)
FOLLOW-UP VISIT 8	30	22 (73.3%)	22 (10.5%)
FOLLOW-UP VISIT 9	14	8 (57.1%)	8 (3.8%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	139 (80.8%)	139 (67.5%)
FOLLOW-UP VISIT 1	139	80 (57.6%)	80 (38.8%)
FOLLOW-UP VISIT 2	124	70 (56.5%)	70 (34.0%)
FOLLOW-UP VISIT 3	103	60 (58.3%)	60 (29.1%)
FOLLOW-UP VISIT 4	86	45 (52.3%)	45 (21.8%)
FOLLOW-UP VISIT 5	70	33 (47.1%)	33 (16.0%)
FOLLOW-UP VISIT 6	56	28 (50.0%)	28 (13.6%)
FOLLOW-UP VISIT 7	39	23 (59.0%)	23 (11.2%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:41.

Table 4.1.1: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	76.22 (16.93)	74.85 (16.80)	-1.95 (1.18), [-4.27, 0.36]	163	76.02 (16.81)	75.48 (16.42)	-1.02 (1.22), [-3.42, 1.39]	-0.83	-0.94 [-3.65, 1.77], 0.496	-0.07 [-0.29, 0.14]
Cycle 2 - Day 1	151	77.10 (16.22)	75.22 (19.95)	-2.36 (1.41), [-5.14, 0.42]	153	75.65 (16.95)	75.22 (18.01)	-1.28 (1.43), [-4.10, 1.54]	-1.44	-1.08 [-4.50, 2.35], 0.537	-0.07 [-0.30, 0.15]
Cycle 3 - Day 1	136	75.74 (17.29)	74.45 (17.86)	-2.29 (1.39), [-5.02, 0.45]	123	77.17 (15.64)	77.37 (16.75)	-0.44 (1.45), [-3.30, 2.42]	-1.49	-1.85 [-5.29, 1.60], 0.293	-0.13 [-0.37, 0.11]
Cycle 4 - Day 1	127	76.31 (17.04)	75.72 (19.13)	-1.22 (1.49), [-4.15, 1.72]	110	77.35 (15.56)	76.06 (17.53)	-1.32 (1.59), [-4.44, 1.80]	0.70	0.11 [-3.73, 3.94], 0.956	0.01 [-0.25, 0.26]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 4.1.2: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	87.40 (15.91)	87.94 (14.28)	-1.39 (0.94), [-3.24, 0.46]	163	91.04 (12.69)	89.26 (12.50)	-1.92 (0.98), [-3.85, 0.00]	2.33	0.53 [-1.65, 2.72], 0.630	0.05 [-0.16, 0.27]
Cycle 2 - Day 1	151	88.17 (14.32)	87.99 (15.64)	-1.58 (1.11), [-3.76, 0.60]	153	90.63 (12.97)	88.10 (14.20)	-3.18 (1.13), [-5.41, -0.96]	2.35	1.60 [-1.09, 4.30], 0.242	0.13 [-0.09, 0.36]
Cycle 3 - Day 1	136	87.11 (16.15)	87.84 (15.54)	-1.23 (1.08), [-3.34, 0.89]	123	92.90 (11.15)	91.33 (11.48)	-1.11 (1.13), [-3.33, 1.11]	2.31	-0.12 [-2.79, 2.55], 0.930	-0.01 [-0.25, 0.23]
Cycle 4 - Day 1	127	87.24 (14.93)	87.66 (14.93)	-1.35 (1.08), [-3.47, 0.77]	110	92.91 (10.70)	91.03 (10.93)	-1.47 (1.14), [-3.73, 0.78]	2.30	0.12 [-2.59, 2.83], 0.931	0.01 [-0.24, 0.27]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 4.1.3: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	84.25 (24.92)	82.08 (20.94)	-4.23 (1.53), [-7.25, -1.21]	163	84.56 (20.58)	84.36 (19.97)	-1.62 (1.59), [-4.76, 1.51]	-1.96	-2.61 [-6.15, 0.93], 0.148	-0.16 [-0.38, 0.06]
Cycle 2 - Day 1	151	85.54 (23.47)	83.77 (23.64)	-3.29 (1.79), [-6.80, 0.23]	153	84.53 (20.51)	83.33 (22.38)	-2.93 (1.82), [-6.50, 0.64]	-0.57	-0.36 [-4.65, 3.93], 0.870	-0.02 [-0.24, 0.21]
Cycle 3 - Day 1	136	83.09 (25.42)	81.86 (24.72)	-3.76 (1.84), [-7.39, -0.13]	123	87.67 (18.21)	85.77 (20.76)	-1.87 (1.93), [-5.67, 1.93]	0.67	-1.89 [-6.50, 2.72], 0.421	-0.10 [-0.34, 0.14]
Cycle 4 - Day 1	127	83.60 (24.67)	80.18 (23.55)	-5.66 (1.84), [-9.29, -2.03]	110	88.79 (16.76)	88.33 (16.67)	-0.08 (1.96), [-3.93, 3.77]	-2.96	-5.58 [-10.25, -0.91], 0.019	-0.30 [-0.56, -0.05]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.4: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	84.76 (18.54)	84.76 (19.01)	0.24 (1.23), [-2.19, 2.67]	163	85.17 (16.64)	84.47 (15.31)	-0.43 (1.28), [-2.94, 2.08]	0.71	0.67 [-2.16, 3.50], 0.642	0.05 [-0.17, 0.27]
Cycle 2 - Day 1	151	85.10 (18.32)	84.16 (21.16)	-0.79 (1.38), [-3.50, 1.91]	153	85.35 (16.99)	85.46 (15.34)	0.72 (1.40), [-2.04, 3.48]	-1.05	-1.52 [-4.77, 1.74], 0.361	-0.10 [-0.33, 0.12]
Cycle 3 - Day 1	136	85.23 (18.03)	84.93 (19.79)	0.98 (1.48), [-1.93, 3.89]	123	86.25 (14.35)	84.21 (17.49)	-1.18 (1.54), [-4.21, 1.85]	1.73	2.16 [-1.52, 5.84], 0.249	0.14 [-0.10, 0.39]
Cycle 4 - Day 1	127	85.30 (17.04)	84.58 (21.65)	0.54 (1.47), [-2.36, 3.43]	110	85.68 (15.56)	84.02 (18.10)	-0.82 (1.56), [-3.89, 2.24]	0.94	1.36 [-2.35, 5.07], 0.470	0.09 [-0.16, 0.35]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.5: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	87.80 (16.10)	86.91 (16.73)	-0.82 (1.15), [-3.08, 1.45]	163	89.67 (15.95)	88.41 (14.75)	-0.77 (1.19), [-3.11, 1.57]	0.36	-0.05 [-2.70, 2.61], 0.973	0.00 [-0.22, 0.21]
Cycle 2 - Day 1	151	87.86 (15.98)	86.53 (18.73)	-1.19 (1.27), [-3.69, 1.31]	153	89.76 (15.78)	88.89 (16.33)	-0.21 (1.29), [-2.75, 2.33]	-0.45	-0.98 [-3.98, 2.02], 0.521	-0.07 [-0.30, 0.15]
Cycle 3 - Day 1	136	87.38 (16.79)	86.89 (19.50)	-0.20 (1.34), [-2.84, 2.44]	123	91.19 (13.88)	88.89 (14.42)	-0.74 (1.39), [-3.48, 2.01]	1.81	0.54 [-2.78, 3.86], 0.749	0.04 [-0.20, 0.28]
Cycle 4 - Day 1	127	87.01 (16.66)	86.22 (19.26)	-1.06 (1.44), [-3.89, 1.78]	110	90.76 (13.66)	87.58 (16.66)	-1.36 (1.52), [-4.35, 1.62]	2.39	0.31 [-3.37, 3.99], 0.869	0.02 [-0.23, 0.28]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.6: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	84.35 (21.02)	85.72 (18.34)	0.39 (1.41), [-2.39, 3.16]	163	86.81 (19.11)	86.98 (18.54)	0.93 (1.45), [-1.93, 3.78]	1.20	-0.54 [-3.78, 2.70], 0.743	-0.04 [-0.25, 0.18]
Cycle 2 - Day 1	151	85.43 (20.21)	86.53 (21.41)	0.90 (1.59), [-2.22, 4.02]	153	87.04 (19.04)	86.17 (21.01)	-0.15 (1.61), [-3.31, 3.02]	1.98	1.05 [-2.72, 4.82], 0.584	0.06 [-0.16, 0.29]
Cycle 3 - Day 1	136	83.95 (21.12)	85.78 (20.34)	0.97 (1.71), [-2.39, 4.33]	123	89.70 (16.32)	89.43 (17.63)	2.23 (1.77), [-1.26, 5.72]	2.11	-1.26 [-5.54, 3.02], 0.562	-0.07 [-0.32, 0.17]
Cycle 4 - Day 1	127	84.12 (20.13)	83.73 (23.05)	-0.71 (1.77), [-4.20, 2.78]	110	90.00 (15.67)	88.18 (17.97)	0.70 (1.87), [-2.97, 4.37]	1.42	-1.41 [-5.95, 3.14], 0.542	-0.08 [-0.33, 0.18]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.7: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Fatigue scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	20.05 (19.34)	23.33 (19.03)	4.95 (1.38), [2.23, 7.67]	163	19.50 (19.13)	22.11 (17.23)	4.19 (1.43), [1.37, 7.01]	0.66	0.76 [-2.43, 3.96], 0.639	0.05 [-0.17, 0.27]
Cycle 2 - Day 1	151	19.57 (18.62)	22.88 (20.17)	4.97 (1.52), [1.97, 7.97]	153	19.54 (19.37)	22.15 (18.58)	4.16 (1.55), [1.11, 7.21]	0.70	0.81 [-2.79, 4.41], 0.659	0.05 [-0.17, 0.28]
Cycle 3 - Day 1	136	20.67 (19.79)	24.67 (22.25)	5.47 (1.67), [2.18, 8.77]	123	17.25 (17.95)	20.51 (19.19)	2.95 (1.75), [-0.49, 6.39]	0.75	2.53 [-1.67, 6.72], 0.237	0.15 [-0.10, 0.39]
Cycle 4 - Day 1	127	21.17 (19.67)	23.71 (20.83)	4.41 (1.73), [1.02, 7.81]	110	16.46 (17.14)	22.63 (20.13)	5.46 (1.83), [1.86, 9.06]	-3.62	-1.05 [-5.48, 3.38], 0.641	-0.06 [-0.32, 0.19]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.8: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Pain scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	13.92 (20.66)	15.23 (21.58)	3.24 (1.68), [-0.06, 6.54]	163	12.47 (18.73)	14.09 (18.97)	2.14 (1.73), [-1.27, 5.55]	-0.31	1.10 [-2.76, 4.96], 0.575	0.06 [-0.16, 0.28]
Cycle 2 - Day 1	151	13.25 (19.84)	14.02 (23.10)	2.32 (1.83), [-1.28, 5.91]	153	12.96 (19.14)	14.05 (19.69)	2.46 (1.86), [-1.21, 6.12]	-0.32	-0.14 [-4.44, 4.17], 0.950	-0.01 [-0.23, 0.22]
Cycle 3 - Day 1	136	13.85 (20.74)	16.67 (26.76)	4.05 (2.11), [-0.09, 8.19]	123	11.92 (16.87)	11.65 (19.67)	1.35 (2.20), [-2.97, 5.68]	3.09	2.69 [-2.64, 8.03], 0.321	0.12 [-0.12, 0.37]
Cycle 4 - Day 1	127	13.12 (19.99)	15.49 (24.32)	3.35 (1.91), [-0.41, 7.12]	110	12.73 (18.61)	12.88 (18.84)	2.61 (2.01), [-1.35, 6.56]	2.21	0.75 [-3.99, 5.48], 0.756	0.04 [-0.22, 0.30]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.9: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	11.18 (20.98)	10.60 (18.61)	-0.68 (1.34), [-3.33, 1.96]	162	10.91 (20.63)	9.33 (19.01)	-2.40 (1.39), [-5.14, 0.34]	1.00	1.71 [-1.39, 4.82], 0.278	0.12 [-0.10, 0.34]
Cycle 2 - Day 1	151	11.48 (21.45)	10.60 (21.56)	-1.28 (1.46), [-4.14, 1.59]	152	10.96 (20.93)	10.09 (21.03)	-1.41 (1.49), [-4.35, 1.52]	-0.01	0.14 [-3.29, 3.57], 0.938	0.01 [-0.22, 0.23]
Cycle 3 - Day 1	136	11.27 (20.78)	11.76 (22.78)	0.71 (1.62), [-2.47, 3.89]	122	9.29 (18.81)	7.65 (18.07)	-2.40 (1.69), [-5.72, 0.91]	2.13	3.11 [-0.92, 7.15], 0.130	0.19 [-0.06, 0.43]
Cycle 4 - Day 1	127	12.07 (21.28)	10.50 (20.45)	-1.49 (1.62), [-4.69, 1.71]	109	7.95 (16.91)	6.42 (15.37)	-3.38 (1.73), [-6.78, 0.01]	-0.05	1.89 [-2.25, 6.03], 0.369	0.12 [-0.14, 0.37]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.10: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	2.03 (6.85)	2.98 (7.38)	1.18 (0.69), [-0.18, 2.54]	163	2.15 (6.18)	3.12 (8.32)	1.36 (0.72), [-0.05, 2.77]	-0.02	-0.18 [-1.78, 1.42], 0.826	-0.02 [-0.24, 0.19]
Cycle 2 - Day 1	151	1.66 (5.69)	2.87 (8.34)	1.34 (0.85), [-0.34, 3.02]	153	2.18 (6.25)	3.81 (10.73)	1.93 (0.86), [0.23, 3.64]	-0.42	-0.60 [-2.69, 1.50], 0.575	-0.06 [-0.29, 0.16]
Cycle 3 - Day 1	136	1.96 (7.04)	2.33 (6.78)	0.80 (0.78), [-0.74, 2.33]	123	2.03 (5.88)	3.12 (9.86)	1.09 (0.81), [-0.51, 2.69]	-0.72	-0.29 [-2.20, 1.62], 0.764	-0.04 [-0.28, 0.21]
Cycle 4 - Day 1	127	1.84 (7.04)	3.02 (11.39)	1.41 (0.96), [-0.49, 3.30]	110	1.52 (4.81)	2.73 (7.67)	1.06 (1.03), [-0.96, 3.08]	-0.03	0.35 [-2.18, 2.89], 0.784	0.04 [-0.22, 0.29]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

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Table 4.1.11: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	8.94 (19.92)	9.72 (18.98)	1.80 (1.41), [-0.99, 4.58]	163	7.36 (15.28)	9.48 (16.90)	2.01 (1.46), [-0.87, 4.89]	-1.33	-0.21 [-3.47, 3.04], 0.897	-0.01 [-0.23, 0.20]
Cycle 2 - Day 1	151	8.39 (18.55)	9.49 (21.56)	1.49 (1.58), [-1.62, 4.59]	153	7.41 (15.40)	10.02 (19.15)	2.71 (1.61), [-0.45, 5.87]	-1.51	-1.22 [-4.97, 2.53], 0.522	-0.07 [-0.30, 0.15]
Cycle 3 - Day 1	136	9.31 (20.56)	10.05 (19.59)	1.56 (1.60), [-1.58, 4.70]	123	7.05 (14.94)	8.13 (17.77)	0.72 (1.66), [-2.55, 3.99]	-0.35	0.84 [-3.06, 4.74], 0.672	0.05 [-0.19, 0.30]
Cycle 4 - Day 1	127	8.40 (19.68)	10.76 (21.37)	2.34 (1.73), [-1.07, 5.75]	110	7.27 (14.55)	9.39 (16.36)	2.60 (1.83), [-1.00, 6.20]	0.24	-0.26 [-4.65, 4.13], 0.907	-0.02 [-0.27, 0.24]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 4.1.12: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Insomnia scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	19.72 (25.26)	19.61 (23.25)	1.86 (1.82), [-1.72, 5.45]	163	17.79 (25.74)	18.20 (22.57)	1.24 (1.89), [-2.48, 4.95]	-0.51	0.63 [-3.58, 4.83], 0.769	0.03 [-0.18, 0.25]
Cycle 2 - Day 1	151	19.43 (24.75)	18.54 (26.00)	0.34 (2.01), [-3.61, 4.29]	153	17.86 (26.22)	16.56 (23.61)	-0.76 (2.05), [-4.79, 3.27]	0.42	1.10 [-3.65, 5.85], 0.649	0.05 [-0.17, 0.28]
Cycle 3 - Day 1	136	19.85 (25.13)	22.55 (26.57)	3.04 (2.18), [-1.25, 7.33]	123	17.34 (25.73)	18.70 (25.66)	0.48 (2.27), [-3.99, 4.95]	1.34	2.55 [-2.88, 7.99], 0.356	0.11 [-0.13, 0.36]
Cycle 4 - Day 1	127	18.37 (24.02)	20.73 (28.46)	2.21 (2.31), [-2.34, 6.76]	110	18.79 (25.75)	22.42 (26.37)	3.99 (2.45), [-0.84, 8.82]	-1.27	-1.77 [-7.72, 4.17], 0.557	-0.08 [-0.33, 0.18]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 4.1.13: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	15.65 (23.18)	12.47 (19.89)	-0.88 (1.59), [-4.00, 2.25]	163	14.72 (23.74)	10.94 (19.88)	-2.01 (1.65), [-5.25, 1.24]	0.60	1.13 [-2.51, 4.77], 0.542	0.07 [-0.15, 0.28]
Cycle 2 - Day 1	151	15.01 (22.34)	14.57 (24.21)	1.20 (1.88), [-2.49, 4.89]	153	14.81 (23.84)	12.64 (23.26)	-0.31 (1.91), [-4.06, 3.44]	1.74	1.52 [-3.01, 6.04], 0.510	0.08 [-0.15, 0.30]
Cycle 3 - Day 1	136	14.95 (22.89)	12.25 (22.52)	-1.47 (1.90), [-5.21, 2.26]	123	13.82 (22.15)	10.57 (21.47)	-2.65 (1.98), [-6.55, 1.26]	0.56	1.17 [-3.54, 5.89], 0.624	0.06 [-0.18, 0.30]
Cycle 4 - Day 1	127	15.75 (23.32)	11.02 (21.44)	-2.36 (1.88), [-6.07, 1.35]	110	12.42 (21.11)	9.39 (19.23)	-3.06 (2.00), [-7.00, 0.88]	-1.69	0.70 [-4.04, 5.44], 0.771	0.04 [-0.22, 0.29]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 4.1.14: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Constipation scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	11.18 (19.28)	9.59 (16.26)	-1.56 (1.29), [-4.10, 0.98]	163	9.61 (19.85)	9.10 (15.76)	-0.58 (1.33), [-3.21, 2.05]	-1.08	-0.98 [-3.95, 1.99], 0.516	-0.07 [-0.29, 0.15]
Cycle 2 - Day 1	151	11.04 (19.14)	9.27 (19.31)	-1.50 (1.56), [-4.57, 1.57]	153	10.24 (20.33)	8.71 (17.84)	-1.85 (1.58), [-4.96, 1.26]	-0.24	0.35 [-3.44, 4.14], 0.855	0.02 [-0.20, 0.25]
Cycle 3 - Day 1	136	11.52 (19.19)	9.31 (18.00)	-0.97 (1.56), [-4.04, 2.11]	123	6.50 (15.77)	9.49 (17.35)	-0.34 (1.64), [-3.57, 2.88]	-5.19	-0.62 [-4.56, 3.31], 0.755	-0.04 [-0.28, 0.21]
Cycle 4 - Day 1	127	12.07 (20.00)	9.45 (18.26)	-2.21 (1.53), [-5.22, 0.80]	110	7.88 (18.02)	9.39 (19.23)	0.46 (1.62), [-2.72, 3.64]	-4.14	-2.67 [-6.52, 1.18], 0.173	-0.18 [-0.43, 0.08]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 4.1.15: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	164	3.05 (11.57)	5.08 (11.00)	2.88 (1.09), [0.73, 5.02]	163	3.89 (11.35)	5.28 (11.46)	2.77 (1.13), [0.54, 5.00]	0.64	0.10 [-2.43, 2.64], 0.935	0.01 [-0.21, 0.23]
Cycle 2 - Day 1	151	2.87 (11.51)	4.64 (12.79)	2.08 (1.28), [-0.44, 4.61]	153	3.92 (11.43)	6.10 (15.02)	3.37 (1.30), [0.80, 5.93]	-0.41	-1.28 [-4.39, 1.83], 0.418	-0.09 [-0.32, 0.13]
Cycle 3 - Day 1	136	2.94 (11.81)	4.17 (12.46)	1.46 (1.27), [-1.05, 3.97]	123	3.79 (10.63)	5.15 (14.80)	2.07 (1.33), [-0.55, 4.69]	-0.13	-0.61 [-3.77, 2.56], 0.705	-0.05 [-0.29, 0.20]
Cycle 4 - Day 1	127	2.62 (9.01)	7.87 (19.90)	5.08 (1.60), [1.93, 8.23]	110	3.64 (11.37)	5.76 (12.66)	2.88 (1.70), [-0.48, 6.23]	3.13	2.20 [-2.06, 6.47], 0.309	0.13 [-0.12, 0.39]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table A4.1.1.1: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-3.86 (1.10), [-6.03, -1.69]	-3.02 (1.19), [-5.35, -0.68]	-0.85 [-3.51, 1.82], 0.532
Month 3	-3.61 (1.18), [-5.92, -1.29]	-3.35 (1.23), [-5.76, -0.93]	-0.26 [-3.11, 2.59], 0.858
Month 6	-3.67 (1.13), [-5.89, -1.45]	-3.24 (1.18), [-5.57, -0.92]	-0.42 [-3.12, 2.27], 0.757
Month 9	-3.73 (1.10), [-5.90, -1.56]	-3.14 (1.16), [-5.42, -0.86]	-0.59 [-3.21, 2.03], 0.658
Month 12	-3.79 (1.10), [-5.95, -1.63]	-3.04 (1.17), [-5.34, -0.73]	-0.75 [-3.38, 1.87], 0.572
Month 15	-3.85 (1.11), [-6.04, -1.66]	-2.93 (1.21), [-5.31, -0.56]	-0.92 [-3.63, 1.79], 0.506
Month 18	-3.91 (1.15), [-6.17, -1.65]	-2.83 (1.27), [-5.33, -0.33]	-1.08 [-3.96, 1.80], 0.459
Month 21	-3.97 (1.20), [-6.34, -1.61]	-2.73 (1.36), [-5.39, -0.06]	-1.25 [-4.36, 1.86], 0.430
Month 24	-4.03 (1.27), [-6.54, -1.53]	-2.62 (1.46), [-5.50, 0.25]	-1.41 [-4.81, 1.98], 0.412
Month 27	-4.10 (1.36), [-6.77, -1.42]	-2.52 (1.58), [-5.63, 0.59]	-1.58 [-5.29, 2.14], 0.403
Month 30	-4.16 (1.45), [-7.03, -1.29]	-2.41 (1.71), [-5.78, 0.95]	-1.74 [-5.81, 2.32], 0.399
Month 33	-4.22 (1.56), [-7.30, -1.14]	-2.31 (1.85), [-5.95, 1.33]	-1.91 [-6.35, 2.53], 0.398
Month 36	-4.28 (1.67), [-7.58, -0.98]	-2.21 (1.99), [-6.14, 1.73]	-2.07 [-6.91, 2.76], 0.398
Month 39	-4.34 (1.79), [-7.88, -0.80]	-2.10 (2.15), [-6.34, 2.13]	-2.24 [-7.48, 3.00], 0.400

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:35.

Table A4.1.1.2: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-2.91 (0.96), [-4.80, -1.02]	-3.89 (1.04), [-5.93, -1.85]	0.98 [-1.40, 3.36], 0.418
Month 3	-2.00 (0.96), [-3.89, -0.11]	-3.19 (1.00), [-5.15, -1.22]	1.19 [-1.12, 3.50], 0.313
Month 6	-2.25 (0.93), [-4.08, -0.41]	-3.38 (0.97), [-5.29, -1.46]	1.13 [-1.09, 3.35], 0.318
Month 9	-2.50 (0.93), [-4.32, -0.67]	-3.57 (0.98), [-5.49, -1.65]	1.07 [-1.14, 3.29], 0.342
Month 12	-2.75 (0.94), [-4.60, -0.89]	-3.76 (1.01), [-5.74, -1.78]	1.01 [-1.28, 3.31], 0.386
Month 15	-2.99 (0.98), [-4.92, -1.07]	-3.95 (1.07), [-6.05, -1.85]	0.96 [-1.50, 3.41], 0.445
Month 18	-3.24 (1.03), [-5.28, -1.21]	-4.14 (1.15), [-6.40, -1.88]	0.90 [-1.79, 3.58], 0.511
Month 21	-3.49 (1.10), [-5.66, -1.32]	-4.33 (1.25), [-6.79, -1.88]	0.84 [-2.12, 3.80], 0.577
Month 24	-3.74 (1.19), [-6.08, -1.40]	-4.52 (1.36), [-7.20, -1.84]	0.78 [-2.49, 4.06], 0.638
Month 27	-3.99 (1.28), [-6.51, -1.47]	-4.71 (1.48), [-7.64, -1.79]	0.72 [-2.89, 4.34], 0.693
Month 30	-4.24 (1.38), [-6.96, -1.51]	-4.90 (1.62), [-8.09, -1.72]	0.67 [-3.31, 4.64], 0.741
Month 33	-4.49 (1.49), [-7.42, -1.55]	-5.10 (1.76), [-8.56, -1.63]	0.61 [-3.74, 4.96], 0.783
Month 36	-4.74 (1.60), [-7.90, -1.57]	-5.29 (1.90), [-9.04, -1.54]	0.55 [-4.19, 5.29], 0.819
Month 39	-4.98 (1.72), [-8.38, -1.59]	-5.48 (2.05), [-9.52, -1.43]	0.49 [-4.65, 5.63], 0.850

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:39.

Table A4.1.1.3: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-5.13 (1.39), [-7.88, -2.39]	-2.70 (1.51), [-5.67, 0.27]	-2.43 [-5.82, 0.95], 0.158
Month 3	-4.51 (1.51), [-7.47, -1.55]	-3.24 (1.57), [-6.33, -0.15]	-1.27 [-4.94, 2.39], 0.495
Month 6	-4.69 (1.43), [-7.51, -1.87]	-3.09 (1.50), [-6.04, -0.14]	-1.60 [-5.03, 1.83], 0.360
Month 9	-4.86 (1.39), [-7.60, -2.12]	-2.94 (1.47), [-5.83, -0.05]	-1.92 [-5.24, 1.39], 0.254
Month 12	-5.04 (1.38), [-7.76, -2.31]	-2.79 (1.48), [-5.70, 0.13]	-2.25 [-5.57, 1.07], 0.184
Month 15	-5.21 (1.41), [-7.98, -2.44]	-2.64 (1.54), [-5.66, 0.39]	-2.58 [-6.04, 0.89], 0.144
Month 18	-5.39 (1.46), [-8.27, -2.51]	-2.48 (1.63), [-5.69, 0.72]	-2.90 [-6.62, 0.81], 0.125
Month 21	-5.56 (1.54), [-8.60, -2.52]	-2.33 (1.75), [-5.78, 1.12]	-3.23 [-7.29, 0.83], 0.118
Month 24	-5.74 (1.65), [-8.99, -2.49]	-2.18 (1.90), [-5.93, 1.56]	-3.56 [-8.03, 0.92], 0.119
Month 27	-5.91 (1.77), [-9.41, -2.42]	-2.03 (2.07), [-6.11, 2.05]	-3.88 [-8.83, 1.06], 0.123
Month 30	-6.09 (1.91), [-9.86, -2.31]	-1.88 (2.25), [-6.33, 2.57]	-4.21 [-9.66, 1.25], 0.130
Month 33	-6.26 (2.07), [-10.34, -2.19]	-1.73 (2.45), [-6.57, 3.11]	-4.53 [-10.53, 1.46], 0.137
Month 36	-6.44 (2.23), [-10.84, -2.04]	-1.58 (2.66), [-6.83, 3.67]	-4.86 [-11.42, 1.69], 0.145
Month 39	-6.61 (2.40), [-11.35, -1.88]	-1.43 (2.87), [-7.10, 4.25]	-5.19 [-12.32, 1.95], 0.153

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:43.

Table A4.1.1.4: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-2.51 (1.17), [-4.80, -0.21]	-1.58 (1.25), [-4.04, 0.87]	-0.93 [-3.75, 1.90], 0.519
Month 3	-1.89 (1.18), [-4.21, 0.42]	-2.14 (1.23), [-4.56, 0.27]	0.25 [-2.55, 3.05], 0.861
Month 6	-2.07 (1.15), [-4.33, 0.19]	-1.98 (1.20), [-4.34, 0.38]	-0.08 [-2.79, 2.63], 0.953
Month 9	-2.24 (1.14), [-4.48, 0.01]	-1.82 (1.20), [-4.18, 0.53]	-0.41 [-3.10, 2.28], 0.764
Month 12	-2.41 (1.15), [-4.67, -0.14]	-1.66 (1.22), [-4.07, 0.74]	-0.74 [-3.50, 2.01], 0.597
Month 15	-2.58 (1.18), [-4.90, -0.25]	-1.50 (1.27), [-4.01, 1.00]	-1.07 [-3.96, 1.82], 0.466
Month 18	-2.75 (1.23), [-5.17, -0.33]	-1.34 (1.35), [-4.00, 1.31]	-1.40 [-4.50, 1.69], 0.373
Month 21	-2.92 (1.29), [-5.46, -0.37]	-1.18 (1.44), [-4.02, 1.65]	-1.73 [-5.08, 1.61], 0.308
Month 24	-3.09 (1.37), [-5.79, -0.39]	-1.02 (1.55), [-4.07, 2.02]	-2.06 [-5.70, 1.58], 0.265
Month 27	-3.26 (1.46), [-6.13, -0.38]	-0.86 (1.67), [-4.15, 2.42]	-2.39 [-6.36, 1.57], 0.236
Month 30	-3.43 (1.56), [-6.50, -0.36]	-0.70 (1.80), [-4.25, 2.84]	-2.73 [-7.05, 1.60], 0.215
Month 33	-3.60 (1.67), [-6.88, -0.32]	-0.54 (1.94), [-4.36, 3.27]	-3.06 [-7.75, 1.64], 0.201
Month 36	-3.77 (1.78), [-7.27, -0.27]	-0.38 (2.08), [-4.49, 3.72]	-3.39 [-8.47, 1.69], 0.190
Month 39	-3.94 (1.90), [-7.68, -0.20]	-0.22 (2.23), [-4.62, 4.18]	-3.72 [-9.20, 1.76], 0.182

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:47.

Table A4.1.1.5: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-3.17 (1.11), [-5.36, -0.98]	-2.22 (1.20), [-4.57, 0.13]	-0.96 [-3.68, 1.77], 0.491
Month 3	-1.48 (1.09), [-3.63, 0.67]	-1.30 (1.14), [-3.55, 0.94]	-0.18 [-2.78, 2.42], 0.894
Month 6	-1.96 (1.07), [-4.06, 0.15]	-1.56 (1.12), [-3.76, 0.64]	-0.40 [-2.93, 2.14], 0.759
Month 9	-2.43 (1.07), [-4.54, -0.32]	-1.82 (1.13), [-4.04, 0.40]	-0.61 [-3.16, 1.93], 0.635
Month 12	-2.91 (1.09), [-5.06, -0.76]	-2.07 (1.16), [-4.36, 0.21]	-0.83 [-3.47, 1.81], 0.535
Month 15	-3.38 (1.13), [-5.61, -1.16]	-2.33 (1.22), [-4.74, 0.08]	-1.05 [-3.86, 1.76], 0.462
Month 18	-3.86 (1.19), [-6.20, -1.52]	-2.59 (1.31), [-5.16, -0.02]	-1.27 [-4.31, 1.77], 0.411
Month 21	-4.34 (1.26), [-6.82, -1.85]	-2.85 (1.41), [-5.62, -0.08]	-1.49 [-4.80, 1.82], 0.377
Month 24	-4.81 (1.35), [-7.47, -2.16]	-3.10 (1.52), [-6.10, -0.11]	-1.71 [-5.34, 1.92], 0.355
Month 27	-5.29 (1.44), [-8.13, -2.45]	-3.36 (1.65), [-6.61, -0.11]	-1.93 [-5.90, 2.05], 0.340
Month 30	-5.76 (1.55), [-8.81, -2.72]	-3.62 (1.78), [-7.13, -0.10]	-2.15 [-6.48, 2.19], 0.331
Month 33	-6.24 (1.66), [-9.51, -2.97]	-3.88 (1.93), [-7.67, -0.08]	-2.36 [-7.08, 2.36], 0.324
Month 36	-6.72 (1.77), [-10.21, -3.22]	-4.13 (2.07), [-8.22, -0.04]	-2.58 [-7.70, 2.53], 0.320
Month 39	-7.19 (1.90), [-10.93, -3.45]	-4.39 (2.23), [-8.78, 0.00]	-2.80 [-8.32, 2.72], 0.318

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:50.

Table A4.1.1.6: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-1.11 (1.27), [-3.61, 1.39]	-0.49 (1.36), [-3.16, 2.18]	-0.63 [-3.67, 2.42], 0.686
Month 3	-1.35 (1.44), [-4.18, 1.47]	-1.42 (1.49), [-4.35, 1.50]	0.07 [-3.44, 3.59], 0.968
Month 6	-1.28 (1.36), [-3.95, 1.40]	-1.15 (1.41), [-3.93, 1.62]	-0.12 [-3.39, 3.14], 0.940
Month 9	-1.20 (1.31), [-3.77, 1.37]	-0.88 (1.36), [-3.56, 1.80]	-0.32 [-3.42, 2.78], 0.839
Month 12	-1.13 (1.28), [-3.64, 1.38]	-0.61 (1.35), [-3.27, 2.04]	-0.52 [-3.55, 2.52], 0.738
Month 15	-1.05 (1.27), [-3.56, 1.45]	-0.34 (1.37), [-3.04, 2.35]	-0.71 [-3.78, 2.36], 0.649
Month 18	-0.98 (1.29), [-3.52, 1.57]	-0.07 (1.42), [-2.87, 2.73]	-0.91 [-4.12, 2.30], 0.578
Month 21	-0.90 (1.34), [-3.54, 1.74]	0.20 (1.51), [-2.77, 3.17]	-1.10 [-4.54, 2.33], 0.528
Month 24	-0.83 (1.41), [-3.61, 1.95]	0.47 (1.62), [-2.71, 3.66]	-1.30 [-5.03, 2.44], 0.494
Month 27	-0.75 (1.50), [-3.71, 2.20]	0.74 (1.75), [-2.70, 4.18]	-1.49 [-5.58, 2.60], 0.472
Month 30	-0.68 (1.60), [-3.84, 2.49]	1.01 (1.89), [-2.72, 4.74]	-1.69 [-6.18, 2.80], 0.459
Month 33	-0.60 (1.72), [-4.00, 2.80]	1.28 (2.05), [-2.76, 5.33]	-1.88 [-6.81, 3.04], 0.451
Month 36	-0.53 (1.85), [-4.18, 3.13]	1.55 (2.22), [-2.82, 5.93]	-2.08 [-7.46, 3.30], 0.446
Month 39	-0.45 (1.99), [-4.38, 3.48]	1.83 (2.39), [-2.90, 6.55]	-2.28 [-8.13, 3.58], 0.444

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:54.

Table A4.1.1.7: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Fatigue scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	5.24 (1.28), [2.73, 7.75]	3.38 (1.38), [0.67, 6.09]	1.86 [-1.25, 4.97], 0.241
Month 3	5.66 (1.32), [3.06, 8.26]	4.29 (1.38), [1.58, 7.00]	1.37 [-1.81, 4.55], 0.397
Month 6	5.54 (1.27), [3.04, 8.05]	4.03 (1.33), [1.42, 6.65]	1.51 [-1.52, 4.53], 0.327
Month 9	5.42 (1.25), [2.96, 7.89]	3.78 (1.32), [1.18, 6.37]	1.64 [-1.33, 4.62], 0.277
Month 12	5.30 (1.26), [2.82, 7.78]	3.52 (1.35), [0.87, 6.17]	1.78 [-1.25, 4.81], 0.248
Month 15	5.18 (1.30), [2.63, 7.73]	3.26 (1.41), [0.49, 6.03]	1.92 [-1.28, 5.12], 0.238
Month 18	5.06 (1.36), [2.39, 7.73]	3.00 (1.50), [0.04, 5.96]	2.06 [-1.40, 5.51], 0.242
Month 21	4.94 (1.44), [2.11, 7.77]	2.74 (1.62), [-0.45, 5.94]	2.19 [-1.59, 5.98], 0.254
Month 24	4.82 (1.54), [1.79, 7.85]	2.49 (1.76), [-0.99, 5.96]	2.33 [-1.84, 6.50], 0.272
Month 27	4.70 (1.66), [1.43, 7.96]	2.23 (1.92), [-1.56, 6.01]	2.47 [-2.13, 7.06], 0.291
Month 30	4.58 (1.78), [1.06, 8.09]	1.97 (2.09), [-2.15, 6.09]	2.60 [-2.45, 7.66], 0.310
Month 33	4.45 (1.92), [0.66, 8.25]	1.71 (2.27), [-2.76, 6.19]	2.74 [-2.79, 8.27], 0.329
Month 36	4.33 (2.07), [0.25, 8.41]	1.45 (2.45), [-3.39, 6.30]	2.88 [-3.15, 8.91], 0.347
Month 39	4.21 (2.22), [-0.17, 8.60]	1.20 (2.65), [-4.02, 6.42]	3.02 [-3.52, 9.56], 0.364

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 9:59:58.

Table A4.1.1.8: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Pain scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	4.73 (1.55), [1.69, 7.77]	4.93 (1.64), [1.69, 8.16]	-0.19 [-3.91, 3.52], 0.918
Month 3	3.98 (1.57), [0.88, 7.07]	4.85 (1.64), [1.62, 8.08]	-0.87 [-4.62, 2.87], 0.647
Month 6	4.19 (1.54), [1.15, 7.22]	4.87 (1.61), [1.70, 8.04]	-0.68 [-4.33, 2.96], 0.713
Month 9	4.40 (1.53), [1.39, 7.41]	4.89 (1.61), [1.73, 8.05]	-0.49 [-4.11, 3.13], 0.789
Month 12	4.61 (1.54), [1.59, 7.64]	4.91 (1.62), [1.72, 8.11]	-0.30 [-3.96, 3.36], 0.871
Month 15	4.82 (1.56), [1.76, 7.89]	4.93 (1.67), [1.66, 8.21]	-0.11 [-3.88, 3.66], 0.954
Month 18	5.04 (1.60), [1.89, 8.18]	4.96 (1.73), [1.55, 8.36]	0.08 [-3.86, 4.02], 0.968
Month 21	5.25 (1.65), [2.00, 8.50]	4.98 (1.81), [1.41, 8.54]	0.27 [-3.90, 4.44], 0.898
Month 24	5.46 (1.72), [2.08, 8.84]	5.00 (1.91), [1.24, 8.76]	0.46 [-3.98, 4.90], 0.838
Month 27	5.67 (1.80), [2.13, 9.21]	5.02 (2.02), [1.04, 9.00]	0.65 [-4.10, 5.41], 0.787
Month 30	5.88 (1.89), [2.17, 9.60]	5.04 (2.15), [0.81, 9.27]	0.84 [-4.25, 5.94], 0.745
Month 33	6.10 (1.99), [2.18, 10.01]	5.06 (2.29), [0.57, 9.56]	1.03 [-4.43, 6.50], 0.710
Month 36	6.31 (2.10), [2.18, 10.44]	5.08 (2.43), [0.31, 9.86]	1.22 [-4.63, 7.08], 0.681
Month 39	6.52 (2.21), [2.17, 10.87]	5.11 (2.58), [0.03, 10.18]	1.42 [-4.84, 7.67], 0.656

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:02.

Table A4.1.1.9: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-0.68 (1.16), [-2.96, 1.61]	-2.10 (1.25), [-4.57, 0.36]	1.43 [-1.38, 4.23], 0.318
Month 3	-0.72 (1.28), [-3.24, 1.80]	-0.57 (1.34), [-3.19, 2.06]	-0.15 [-3.28, 2.98], 0.923
Month 6	-0.70 (1.21), [-3.08, 1.68]	-0.99 (1.26), [-3.48, 1.49]	0.29 [-2.61, 3.19], 0.844
Month 9	-0.69 (1.17), [-2.98, 1.61]	-1.42 (1.23), [-3.84, 1.00]	0.73 [-2.04, 3.50], 0.603
Month 12	-0.67 (1.15), [-2.94, 1.60]	-1.85 (1.23), [-4.27, 0.58]	1.18 [-1.58, 3.93], 0.402
Month 15	-0.65 (1.17), [-2.96, 1.65]	-2.27 (1.28), [-4.79, 0.24]	1.62 [-1.25, 4.49], 0.267
Month 18	-0.64 (1.22), [-3.04, 1.76]	-2.70 (1.36), [-5.37, -0.03]	2.06 [-1.02, 5.15], 0.189
Month 21	-0.62 (1.29), [-3.17, 1.92]	-3.13 (1.47), [-6.01, -0.24]	2.50 [-0.88, 5.89], 0.146
Month 24	-0.61 (1.39), [-3.34, 2.13]	-3.56 (1.60), [-6.71, -0.40]	2.95 [-0.81, 6.70], 0.123
Month 27	-0.59 (1.50), [-3.55, 2.37]	-3.98 (1.75), [-7.43, -0.53]	3.39 [-0.78, 7.56], 0.111
Month 30	-0.58 (1.63), [-3.79, 2.64]	-4.41 (1.92), [-8.19, -0.63]	3.83 [-0.79, 8.46], 0.104
Month 33	-0.56 (1.77), [-4.05, 2.93]	-4.84 (2.09), [-8.96, -0.71]	4.28 [-0.83, 9.38], 0.100
Month 36	-0.54 (1.92), [-4.32, 3.23]	-5.26 (2.28), [-9.75, -0.77]	4.72 [-0.88, 10.32], 0.098
Month 39	-0.53 (2.07), [-4.61, 3.56]	-5.69 (2.47), [-10.56, -0.82]	5.16 [-0.95, 11.28], 0.097

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:06.

Table A4.1.1.10: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	0.81 (0.52), [-0.22, 1.84]	0.98 (0.56), [-0.13, 2.09]	-0.17 [-1.44, 1.09], 0.788
Month 3	1.11 (0.64), [-0.15, 2.36]	1.24 (0.67), [-0.07, 2.55]	-0.14 [-1.74, 1.47], 0.867
Month 6	1.02 (0.60), [-0.15, 2.19]	1.17 (0.62), [-0.05, 2.39]	-0.15 [-1.62, 1.32], 0.844
Month 9	0.94 (0.56), [-0.16, 2.04]	1.10 (0.59), [-0.06, 2.26]	-0.16 [-1.52, 1.21], 0.821
Month 12	0.86 (0.53), [-0.19, 1.91]	1.03 (0.57), [-0.09, 2.15]	-0.17 [-1.46, 1.12], 0.799
Month 15	0.78 (0.52), [-0.24, 1.80]	0.96 (0.56), [-0.15, 2.06]	-0.18 [-1.43, 1.08], 0.781
Month 18	0.70 (0.51), [-0.32, 1.71]	0.88 (0.57), [-0.24, 2.01]	-0.19 [-1.46, 1.08], 0.770
Month 21	0.61 (0.52), [-0.42, 1.65]	0.81 (0.59), [-0.36, 1.98]	-0.20 [-1.52, 1.13], 0.768
Month 24	0.53 (0.54), [-0.54, 1.61]	0.74 (0.62), [-0.50, 1.98]	-0.21 [-1.63, 1.21], 0.771
Month 27	0.45 (0.57), [-0.68, 1.58]	0.67 (0.67), [-0.66, 2.00]	-0.22 [-1.76, 1.33], 0.779
Month 30	0.37 (0.61), [-0.84, 1.58]	0.60 (0.72), [-0.84, 2.03]	-0.23 [-1.92, 1.46], 0.788
Month 33	0.29 (0.65), [-1.01, 1.59]	0.52 (0.78), [-1.03, 2.08]	-0.24 [-2.10, 1.62], 0.798
Month 36	0.20 (0.70), [-1.20, 1.60]	0.45 (0.84), [-1.23, 2.13]	-0.25 [-2.28, 1.79], 0.808
Month 39	0.12 (0.76), [-1.39, 1.63]	0.38 (0.91), [-1.44, 2.20]	-0.26 [-2.48, 1.97], 0.817

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:09.

Table A4.1.1.11: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	4.23 (1.36), [1.55, 6.91]	3.79 (1.47), [0.89, 6.69]	0.44 [-2.91, 3.80], 0.796
Month 3	2.18 (1.36), [-0.50, 4.86]	2.66 (1.42), [-0.14, 5.46]	-0.47 [-3.74, 2.80], 0.776
Month 6	2.76 (1.32), [0.16, 5.35]	2.98 (1.38), [0.26, 5.69]	-0.22 [-3.34, 2.91], 0.892
Month 9	3.34 (1.31), [0.76, 5.91]	3.30 (1.38), [0.58, 6.01]	0.04 [-3.07, 3.15], 0.980
Month 12	3.91 (1.33), [1.29, 6.54]	3.61 (1.43), [0.80, 6.42]	0.30 [-2.93, 3.53], 0.856
Month 15	4.49 (1.39), [1.75, 7.23]	3.93 (1.52), [0.95, 6.92]	0.55 [-2.92, 4.03], 0.754
Month 18	5.06 (1.48), [2.16, 7.97]	4.25 (1.64), [1.02, 7.48]	0.81 [-3.01, 4.63], 0.676
Month 21	5.64 (1.59), [2.51, 8.77]	4.57 (1.79), [1.04, 8.10]	1.07 [-3.17, 5.30], 0.620
Month 24	6.22 (1.72), [2.83, 9.60]	4.89 (1.97), [1.02, 8.77]	1.32 [-3.38, 6.03], 0.579
Month 27	6.79 (1.86), [3.12, 10.46]	5.21 (2.16), [0.96, 9.46]	1.58 [-3.64, 6.80], 0.551
Month 30	7.37 (2.02), [3.39, 11.35]	5.53 (2.36), [0.88, 10.18]	1.84 [-3.92, 7.60], 0.530
Month 33	7.95 (2.19), [3.63, 12.26]	5.85 (2.57), [0.78, 10.92]	2.10 [-4.23, 8.42], 0.514
Month 36	8.52 (2.36), [3.86, 13.18]	6.17 (2.79), [0.67, 11.67]	2.35 [-4.55, 9.26], 0.502
Month 39	9.10 (2.54), [4.08, 14.11]	6.49 (3.01), [0.55, 12.43]	2.61 [-4.89, 10.11], 0.493

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:13.

Table A4.1.1.12: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Insomnia scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	2.23 (1.55), [-0.82, 5.27]	2.81 (1.66), [-0.46, 6.08]	-0.58 [-4.31, 3.14], 0.758
Month 3	3.27 (1.69), [-0.05, 6.59]	1.82 (1.76), [-1.64, 5.28]	1.45 [-2.65, 5.56], 0.487
Month 6	2.98 (1.61), [-0.19, 6.15]	2.10 (1.68), [-1.22, 5.41]	0.88 [-2.98, 4.74], 0.654
Month 9	2.68 (1.57), [-0.39, 5.76]	2.37 (1.65), [-0.86, 5.61]	0.31 [-3.41, 4.03], 0.870
Month 12	2.39 (1.55), [-0.65, 5.43]	2.65 (1.65), [-0.58, 5.89]	-0.26 [-3.95, 3.43], 0.889
Month 15	2.10 (1.55), [-0.96, 5.16]	2.93 (1.68), [-0.38, 6.24]	-0.83 [-4.61, 2.94], 0.664
Month 18	1.81 (1.59), [-1.33, 4.94]	3.21 (1.76), [-0.25, 6.67]	-1.41 [-5.37, 2.56], 0.485
Month 21	1.51 (1.66), [-1.75, 4.78]	3.49 (1.86), [-0.18, 7.16]	-1.98 [-6.22, 2.27], 0.360
Month 24	1.22 (1.75), [-2.22, 4.66]	3.77 (1.99), [-0.16, 7.69]	-2.55 [-7.15, 2.06], 0.276
Month 27	0.93 (1.85), [-2.73, 4.58]	4.05 (2.15), [-0.18, 8.28]	-3.12 [-8.14, 1.90], 0.222
Month 30	0.63 (1.98), [-3.27, 4.53]	4.33 (2.32), [-0.24, 8.89]	-3.69 [-9.18, 1.79], 0.186
Month 33	0.34 (2.12), [-3.84, 4.52]	4.61 (2.50), [-0.33, 9.54]	-4.26 [-10.25, 1.72], 0.161
Month 36	0.05 (2.27), [-4.43, 4.52]	4.88 (2.70), [-0.43, 10.20]	-4.84 [-11.35, 1.68], 0.144
Month 39	-0.25 (2.43), [-5.04, 4.55]	5.16 (2.90), [-0.56, 10.89]	-5.41 [-12.47, 1.65], 0.132

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:17.

Table A4.1.1.13: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-1.32 (1.25), [-3.79, 1.14]	-2.50 (1.35), [-5.15, 0.16]	1.17 [-1.85, 4.19], 0.445
Month 3	0.64 (1.53), [-2.35, 3.64]	-0.51 (1.59), [-3.63, 2.61]	1.16 [-2.67, 4.99], 0.553
Month 6	0.08 (1.42), [-2.71, 2.88]	-1.08 (1.48), [-3.99, 1.83]	1.16 [-2.33, 4.66], 0.514
Month 9	-0.48 (1.33), [-3.10, 2.15]	-1.64 (1.40), [-4.40, 1.12]	1.17 [-2.07, 4.40], 0.479
Month 12	-1.04 (1.27), [-3.55, 1.47]	-2.21 (1.36), [-4.88, 0.46]	1.17 [-1.90, 4.23], 0.453
Month 15	-1.60 (1.24), [-4.04, 0.84]	-2.77 (1.35), [-5.43, -0.11]	1.17 [-1.83, 4.18], 0.443
Month 18	-2.16 (1.24), [-4.60, 0.28]	-3.34 (1.38), [-6.06, -0.62]	1.18 [-1.88, 4.24], 0.449
Month 21	-2.72 (1.27), [-5.22, -0.22]	-3.90 (1.45), [-6.76, -1.05]	1.18 [-2.05, 4.41], 0.471
Month 24	-3.28 (1.33), [-5.90, -0.67]	-4.47 (1.54), [-7.52, -1.42]	1.19 [-2.30, 4.68], 0.503
Month 27	-3.85 (1.41), [-6.63, -1.06]	-5.04 (1.66), [-8.32, -1.75]	1.19 [-2.64, 5.02], 0.539
Month 30	-4.41 (1.51), [-7.40, -1.42]	-5.60 (1.81), [-9.17, -2.03]	1.19 [-3.03, 5.41], 0.576
Month 33	-4.97 (1.63), [-8.20, -1.74]	-6.17 (1.96), [-10.05, -2.28]	1.20 [-3.46, 5.85], 0.611
Month 36	-5.53 (1.77), [-9.02, -2.03]	-6.73 (2.13), [-10.95, -2.51]	1.20 [-3.92, 6.32], 0.643
Month 39	-6.09 (1.91), [-9.87, -2.31]	-7.30 (2.31), [-11.88, -2.72]	1.21 [-4.41, 6.82], 0.671

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:21.

Table A4.1.1.14: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Constipation scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-0.10 (1.11), [-2.29, 2.09]	0.05 (1.21), [-2.33, 2.43]	-0.15 [-2.85, 2.55], 0.913
Month 3	-0.46 (1.27), [-2.95, 2.03]	-0.14 (1.32), [-2.74, 2.46]	-0.32 [-3.44, 2.81], 0.842
Month 6	-0.36 (1.19), [-2.69, 1.97]	-0.09 (1.24), [-2.52, 2.34]	-0.27 [-3.13, 2.59], 0.853
Month 9	-0.26 (1.13), [-2.48, 1.97]	-0.03 (1.19), [-2.38, 2.31]	-0.22 [-2.92, 2.47], 0.871
Month 12	-0.16 (1.11), [-2.34, 2.03]	0.02 (1.19), [-2.32, 2.36]	-0.18 [-2.84, 2.49], 0.897
Month 15	-0.06 (1.12), [-2.27, 2.15]	0.07 (1.23), [-2.35, 2.49]	-0.13 [-2.88, 2.63], 0.927
Month 18	0.04 (1.17), [-2.26, 2.34]	0.12 (1.31), [-2.46, 2.71]	-0.08 [-3.05, 2.88], 0.956
Month 21	0.14 (1.24), [-2.30, 2.59]	0.18 (1.42), [-2.63, 2.98]	-0.04 [-3.31, 3.24], 0.983
Month 24	0.24 (1.34), [-2.40, 2.88]	0.23 (1.56), [-2.85, 3.31]	0.01 [-3.64, 3.67], 0.995
Month 27	0.34 (1.46), [-2.53, 3.21]	0.28 (1.72), [-3.10, 3.67]	0.06 [-4.03, 4.14], 0.978
Month 30	0.44 (1.59), [-2.69, 3.58]	0.34 (1.89), [-3.39, 4.07]	0.10 [-4.45, 4.66], 0.964
Month 33	0.54 (1.73), [-2.88, 3.96]	0.39 (2.07), [-3.70, 4.48]	0.15 [-4.90, 5.20], 0.953
Month 36	0.64 (1.89), [-3.08, 4.37]	0.44 (2.26), [-4.03, 4.91]	0.20 [-5.36, 5.76], 0.944
Month 39	0.74 (2.05), [-3.30, 4.78]	0.50 (2.46), [-4.36, 5.36]	0.24 [-5.85, 6.34], 0.937

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:24.

Table A4.1.1.15: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	2.54 (0.88), [0.80, 4.28]	2.29 (0.97), [0.38, 4.20]	0.25 [-1.93, 2.42], 0.823
Month 3	1.76 (0.96), [-0.12, 3.64]	2.48 (1.00), [0.51, 4.45]	-0.72 [-3.06, 1.63], 0.548
Month 6	1.98 (0.90), [0.22, 3.75]	2.43 (0.94), [0.57, 4.28]	-0.45 [-2.60, 1.71], 0.684
Month 9	2.20 (0.87), [0.50, 3.91]	2.38 (0.92), [0.56, 4.19]	-0.17 [-2.24, 1.89], 0.868
Month 12	2.42 (0.87), [0.71, 4.13]	2.33 (0.94), [0.47, 4.18]	0.10 [-2.01, 2.20], 0.928
Month 15	2.64 (0.90), [0.87, 4.41]	2.28 (1.00), [0.31, 4.25]	0.37 [-1.89, 2.62], 0.749
Month 18	2.86 (0.96), [0.98, 4.75]	2.23 (1.09), [0.07, 4.38]	0.64 [-1.87, 3.14], 0.617
Month 21	3.08 (1.04), [1.03, 5.13]	2.18 (1.21), [-0.21, 4.56]	0.91 [-1.92, 3.73], 0.527
Month 24	3.30 (1.14), [1.06, 5.55]	2.12 (1.34), [-0.53, 4.78]	1.18 [-2.01, 4.37], 0.467
Month 27	3.52 (1.25), [1.05, 6.00]	2.07 (1.49), [-0.87, 5.02]	1.45 [-2.15, 5.05], 0.427
Month 30	3.74 (1.38), [1.02, 6.46]	2.02 (1.65), [-1.24, 5.28]	1.72 [-2.30, 5.74], 0.399
Month 33	3.96 (1.51), [0.98, 6.95]	1.97 (1.82), [-1.62, 5.56]	1.99 [-2.47, 6.46], 0.380
Month 36	4.18 (1.65), [0.93, 7.44]	1.92 (1.99), [-2.01, 5.85]	2.26 [-2.66, 7.18], 0.365
Month 39	4.40 (1.79), [0.87, 7.94]	1.87 (2.16), [-2.40, 6.15]	2.53 [-2.85, 7.92], 0.354

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:28.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	29 (19.2%)	33 (21.6%)
Odds ratio (95% CI)	0.897 (0.510, 1.575)	
P-value for Odds Ratio	0.7043	
Relative Risk (95% CI)	0.91 (0.58, 1.42)	
P-value for Relative Risk	0.6754	
Risk difference (95% CI)	-0.58 (-9.61, 8.45)	
P-value for Risk Difference	0.9002	
Improvement	28 (18.5%)	33 (21.6%)
Odds ratio (95% CI)	0.802 (0.453, 1.419)	
P-value for Odds Ratio	0.4486	
Relative Risk (95% CI)	0.85 (0.54, 1.32)	
P-value for Relative Risk	0.4638	
Risk difference (95% CI)	-4.10 (-12.84, 4.64)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3580	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	32 (23.5%)	23 (18.7%)
Odds ratio (95% CI)	1.425 (0.772, 2.631)	
P-value for Odds Ratio	0.2577	
Relative Risk (95% CI)	1.32 (0.83, 2.12)	
P-value for Relative Risk	0.2416	
Risk difference (95% CI)	4.69 (-4.91, 14.29)	
P-value for Risk Difference	0.3383	
Improvement	23 (16.9%)	21 (17.1%)
Odds ratio (95% CI)	0.975 (0.508, 1.873)	
P-value for Odds Ratio	0.9404	
Relative Risk (95% CI)	0.98 (0.57, 1.68)	
P-value for Relative Risk	0.9375	
Risk difference (95% CI)	-0.27 (-9.49, 8.94)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9535	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	25 (19.7%)	26 (23.6%)
Odds ratio (95% CI)	0.887 (0.464, 1.695)	
P-value for Odds Ratio	0.7167	
Relative Risk (95% CI)	0.89 (0.56, 1.42)	
P-value for Relative Risk	0.6356	
Risk difference (95% CI)	-3.78 (-15.28, 7.72)	
P-value for Risk Difference	0.5194	
Improvement	27 (21.3%)	22 (20.0%)
Odds ratio (95% CI)	1.003 (0.527, 1.911)	
P-value for Odds Ratio	0.9915	
Relative Risk (95% CI)	1.04 (0.63, 1.71)	
P-value for Relative Risk	0.8772	
Risk difference (95% CI)	-1.42 (-11.67, 8.83)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7855	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	138	131
Deterioration	38 (27.5%)	36 (27.5%)
Odds ratio (95% CI)	0.996 (0.580, 1.711)	
P-value for Odds Ratio	0.9885	
Relative Risk (95% CI)	0.97 (0.66, 1.44)	
P-value for Relative Risk	0.8965	
Risk difference (95% CI)	0.89 (-9.76, 11.54)	
P-value for Risk Difference	0.8702	
Improvement	19 (13.8%)	21 (16.0%)
Odds ratio (95% CI)	0.836 (0.422, 1.655)	
P-value for Odds Ratio	0.6076	
Relative Risk (95% CI)	0.88 (0.49, 1.56)	
P-value for Relative Risk	0.6584	
Risk difference (95% CI)	-3.78 (-11.97, 4.40)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

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(pingping.xu 11AUG2025 12:07 SAS Linux 9.4)

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3652	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	22 (20.2%)	12 (16.2%)
Odds ratio (95% CI)	1.455 (0.645, 3.279)	
P-value for Odds Ratio	0.3659	
Relative Risk (95% CI)	1.33 (0.72, 2.44)	
P-value for Relative Risk	0.3615	
Risk difference (95% CI)	4.01 (-6.28, 14.29)	
P-value for Risk Difference	0.4451	
Improvement	21 (19.3%)	14 (18.9%)
Odds ratio (95% CI)	0.959 (0.443, 2.074)	
P-value for Odds Ratio	0.9151	
Relative Risk (95% CI)	1.00 (0.55, 1.82)	
P-value for Relative Risk	0.9981	
Risk difference (95% CI)	-1.09 (-12.67, 10.48)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

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(pingping.xu 11AUG2025 12:07 SAS Linux 9.4)

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8529	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	30 (28.8%)	9 (14.1%)
Odds ratio (95% CI)	2.636 (1.143, 6.081)	
P-value for Odds Ratio	0.0230	
Relative Risk (95% CI)	2.08 (1.06, 4.07)	
P-value for Relative Risk	0.0325	
Risk difference (95% CI)	14.75 (2.68, 26.83)	
P-value for Risk Difference	0.0166	
Improvement	17 (16.3%)	16 (25.0%)
Odds ratio (95% CI)	0.539 (0.246, 1.183)	
P-value for Odds Ratio	0.1234	
Relative Risk (95% CI)	0.62 (0.34, 1.14)	
P-value for Relative Risk	0.1264	
Risk difference (95% CI)	-9.67 (-22.26, 2.93)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1325	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	19 (22.4%)	11 (20.0%)
Odds ratio (95% CI)	1.239 (0.529, 2.900)	
P-value for Odds Ratio	0.6216	
Relative Risk (95% CI)	1.16 (0.61, 2.22)	
P-value for Relative Risk	0.6518	
Risk difference (95% CI)	5.77 (-8.85, 20.39)	
P-value for Risk Difference	0.4392	
Improvement	17 (20.0%)	8 (14.5%)
Odds ratio (95% CI)	1.445 (0.574, 3.642)	
P-value for Odds Ratio	0.4348	
Relative Risk (95% CI)	1.37 (0.63, 2.97)	
P-value for Relative Risk	0.4224	
Risk difference (95% CI)	4.53 (-8.39, 17.44)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4921	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	21 (29.6%)	7 (16.3%)
Odds ratio (95% CI)	2.453 (0.921, 6.535)	
P-value for Odds Ratio	0.0726	
Relative Risk (95% CI)	1.89 (0.89, 4.02)	
P-value for Relative Risk	0.0992	
Risk difference (95% CI)	13.54 (-4.45, 31.53)	
P-value for Risk Difference	0.1403	
Improvement	11 (15.5%)	8 (18.6%)
Odds ratio (95% CI)	0.740 (0.265, 2.066)	
P-value for Odds Ratio	0.5650	
Relative Risk (95% CI)	0.78 (0.34, 1.80)	
P-value for Relative Risk	0.5630	
Risk difference (95% CI)	-4.40 (-18.63, 9.83)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5447	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	12 (21.8%)	9 (28.1%)
Odds ratio (95% CI)	0.748 (0.272, 2.057)	
P-value for Odds Ratio	0.5733	
Relative Risk (95% CI)	0.79 (0.37, 1.67)	
P-value for Relative Risk	0.5367	
Risk difference (95% CI)	-3.65 (-23.93, 16.63)	
P-value for Risk Difference	0.7242	
Improvement	8 (14.5%)	7 (21.9%)
Odds ratio (95% CI)	0.544 (0.170, 1.739)	
P-value for Odds Ratio	0.3049	
Relative Risk (95% CI)	0.63 (0.26, 1.55)	
P-value for Relative Risk	0.3167	
Risk difference (95% CI)	-8.19 (-24.49, 8.11)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3248	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	15 (36.6%)	6 (21.4%)
Odds ratio (95% CI)	2.234 (0.682, 7.319)	
P-value for Odds Ratio	0.1843	
Relative Risk (95% CI)	1.55 (0.72, 3.32)	
P-value for Relative Risk	0.2616	
Risk difference (95% CI)	13.16 (-6.94, 33.25)	
P-value for Risk Difference	0.1994	
Improvement	3 (7.3%)	4 (14.3%)
Odds ratio (95% CI)	0.468 (0.095, 2.301)	
P-value for Odds Ratio	0.3497	
Relative Risk (95% CI)	0.51 (0.12, 2.11)	
P-value for Relative Risk	0.3546	
Risk difference (95% CI)	-6.55 (-25.60, 12.51)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5009	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	10 (38.5%)	5 (22.7%)
Odds ratio (95% CI)	1.998 (0.514, 7.764)	
P-value for Odds Ratio	0.3178	
Relative Risk (95% CI)	1.41 (0.59, 3.40)	
P-value for Relative Risk	0.4413	
Risk difference (95% CI)	15.82 (15.82, 15.82)*	
Improvement	3 (11.5%)	5 (22.7%)
Odds ratio (95% CI)	0.466 (0.085, 2.565)	
P-value for Odds Ratio	0.3803	
Relative Risk (95% CI)	0.52 (0.13, 2.11)	
P-value for Relative Risk	0.3611	
Risk difference (95% CI)	-9.50 (-30.41, 11.42)	
P-value for Risk Difference	0.3734	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	5 (23.8%)	4 (26.7%)
Odds ratio (95% CI)	0.608 (0.105, 3.507)	
P-value for Odds Ratio	0.5775	
Relative Risk (95% CI)	0.72 (0.20, 2.61)	
P-value for Relative Risk	0.6124	
Risk difference (95% CI)	-12.21 (-45.26, 20.84)	
P-value for Risk Difference	0.4689	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	2 (28.6%)	3 (30.0%)
Odds ratio (95% CI)	2.811 (0.145, 54.374)	
P-value for Odds Ratio	0.4940	
Relative Risk (95% CI)	2.64 (0.18, 39.37)	
P-value for Relative Risk	0.4810	
Risk difference (95% CI)	6.47 (-63.89, 76.84)	
P-value for Risk Difference	0.8569	
Improvement	0	1 (10.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.03, 9.46)	
P-value for Relative Risk	0.6460	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	2 (100.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.30 (0.03, 3.49)	
P-value for Relative Risk	0.2433	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	26 (17.2%)	28 (18.3%)
Odds ratio (95% CI)	0.939 (0.516, 1.709)	
P-value for Odds Ratio	0.8366	
Relative Risk (95% CI)	0.93 (0.58, 1.50)	
P-value for Relative Risk	0.7769	
Risk difference (95% CI)	-1.21 (-9.21, 6.78)	
P-value for Risk Difference	0.7659	
Improvement	26 (17.2%)	16 (10.5%)
Odds ratio (95% CI)	1.797 (0.914, 3.532)	
P-value for Odds Ratio	0.0891	
Relative Risk (95% CI)	1.64 (0.92, 2.92)	
P-value for Relative Risk	0.0944	
Risk difference (95% CI)	5.82 (-1.85, 13.49)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1368	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	18 (13.2%)	20 (16.3%)
Odds ratio (95% CI)	0.807 (0.404, 1.613)	
P-value for Odds Ratio	0.5438	
Relative Risk (95% CI)	0.84 (0.46, 1.51)	
P-value for Relative Risk	0.5564	
Risk difference (95% CI)	-3.58 (-12.24, 5.09)	
P-value for Risk Difference	0.4184	
Improvement	19 (14.0%)	7 (5.7%)
Odds ratio (95% CI)	2.691 (1.087, 6.661)	
P-value for Odds Ratio	0.0324	
Relative Risk (95% CI)	2.45 (1.06, 5.62)	
P-value for Relative Risk	0.0351	
Risk difference (95% CI)	9.22 (0.59, 17.84)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0362	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	19 (15.0%)	18 (16.4%)
Odds ratio (95% CI)	0.948 (0.463, 1.940)	
P-value for Odds Ratio	0.8835	
Relative Risk (95% CI)	0.97 (0.54, 1.74)	
P-value for Relative Risk	0.9180	
Risk difference (95% CI)	-1.65 (-10.74, 7.44)	
P-value for Risk Difference	0.7220	
Improvement	21 (16.5%)	10 (9.1%)
Odds ratio (95% CI)	2.100 (0.934, 4.721)	
P-value for Odds Ratio	0.0728	
Relative Risk (95% CI)	1.87 (0.93, 3.79)	
P-value for Relative Risk	0.0812	
Risk difference (95% CI)	10.59 (0.80, 20.39)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0340	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	28 (20.1%)	25 (19.1%)
Odds ratio (95% CI)	1.073 (0.584, 1.973)	
P-value for Odds Ratio	0.8197	
Relative Risk (95% CI)	1.05 (0.65, 1.70)	
P-value for Relative Risk	0.8437	
Risk difference (95% CI)	1.46 (-7.93, 10.86)	
P-value for Risk Difference	0.7605	
Improvement	24 (17.3%)	11 (8.4%)
Odds ratio (95% CI)	2.365 (1.100, 5.085)	
P-value for Odds Ratio	0.0275	
Relative Risk (95% CI)	2.10 (1.07, 4.12)	
P-value for Relative Risk	0.0304	
Risk difference (95% CI)	10.88 (1.91, 19.85)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0174	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	108	74
Deterioration	20 (18.5%)	12 (16.2%)
Odds ratio (95% CI)	1.379 (0.613, 3.103)	
P-value for Odds Ratio	0.4371	
Relative Risk (95% CI)	1.25 (0.67, 2.36)	
P-value for Relative Risk	0.4836	
Risk difference (95% CI)	3.83 (-10.10, 17.75)	
P-value for Risk Difference	0.5902	
Improvement	18 (16.7%)	4 (5.4%)
Odds ratio (95% CI)	3.507 (1.109, 11.090)	
P-value for Odds Ratio	0.0327	
Relative Risk (95% CI)	3.02 (1.07, 8.51)	
P-value for Relative Risk	0.0366	
Risk difference (95% CI)	8.36 (-5.14, 21.86)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2249	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	21 (20.2%)	17 (26.6%)
Odds ratio (95% CI)	0.710 (0.337, 1.498)	
P-value for Odds Ratio	0.3690	
Relative Risk (95% CI)	0.76 (0.44, 1.32)	
P-value for Relative Risk	0.3319	
Risk difference (95% CI)	-5.30 (-18.87, 8.27)	
P-value for Risk Difference	0.4443	
Improvement	11 (10.6%)	2 (3.1%)
Odds ratio (95% CI)	3.790 (0.800, 17.959)	
P-value for Odds Ratio	0.0932	
Relative Risk (95% CI)	1.71 (1.71, 1.71)*	
Risk difference (95% CI)	6.61 (-8.01, 21.23)	
P-value for Risk Difference	0.3757	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	13 (15.3%)	8 (14.5%)
Odds ratio (95% CI)	1.140 (0.433, 3.002)	
P-value for Odds Ratio	0.7904	
Relative Risk (95% CI)	1.10 (0.49, 2.46)	
P-value for Relative Risk	0.8177	
Risk difference (95% CI)	3.22 (-9.46, 15.90)	
P-value for Risk Difference	0.6185	
Improvement	17 (20.0%)	4 (7.3%)
Odds ratio (95% CI)	3.131 (0.984, 9.965)	
P-value for Odds Ratio	0.0533	
Relative Risk (95% CI)	2.67 (0.95, 7.48)	
P-value for Relative Risk	0.0621	
Risk difference (95% CI)	10.66 (-4.21, 25.53)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1599	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	14 (19.7%)	7 (16.3%)
Odds ratio (95% CI)	1.315 (0.475, 3.641)	
P-value for Odds Ratio	0.5984	
Relative Risk (95% CI)	1.20 (0.53, 2.72)	
P-value for Relative Risk	0.6562	
Risk difference (95% CI)	6.95 (-7.41, 21.31)	
P-value for Risk Difference	0.3427	
Improvement	12 (16.9%)	3 (7.0%)
Odds ratio (95% CI)	3.120 (0.803, 12.119)	
P-value for Odds Ratio	0.1002	
Relative Risk (95% CI)	2.57 (0.78, 8.46)	
P-value for Relative Risk	0.1198	
Risk difference (95% CI)	7.95 (-12.39, 28.28)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4438	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	10 (18.2%)	5 (15.6%)
Odds ratio (95% CI)	1.225 (0.370, 4.053)	
P-value for Odds Ratio	0.7399	
Relative Risk (95% CI)	1.22 (0.47, 3.21)	
P-value for Relative Risk	0.6811	
Risk difference (95% CI)	-0.02 (-18.22, 18.18)	
P-value for Risk Difference	0.9981	
Improvement	9 (16.4%)	1 (3.1%)
Odds ratio (95% CI)	6.295 (0.756, 52.402)	
P-value for Odds Ratio	0.0889	
Relative Risk (95% CI)	5.26 (0.70, 39.60)	
P-value for Relative Risk	0.1067	
Risk difference (95% CI)	12.45 (-12.41, 37.31)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3263	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	11 (26.8%)	8 (28.6%)
Odds ratio (95% CI)	0.834 (0.263, 2.652)	
P-value for Odds Ratio	0.7589	
Relative Risk (95% CI)	0.84 (0.41, 1.71)	
P-value for Relative Risk	0.6290	
Risk difference (95% CI)	-2.92 (-25.26, 19.42)	
P-value for Risk Difference	0.7978	
Improvement	3 (7.3%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.92 (0.36, 23.58)	
P-value for Relative Risk	0.2932	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	9 (34.6%)	4 (18.2%)
Odds ratio (95% CI)	2.367 (0.573, 9.773)	
P-value for Odds Ratio	0.2336	
Relative Risk (95% CI)	1.61 (0.58, 4.48)	
P-value for Relative Risk	0.3621	
Risk difference (95% CI)	19.86 (19.86, 19.86)*	
Improvement	2 (7.7%)	1 (4.5%)
Odds ratio (95% CI)	1.802 (0.145, 22.326)	
P-value for Odds Ratio	0.6466	
Relative Risk (95% CI)	1.76 (0.18, 17.69)	
P-value for Relative Risk	0.6308	
Risk difference (95% CI)	2.79 (-21.80, 27.39)	
P-value for Risk Difference	0.8239	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	5 (23.8%)	3 (20.0%)
Odds ratio (95% CI)	1.784 (0.300, 10.618)	
P-value for Odds Ratio	0.5248	
Relative Risk (95% CI)	1.56 (0.42, 5.74)	
P-value for Relative Risk	0.5072	
Risk difference (95% CI)	8.29 (-25.47, 42.04)	
P-value for Risk Difference	0.6304	
Improvement	2 (9.5%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.58 (0.25, 85.33)	
P-value for Relative Risk	0.2572	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	3 (42.9%)	2 (20.0%)
Odds ratio (95% CI)	9.990 (0.465, 214.484)	
P-value for Odds Ratio	0.1413	
Relative Risk (95% CI)	3.84 (0.57, 26.02)	
P-value for Relative Risk	0.1682	
Risk difference (95% CI)	31.65 (31.65, 31.65)*	
Improvement	1 (14.3%)	1 (10.0%)
Odds ratio (95% CI)	0.000 (0.000, 3.13E171)	
P-value for Odds Ratio	0.9600	
Relative Risk (95% CI)	0.15 (0.00, 30.00)	
P-value for Relative Risk	0.4801	
Risk difference (95% CI)	-11.84 (-11.84, -11.84)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	33 (21.9%)	37 (24.2%)
Odds ratio (95% CI)	0.885 (0.517, 1.514)	
P-value for Odds Ratio	0.6555	
Relative Risk (95% CI)	0.91 (0.60, 1.37)	
P-value for Relative Risk	0.6486	
Risk difference (95% CI)	-2.23 (-11.67, 7.20)	
P-value for Risk Difference	0.6426	
Improvement	27 (17.9%)	31 (20.3%)
Odds ratio (95% CI)	0.836 (0.470, 1.488)	
P-value for Odds Ratio	0.5424	
Relative Risk (95% CI)	0.86 (0.54, 1.37)	
P-value for Relative Risk	0.5299	
Risk difference (95% CI)	-2.50 (-11.28, 6.28)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5769	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	33 (24.3%)	31 (25.2%)
Odds ratio (95% CI)	0.953 (0.535, 1.696)	
P-value for Odds Ratio	0.8695	
Relative Risk (95% CI)	0.94 (0.62, 1.43)	
P-value for Relative Risk	0.7665	
Risk difference (95% CI)	-0.77 (-11.10, 9.55)	
P-value for Risk Difference	0.8834	
Improvement	30 (22.1%)	21 (17.1%)
Odds ratio (95% CI)	1.348 (0.722, 2.515)	
P-value for Odds Ratio	0.3482	
Relative Risk (95% CI)	1.27 (0.77, 2.10)	
P-value for Relative Risk	0.3540	
Risk difference (95% CI)	4.75 (-4.98, 14.47)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3386	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	43 (33.9%)	26 (23.6%)
Odds ratio (95% CI)	1.686 (0.943, 3.014)	
P-value for Odds Ratio	0.0779	
Relative Risk (95% CI)	1.44 (0.95, 2.19)	
P-value for Relative Risk	0.0842	
Risk difference (95% CI)	10.69 (-0.63, 22.01)	
P-value for Risk Difference	0.0642	
Improvement	24 (18.9%)	22 (20.0%)
Odds ratio (95% CI)	0.974 (0.508, 1.866)	
P-value for Odds Ratio	0.9355	
Relative Risk (95% CI)	0.96 (0.57, 1.62)	
P-value for Relative Risk	0.8859	
Risk difference (95% CI)	0.72 (-9.81, 11.25)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8934	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	38 (27.3%)	34 (26.0%)
Odds ratio (95% CI)	1.079 (0.626, 1.860)	
P-value for Odds Ratio	0.7838	
Relative Risk (95% CI)	1.06 (0.71, 1.58)	
P-value for Relative Risk	0.7774	
Risk difference (95% CI)	1.35 (-9.18, 11.88)	
P-value for Risk Difference	0.8014	
Improvement	36 (25.9%)	25 (19.1%)
Odds ratio (95% CI)	1.552 (0.862, 2.792)	
P-value for Odds Ratio	0.1427	
Relative Risk (95% CI)	1.39 (0.89, 2.17)	
P-value for Relative Risk	0.1510	
Risk difference (95% CI)	7.86 (-2.10, 17.81)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1220	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	32 (29.4%)	15 (20.3%)
Odds ratio (95% CI)	1.865 (0.908, 3.833)	
P-value for Odds Ratio	0.0897	
Relative Risk (95% CI)	1.53 (0.90, 2.60)	
P-value for Relative Risk	0.1153	
Risk difference (95% CI)	10.83 (-3.01, 24.67)	
P-value for Risk Difference	0.1252	
Improvement	24 (22.0%)	15 (20.3%)
Odds ratio (95% CI)	1.085 (0.518, 2.273)	
P-value for Odds Ratio	0.8290	
Relative Risk (95% CI)	1.04 (0.59, 1.85)	
P-value for Relative Risk	0.8854	
Risk difference (95% CI)	4.45 (-8.63, 17.53)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5047	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	29 (27.9%)	11 (17.2%)
Odds ratio (95% CI)	2.009 (0.912, 4.423)	
P-value for Odds Ratio	0.0832	
Relative Risk (95% CI)	1.66 (0.90, 3.07)	
P-value for Relative Risk	0.1056	
Risk difference (95% CI)	13.47 (-0.47, 27.41)	
P-value for Risk Difference	0.0583	
Improvement	22 (21.2%)	11 (17.2%)
Odds ratio (95% CI)	1.315 (0.587, 2.946)	
P-value for Odds Ratio	0.5059	
Relative Risk (95% CI)	1.25 (0.65, 2.40)	
P-value for Relative Risk	0.5078	
Risk difference (95% CI)	4.18 (-8.05, 16.41)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5034	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	27 (31.8%)	14 (25.5%)
Odds ratio (95% CI)	1.348 (0.628, 2.892)	
P-value for Odds Ratio	0.4435	
Relative Risk (95% CI)	1.23 (0.71, 2.13)	
P-value for Relative Risk	0.4582	
Risk difference (95% CI)	6.44 (-9.18, 22.06)	
P-value for Risk Difference	0.4190	
Improvement	26 (30.6%)	9 (16.4%)
Odds ratio (95% CI)	2.298 (0.977, 5.405)	
P-value for Odds Ratio	0.0566	
Relative Risk (95% CI)	1.90 (0.96, 3.75)	
P-value for Relative Risk	0.0647	
Risk difference (95% CI)	14.72 (0.90, 28.54)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0368	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	21 (29.6%)	7 (16.3%)
Odds ratio (95% CI)	2.226 (0.837, 5.919)	
P-value for Odds Ratio	0.1089	
Relative Risk (95% CI)	1.78 (0.83, 3.81)	
P-value for Relative Risk	0.1405	
Risk difference (95% CI)	15.67 (0.30, 31.03)	
P-value for Risk Difference	0.0456	
Improvement	16 (22.5%)	6 (14.0%)
Odds ratio (95% CI)	1.833 (0.650, 5.170)	
P-value for Odds Ratio	0.2517	
Relative Risk (95% CI)	1.65 (0.69, 3.90)	
P-value for Relative Risk	0.2579	
Risk difference (95% CI)	8.30 (-5.79, 22.40)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2482	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	16 (29.1%)	5 (15.6%)
Odds ratio (95% CI)	2.244 (0.727, 6.933)	
P-value for Odds Ratio	0.1600	
Relative Risk (95% CI)	1.82 (0.74, 4.51)	
P-value for Relative Risk	0.1942	
Risk difference (95% CI)	15.58 (-2.37, 33.53)	
P-value for Risk Difference	0.0890	
Improvement	15 (27.3%)	4 (12.5%)
Odds ratio (95% CI)	2.648 (0.789, 8.881)	
P-value for Odds Ratio	0.1148	
Relative Risk (95% CI)	2.22 (0.80, 6.11)	
P-value for Relative Risk	0.1241	
Risk difference (95% CI)	15.02 (-1.67, 31.70)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0778	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	16 (39.0%)	7 (25.0%)
Odds ratio (95% CI)	1.890 (0.648, 5.511)	
P-value for Odds Ratio	0.2435	
Relative Risk (95% CI)	1.54 (0.72, 3.28)	
P-value for Relative Risk	0.2612	
Risk difference (95% CI)	12.97 (-9.45, 35.39)	
P-value for Risk Difference	0.2568	
Improvement	8 (19.5%)	7 (25.0%)
Odds ratio (95% CI)	0.731 (0.225, 2.378)	
P-value for Odds Ratio	0.6031	
Relative Risk (95% CI)	0.79 (0.33, 1.88)	
P-value for Relative Risk	0.5872	
Risk difference (95% CI)	-4.03 (-23.50, 15.45)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6851	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	8 (30.8%)	2 (9.1%)
Odds ratio (95% CI)	4.591 (0.811, 26.000)	
P-value for Odds Ratio	0.0849	
Relative Risk (95% CI)	3.18 (0.78, 13.05)	
P-value for Relative Risk	0.1079	
Risk difference (95% CI)	20.20 (-9.83, 50.24)	
P-value for Risk Difference	0.1874	
Improvement	4 (15.4%)	7 (31.8%)
Odds ratio (95% CI)	0.418 (0.098, 1.793)	
P-value for Odds Ratio	0.2404	
Relative Risk (95% CI)	0.51 (0.17, 1.56)	
P-value for Relative Risk	0.2392	
Risk difference (95% CI)	-15.89 (-41.88, 10.10)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2308	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	8 (38.1%)	4 (26.7%)
Odds ratio (95% CI)	1.420 (0.287, 7.030)	
P-value for Odds Ratio	0.6671	
Relative Risk (95% CI)	1.30 (0.42, 4.03)	
P-value for Relative Risk	0.6440	
Risk difference (95% CI)	6.78 (-26.92, 40.48)	
P-value for Risk Difference	0.6934	
Improvement	5 (23.8%)	6 (40.0%)
Odds ratio (95% CI)	0.451 (0.090, 2.248)	
P-value for Odds Ratio	0.3313	
Relative Risk (95% CI)	0.60 (0.19, 1.90)	
P-value for Relative Risk	0.3883	
Risk difference (95% CI)	-17.84 (-17.84, -17.84)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	3 (42.9%)	2 (20.0%)
Odds ratio (95% CI)	101838.8 (0.000, 8.248E86)	
P-value for Odds Ratio	0.9046	
Relative Risk (95% CI)	91663.60 (0.00, 3.87E136)	
P-value for Relative Risk	0.9411	
Risk difference (95% CI)	40.80 (40.80, 40.80)*	
Improvement	0	2 (20.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.41 (0.06, 2.80)	
P-value for Relative Risk	0.3588	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	25 (16.6%)	18 (11.8%)
Odds ratio (95% CI)	1.525 (0.791, 2.940)	
P-value for Odds Ratio	0.2081	
Relative Risk (95% CI)	1.43 (0.82, 2.51)	
P-value for Relative Risk	0.2116	
Risk difference (95% CI)	4.90 (-2.68, 12.48)	
P-value for Risk Difference	0.2053	
Improvement	22 (14.6%)	17 (11.1%)
Odds ratio (95% CI)	1.362 (0.685, 2.712)	
P-value for Odds Ratio	0.3785	
Relative Risk (95% CI)	1.29 (0.72, 2.32)	
P-value for Relative Risk	0.3865	
Risk difference (95% CI)	2.57 (-4.67, 9.82)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4868	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	23 (16.9%)	26 (21.1%)
Odds ratio (95% CI)	0.774 (0.414, 1.447)	
P-value for Odds Ratio	0.4220	
Relative Risk (95% CI)	0.81 (0.49, 1.34)	
P-value for Relative Risk	0.4055	
Risk difference (95% CI)	-3.48 (-13.37, 6.41)	
P-value for Risk Difference	0.4902	
Improvement	25 (18.4%)	18 (14.6%)
Odds ratio (95% CI)	1.280 (0.646, 2.535)	
P-value for Odds Ratio	0.4790	
Relative Risk (95% CI)	1.24 (0.72, 2.15)	
P-value for Relative Risk	0.4317	
Risk difference (95% CI)	1.32 (-7.26, 9.89)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7635	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	25 (19.7%)	17 (15.5%)
Odds ratio (95% CI)	1.325 (0.667, 2.633)	
P-value for Odds Ratio	0.4219	
Relative Risk (95% CI)	1.25 (0.71, 2.19)	
P-value for Relative Risk	0.4334	
Risk difference (95% CI)	3.98 (-5.69, 13.65)	
P-value for Risk Difference	0.4200	
Improvement	24 (18.9%)	13 (11.8%)
Odds ratio (95% CI)	1.765 (0.838, 3.719)	
P-value for Odds Ratio	0.1352	
Relative Risk (95% CI)	1.66 (0.90, 3.09)	
P-value for Relative Risk	0.1065	
Risk difference (95% CI)	3.80 (-5.74, 13.34)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4354	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	33 (23.7%)	29 (22.1%)
Odds ratio (95% CI)	1.116 (0.629, 1.980)	
P-value for Odds Ratio	0.7077	
Relative Risk (95% CI)	1.10 (0.71, 1.70)	
P-value for Relative Risk	0.6713	
Risk difference (95% CI)	1.28 (-8.82, 11.38)	
P-value for Risk Difference	0.8037	
Improvement	17 (12.2%)	21 (16.0%)
Odds ratio (95% CI)	0.753 (0.372, 1.524)	
P-value for Odds Ratio	0.4303	
Relative Risk (95% CI)	0.81 (0.45, 1.45)	
P-value for Relative Risk	0.4729	
Risk difference (95% CI)	-4.10 (-12.16, 3.96)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3193	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	21 (19.3%)	12 (16.2%)
Odds ratio (95% CI)	1.243 (0.562, 2.751)	
P-value for Odds Ratio	0.5917	
Relative Risk (95% CI)	1.17 (0.62, 2.23)	
P-value for Relative Risk	0.6314	
Risk difference (95% CI)	4.09 (-7.37, 15.56)	
P-value for Risk Difference	0.4839	
Improvement	16 (14.7%)	13 (17.6%)
Odds ratio (95% CI)	0.780 (0.341, 1.784)	
P-value for Odds Ratio	0.5568	
Relative Risk (95% CI)	0.83 (0.43, 1.61)	
P-value for Relative Risk	0.5822	
Risk difference (95% CI)	-3.63 (-14.19, 6.92)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4999	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	17 (16.3%)	7 (10.9%)
Odds ratio (95% CI)	1.477 (0.565, 3.864)	
P-value for Odds Ratio	0.4263	
Relative Risk (95% CI)	1.44 (0.64, 3.25)	
P-value for Relative Risk	0.3813	
Risk difference (95% CI)	2.67 (-7.82, 13.15)	
P-value for Risk Difference	0.6183	
Improvement	13 (12.5%)	13 (20.3%)
Odds ratio (95% CI)	0.532 (0.224, 1.265)	
P-value for Odds Ratio	0.1534	
Relative Risk (95% CI)	0.60 (0.30, 1.21)	
P-value for Relative Risk	0.1522	
Risk difference (95% CI)	-7.07 (-18.20, 4.06)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2133	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	20 (23.5%)	9 (16.4%)
Odds ratio (95% CI)	1.645 (0.674, 4.012)	
P-value for Odds Ratio	0.2739	
Relative Risk (95% CI)	1.47 (0.72, 2.97)	
P-value for Relative Risk	0.2873	
Risk difference (95% CI)	10.43 (-5.74, 26.61)	
P-value for Risk Difference	0.2060	
Improvement	16 (18.8%)	9 (16.4%)
Odds ratio (95% CI)	1.206 (0.486, 2.992)	
P-value for Odds Ratio	0.6868	
Relative Risk (95% CI)	1.14 (0.54, 2.39)	
P-value for Relative Risk	0.7283	
Risk difference (95% CI)	4.08 (-9.01, 17.17)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5415	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	18 (25.4%)	6 (14.0%)
Odds ratio (95% CI)	2.146 (0.751, 6.136)	
P-value for Odds Ratio	0.1540	
Relative Risk (95% CI)	1.63 (0.70, 3.81)	
P-value for Relative Risk	0.2591	
Risk difference (95% CI)	14.81 (-5.22, 34.85)	
P-value for Risk Difference	0.1473	
Improvement	15 (21.1%)	8 (18.6%)
Odds ratio (95% CI)	1.076 (0.402, 2.874)	
P-value for Odds Ratio	0.8845	
Relative Risk (95% CI)	1.06 (0.49, 2.27)	
P-value for Relative Risk	0.8853	
Risk difference (95% CI)	1.08 (-13.59, 15.74)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8854	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	13 (23.6%)	3 (9.4%)
Odds ratio (95% CI)	3.194 (0.811, 12.587)	
P-value for Odds Ratio	0.0969	
Relative Risk (95% CI)	2.52 (0.79, 8.09)	
P-value for Relative Risk	0.1196	
Risk difference (95% CI)	14.21 (-3.92, 32.34)	
P-value for Risk Difference	0.1245	
Improvement	12 (21.8%)	7 (21.9%)
Odds ratio (95% CI)	0.932 (0.317, 2.737)	
P-value for Odds Ratio	0.8979	
Relative Risk (95% CI)	0.96 (0.43, 2.14)	
P-value for Relative Risk	0.9147	
Risk difference (95% CI)	-2.13 (-19.87, 15.60)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8136	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	13 (31.7%)	5 (17.9%)
Odds ratio (95% CI)	2.042 (0.615, 6.781)	
P-value for Odds Ratio	0.2436	
Relative Risk (95% CI)	1.80 (0.74, 4.40)	
P-value for Relative Risk	0.1965	
Risk difference (95% CI)	13.11 (-8.64, 34.85)	
P-value for Risk Difference	0.2375	
Improvement	8 (19.5%)	5 (17.9%)
Odds ratio (95% CI)	1.108 (0.308, 3.990)	
P-value for Odds Ratio	0.8755	
Relative Risk (95% CI)	1.06 (0.40, 2.80)	
P-value for Relative Risk	0.9120	
Risk difference (95% CI)	3.09 (-14.33, 20.50)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7284	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	10 (38.5%)	4 (18.2%)
Odds ratio (95% CI)	2.531 (0.634, 10.111)	
P-value for Odds Ratio	0.1887	
Relative Risk (95% CI)	1.84 (0.68, 4.97)	
P-value for Relative Risk	0.2294	
Risk difference (95% CI)	20.33 (20.33, 20.33)*	
Improvement	5 (19.2%)	3 (13.6%)
Odds ratio (95% CI)	1.846 (0.303, 11.267)	
P-value for Odds Ratio	0.5063	
Relative Risk (95% CI)	1.77 (0.38, 8.26)	
P-value for Relative Risk	0.4652	
Risk difference (95% CI)	4.70 (-19.10, 28.50)	
P-value for Risk Difference	0.6987	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	4 (19.0%)	2 (13.3%)
Odds ratio (95% CI)	0.693 (0.074, 6.503)	
P-value for Odds Ratio	0.7479	
Relative Risk (95% CI)	0.76 (0.11, 5.15)	
P-value for Relative Risk	0.7790	
Risk difference (95% CI)	-3.82 (-34.89, 27.25)	
P-value for Risk Difference	0.8095	
Improvement	5 (23.8%)	4 (26.7%)
Odds ratio (95% CI)	0.910 (0.158, 5.250)	
P-value for Odds Ratio	0.9160	
Relative Risk (95% CI)	0.66 (0.15, 2.82)	
P-value for Relative Risk	0.5754	
Risk difference (95% CI)	1.44 (-32.04, 34.92)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9328	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	3 (42.9%)	2 (20.0%)
Odds ratio (95% CI)	7.365 (0.421, 128.921)	
P-value for Odds Ratio	0.1715	
Relative Risk (95% CI)	3.53 (0.35, 36.06)	
P-value for Relative Risk	0.2869	
Risk difference (95% CI)	36.55 (-19.68, 92.78)	
P-value for Risk Difference	0.2026	
Improvement	1 (14.3%)	1 (10.0%)
Odds ratio (95% CI)	1.452 (0.050, 42.078)	
P-value for Odds Ratio	0.8283	
Relative Risk (95% CI)	3.22 (3.22, 3.22)*	
Risk difference (95% CI)	3.71 (-63.96, 71.38)	
P-value for Risk Difference	0.9144	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	31 (20.5%)	32 (20.9%)
Odds ratio (95% CI)	0.960 (0.549, 1.679)	
P-value for Odds Ratio	0.8861	
Relative Risk (95% CI)	0.98 (0.63, 1.52)	
P-value for Relative Risk	0.9155	
Risk difference (95% CI)	-1.49 (-10.57, 7.59)	
P-value for Risk Difference	0.7471	
Improvement	27 (17.9%)	21 (13.7%)
Odds ratio (95% CI)	1.365 (0.730, 2.550)	
P-value for Odds Ratio	0.3294	
Relative Risk (95% CI)	1.33 (0.79, 2.24)	
P-value for Relative Risk	0.2880	
Risk difference (95% CI)	3.24 (-4.89, 11.37)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4351	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	30 (22.1%)	28 (22.8%)
Odds ratio (95% CI)	0.956 (0.529, 1.725)	
P-value for Odds Ratio	0.8800	
Relative Risk (95% CI)	1.00 (0.63, 1.57)	
P-value for Relative Risk	0.9883	
Risk difference (95% CI)	-3.74 (-14.65, 7.17)	
P-value for Risk Difference	0.5015	
Improvement	28 (20.6%)	13 (10.6%)
Odds ratio (95% CI)	2.177 (1.065, 4.451)	
P-value for Odds Ratio	0.0330	
Relative Risk (95% CI)	1.93 (1.05, 3.55)	
P-value for Relative Risk	0.0344	
Risk difference (95% CI)	9.88 (1.21, 18.55)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0255	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	35 (27.6%)	26 (23.6%)
Odds ratio (95% CI)	1.289 (0.709, 2.346)	
P-value for Odds Ratio	0.4054	
Relative Risk (95% CI)	1.19 (0.77, 1.83)	
P-value for Relative Risk	0.4431	
Risk difference (95% CI)	5.08 (-5.86, 16.02)	
P-value for Risk Difference	0.3628	
Improvement	27 (21.3%)	12 (10.9%)
Odds ratio (95% CI)	2.338 (1.107, 4.936)	
P-value for Odds Ratio	0.0259	
Relative Risk (95% CI)	2.04 (1.09, 3.82)	
P-value for Relative Risk	0.0259	
Risk difference (95% CI)	11.99 (1.86, 22.12)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0204	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	41 (29.5%)	34 (26.0%)
Odds ratio (95% CI)	1.197 (0.699, 2.051)	
P-value for Odds Ratio	0.5123	
Relative Risk (95% CI)	1.14 (0.77, 1.68)	
P-value for Relative Risk	0.5190	
Risk difference (95% CI)	3.65 (-7.05, 14.34)	
P-value for Risk Difference	0.5040	
Improvement	23 (16.5%)	21 (16.0%)
Odds ratio (95% CI)	1.040 (0.540, 2.005)	
P-value for Odds Ratio	0.9058	
Relative Risk (95% CI)	1.04 (0.60, 1.78)	
P-value for Relative Risk	0.8959	
Risk difference (95% CI)	-0.04 (-8.80, 8.72)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9929	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	32 (29.4%)	22 (29.7%)
Odds ratio (95% CI)	1.041 (0.541, 2.004)	
P-value for Odds Ratio	0.9044	
Relative Risk (95% CI)	1.02 (0.65, 1.60)	
P-value for Relative Risk	0.9433	
Risk difference (95% CI)	2.09 (-12.06, 16.23)	
P-value for Risk Difference	0.7725	
Improvement	22 (20.2%)	11 (14.9%)
Odds ratio (95% CI)	1.562 (0.692, 3.527)	
P-value for Odds Ratio	0.2833	
Relative Risk (95% CI)	1.42 (0.74, 2.73)	
P-value for Relative Risk	0.2856	
Risk difference (95% CI)	6.67 (-4.42, 17.76)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2385	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	31 (29.8%)	14 (21.9%)
Odds ratio (95% CI)	1.579 (0.757, 3.296)	
P-value for Odds Ratio	0.2233	
Relative Risk (95% CI)	1.40 (0.81, 2.42)	
P-value for Relative Risk	0.2261	
Risk difference (95% CI)	9.18 (-4.98, 23.35)	
P-value for Risk Difference	0.2038	
Improvement	18 (17.3%)	11 (17.2%)
Odds ratio (95% CI)	1.023 (0.442, 2.368)	
P-value for Odds Ratio	0.9583	
Relative Risk (95% CI)	1.01 (0.52, 1.99)	
P-value for Relative Risk	0.9695	
Risk difference (95% CI)	-1.52 (-13.72, 10.69)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8074	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	28 (32.9%)	19 (34.5%)
Odds ratio (95% CI)	0.930 (0.452, 1.912)	
P-value for Odds Ratio	0.8427	
Relative Risk (95% CI)	0.95 (0.59, 1.53)	
P-value for Relative Risk	0.8440	
Risk difference (95% CI)	-1.73 (-17.87, 14.40)	
P-value for Risk Difference	0.8332	
Improvement	14 (16.5%)	8 (14.5%)
Odds ratio (95% CI)	1.161 (0.446, 3.020)	
P-value for Odds Ratio	0.7603	
Relative Risk (95% CI)	1.11 (0.50, 2.46)	
P-value for Relative Risk	0.8009	
Risk difference (95% CI)	3.23 (-8.67, 15.14)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5943	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	27 (38.0%)	10 (23.3%)
Odds ratio (95% CI)	1.885 (0.793, 4.480)	
P-value for Odds Ratio	0.1513	
Relative Risk (95% CI)	1.59 (0.86, 2.95)	
P-value for Relative Risk	0.1409	
Risk difference (95% CI)	12.26 (-4.84, 29.35)	
P-value for Risk Difference	0.1599	
Improvement	12 (16.9%)	6 (14.0%)
Odds ratio (95% CI)	1.273 (0.435, 3.727)	
P-value for Odds Ratio	0.6597	
Relative Risk (95% CI)	1.21 (0.49, 2.98)	
P-value for Relative Risk	0.6857	
Risk difference (95% CI)	4.63 (-9.60, 18.86)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5237	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	18 (32.7%)	8 (25.0%)
Odds ratio (95% CI)	1.497 (0.555, 4.038)	
P-value for Odds Ratio	0.4250	
Relative Risk (95% CI)	1.26 (0.62, 2.58)	
P-value for Relative Risk	0.5265	
Risk difference (95% CI)	11.26 (-9.04, 31.57)	
P-value for Risk Difference	0.2770	
Improvement	12 (21.8%)	2 (6.3%)
Odds ratio (95% CI)	3.903 (0.798, 19.090)	
P-value for Odds Ratio	0.0926	
Relative Risk (95% CI)	2.80 (0.79, 9.93)	
P-value for Relative Risk	0.1100	
Risk difference (95% CI)	11.08 (-3.98, 26.14)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1492	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	17 (41.5%)	7 (25.0%)
Odds ratio (95% CI)	2.143 (0.724, 6.342)	
P-value for Odds Ratio	0.1684	
Relative Risk (95% CI)	1.59 (0.76, 3.33)	
P-value for Relative Risk	0.2207	
Risk difference (95% CI)	12.90 (-7.74, 33.54)	
P-value for Risk Difference	0.2206	
Improvement	8 (19.5%)	2 (7.1%)
Odds ratio (95% CI)	3.300 (0.636, 17.124)	
P-value for Odds Ratio	0.1552	
Relative Risk (95% CI)	2.76 (0.64, 11.95)	
P-value for Relative Risk	0.1751	
Risk difference (95% CI)	11.23 (-11.26, 33.72)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3277	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	15 (57.7%)	8 (36.4%)
Odds ratio (95% CI)	1.830 (0.541, 6.190)	
P-value for Odds Ratio	0.3312	
Relative Risk (95% CI)	1.35 (0.72, 2.52)	
P-value for Relative Risk	0.3539	
Risk difference (95% CI)	14.92 (14.92, 14.92)*	
Improvement	6 (23.1%)	3 (13.6%)
Odds ratio (95% CI)	1.500 (0.308, 7.297)	
P-value for Odds Ratio	0.6155	
Relative Risk (95% CI)	1.30 (0.36, 4.65)	
P-value for Relative Risk	0.6853	
Risk difference (95% CI)	8.07 (8.07, 8.07)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	11 (52.4%)	4 (26.7%)
Odds ratio (95% CI)	1.687 (0.348, 8.168)	
P-value for Odds Ratio	0.5157	
Relative Risk (95% CI)	1.18 (0.63, 2.19)	
P-value for Relative Risk	0.6066	
Risk difference (95% CI)	9.72 (9.72, 9.72)*	
Improvement	3 (14.3%)	1 (6.7%)
Odds ratio (95% CI)	2.000 (0.153, 26.187)	
P-value for Odds Ratio	0.5974	
Relative Risk (95% CI)	1.82 (0.19, 17.12)	
P-value for Relative Risk	0.6013	
Risk difference (95% CI)	4.64 (-29.08, 38.35)	
P-value for Risk Difference	0.7876	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	5 (71.4%)	4 (40.0%)
Odds ratio (95% CI)	9.151 (0.492, 170.163)	
P-value for Odds Ratio	0.1377	
Relative Risk (95% CI)	2.10 (0.53, 8.31)	
P-value for Relative Risk	0.2921	
Risk difference (95% CI)	42.01 (-5.26, 89.28)	
P-value for Risk Difference	0.0816	
Improvement	1 (14.3%)	2 (20.0%)
Odds ratio (95% CI)	0.289 (0.010, 8.733)	
P-value for Odds Ratio	0.4751	
Relative Risk (95% CI)	0.19 (0.19, 0.19)*	
Risk difference (95% CI)	-19.79 (-108.41, 68.83)	
P-value for Risk Difference	0.6616	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	1 (50.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	27 (17.9%)	34 (22.2%)
Odds ratio (95% CI)	0.744 (0.421, 1.315)	
P-value for Odds Ratio	0.3084	
Relative Risk (95% CI)	0.77 (0.49, 1.22)	
P-value for Relative Risk	0.2650	
Risk difference (95% CI)	-3.22 (-12.18, 5.74)	
P-value for Risk Difference	0.4813	
Improvement	34 (22.5%)	29 (19.0%)
Odds ratio (95% CI)	1.215 (0.691, 2.139)	
P-value for Odds Ratio	0.4985	
Relative Risk (95% CI)	1.17 (0.76, 1.81)	
P-value for Relative Risk	0.4781	
Risk difference (95% CI)	2.67 (-6.24, 11.58)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5566	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	33 (24.3%)	26 (21.1%)
Odds ratio (95% CI)	1.203 (0.667, 2.172)	
P-value for Odds Ratio	0.5387	
Relative Risk (95% CI)	1.18 (0.75, 1.85)	
P-value for Relative Risk	0.4774	
Risk difference (95% CI)	1.86 (-8.29, 12.00)	
P-value for Risk Difference	0.7197	
Improvement	39 (28.7%)	27 (22.0%)
Odds ratio (95% CI)	1.398 (0.787, 2.483)	
P-value for Odds Ratio	0.2526	
Relative Risk (95% CI)	1.29 (0.84, 1.97)	
P-value for Relative Risk	0.2389	
Risk difference (95% CI)	5.59 (-4.93, 16.10)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2976	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	35 (27.6%)	27 (24.5%)
Odds ratio (95% CI)	1.176 (0.652, 2.121)	
P-value for Odds Ratio	0.5893	
Relative Risk (95% CI)	1.12 (0.72, 1.72)	
P-value for Relative Risk	0.6229	
Risk difference (95% CI)	3.56 (-7.64, 14.76)	
P-value for Risk Difference	0.5336	
Improvement	34 (26.8%)	22 (20.0%)
Odds ratio (95% CI)	1.489 (0.801, 2.769)	
P-value for Odds Ratio	0.2083	
Relative Risk (95% CI)	1.37 (0.85, 2.19)	
P-value for Relative Risk	0.1929	
Risk difference (95% CI)	5.85 (-4.95, 16.64)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

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Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2882	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	137	131
Deterioration	37 (27.0%)	31 (23.7%)
Odds ratio (95% CI)	1.177 (0.672, 2.062)	
P-value for Odds Ratio	0.5682	
Relative Risk (95% CI)	1.15 (0.76, 1.73)	
P-value for Relative Risk	0.5049	
Risk difference (95% CI)	1.91 (-8.41, 12.23)	
P-value for Risk Difference	0.7171	
Improvement	34 (24.8%)	30 (22.9%)
Odds ratio (95% CI)	1.127 (0.635, 1.998)	
P-value for Odds Ratio	0.6830	
Relative Risk (95% CI)	1.13 (0.74, 1.73)	
P-value for Relative Risk	0.5718	
Risk difference (95% CI)	0.81 (-9.41, 11.04)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8760	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	30 (27.5%)	11 (14.9%)
Odds ratio (95% CI)	2.418 (1.102, 5.307)	
P-value for Odds Ratio	0.0277	
Relative Risk (95% CI)	1.86 (1.00, 3.47)	
P-value for Relative Risk	0.0497	
Risk difference (95% CI)	13.53 (0.06, 27.01)	
P-value for Risk Difference	0.0491	
Improvement	25 (22.9%)	19 (25.7%)
Odds ratio (95% CI)	0.870 (0.434, 1.743)	
P-value for Odds Ratio	0.6936	
Relative Risk (95% CI)	0.90 (0.54, 1.52)	
P-value for Relative Risk	0.7000	
Risk difference (95% CI)	-2.82 (-15.86, 10.23)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6720	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	22 (21.2%)	12 (18.8%)
Odds ratio (95% CI)	1.228 (0.554, 2.721)	
P-value for Odds Ratio	0.6137	
Relative Risk (95% CI)	1.19 (0.64, 2.23)	
P-value for Relative Risk	0.5870	
Risk difference (95% CI)	1.86 (-10.05, 13.77)	
P-value for Risk Difference	0.7599	
Improvement	27 (26.0%)	15 (23.4%)
Odds ratio (95% CI)	1.158 (0.556, 2.409)	
P-value for Odds Ratio	0.6957	
Relative Risk (95% CI)	1.10 (0.64, 1.91)	
P-value for Relative Risk	0.7284	
Risk difference (95% CI)	3.84 (-10.07, 17.75)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5883	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	19 (22.4%)	11 (20.0%)
Odds ratio (95% CI)	1.207 (0.520, 2.803)	
P-value for Odds Ratio	0.6610	
Relative Risk (95% CI)	1.14 (0.59, 2.20)	
P-value for Relative Risk	0.6983	
Risk difference (95% CI)	5.12 (-9.52, 19.75)	
P-value for Risk Difference	0.4933	
Improvement	22 (25.9%)	11 (20.0%)
Odds ratio (95% CI)	1.380 (0.602, 3.161)	
P-value for Odds Ratio	0.4467	
Relative Risk (95% CI)	1.28 (0.68, 2.42)	
P-value for Relative Risk	0.4494	
Risk difference (95% CI)	4.75 (-9.25, 18.76)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5059	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	16 (22.5%)	8 (18.6%)
Odds ratio (95% CI)	1.389 (0.529, 3.646)	
P-value for Odds Ratio	0.5050	
Relative Risk (95% CI)	1.27 (0.60, 2.69)	
P-value for Relative Risk	0.5396	
Risk difference (95% CI)	8.23 (-9.67, 26.13)	
P-value for Risk Difference	0.3674	
Improvement	18 (25.4%)	11 (25.6%)
Odds ratio (95% CI)	0.911 (0.374, 2.218)	
P-value for Odds Ratio	0.8369	
Relative Risk (95% CI)	0.96 (0.50, 1.82)	
P-value for Relative Risk	0.8927	
Risk difference (95% CI)	-2.11 (-18.46, 14.24)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8002	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	14 (25.5%)	4 (12.5%)
Odds ratio (95% CI)	2.601 (0.760, 8.905)	
P-value for Odds Ratio	0.1280	
Relative Risk (95% CI)	2.08 (0.76, 5.70)	
P-value for Relative Risk	0.1550	
Risk difference (95% CI)	14.53 (-6.51, 35.57)	
P-value for Risk Difference	0.1758	
Improvement	15 (27.3%)	6 (18.8%)
Odds ratio (95% CI)	1.542 (0.522, 4.556)	
P-value for Odds Ratio	0.4335	
Relative Risk (95% CI)	1.40 (0.61, 3.22)	
P-value for Relative Risk	0.4271	
Risk difference (95% CI)	7.33 (-10.30, 24.96)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4152	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	10 (24.4%)	4 (14.3%)
Odds ratio (95% CI)	1.860 (0.513, 6.738)	
P-value for Odds Ratio	0.3449	
Relative Risk (95% CI)	1.67 (0.58, 4.76)	
P-value for Relative Risk	0.3406	
Risk difference (95% CI)	8.31 (-10.93, 27.56)	
P-value for Risk Difference	0.3971	
Improvement	8 (19.5%)	5 (17.9%)
Odds ratio (95% CI)	1.166 (0.330, 4.117)	
P-value for Odds Ratio	0.8113	
Relative Risk (95% CI)	1.13 (0.41, 3.07)	
P-value for Relative Risk	0.8148	
Risk difference (95% CI)	1.81 (-20.31, 23.92)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8728	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	8 (30.8%)	2 (9.1%)
Odds ratio (95% CI)	4.591 (0.811, 26.000)	
P-value for Odds Ratio	0.0849	
Relative Risk (95% CI)	3.23 (0.78, 13.33)	
P-value for Relative Risk	0.1050	
Risk difference (95% CI)	19.35 (-10.04, 48.74)	
P-value for Risk Difference	0.1969	
Improvement	7 (26.9%)	5 (22.7%)
Odds ratio (95% CI)	1.217 (0.279, 5.305)	
P-value for Odds Ratio	0.7935	
Relative Risk (95% CI)	1.06 (0.36, 3.15)	
P-value for Relative Risk	0.9128	
Risk difference (95% CI)	6.02 (-18.52, 30.55)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6307	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	5 (23.8%)	4 (26.7%)
Odds ratio (95% CI)	0.460 (0.073, 2.917)	
P-value for Odds Ratio	0.4101	
Relative Risk (95% CI)	0.95 (0.95, 0.95)*	
Risk difference (95% CI)	-10.51 (-43.61, 22.59)	
P-value for Risk Difference	0.5337	
Improvement	6 (28.6%)	4 (26.7%)
Odds ratio (95% CI)	0.918 (0.176, 4.790)	
P-value for Odds Ratio	0.9192	
Relative Risk (95% CI)	0.92 (0.26, 3.29)	
P-value for Relative Risk	0.8943	
Risk difference (95% CI)	-2.42 (-2.42, -2.42)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	1 (14.3%)	3 (30.0%)
Odds ratio (95% CI)	0.888 (0.032, 24.395)	
P-value for Odds Ratio	0.9441	
Relative Risk (95% CI)	0.42 (0.42, 0.42)*	
Risk difference (95% CI)	-1.76 (-1.76, -1.76)*	
Improvement	2 (28.6%)	2 (20.0%)
Odds ratio (95% CI)	1.937 (0.142, 26.353)	
P-value for Odds Ratio	0.6196	
Relative Risk (95% CI)	1.50 (0.25, 8.98)	
P-value for Relative Risk	0.6569	
Risk difference (95% CI)	10.83 (10.83, 10.83)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.50 (0.32, 63.94)	
P-value for Relative Risk	0.2433	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	60 (39.7%)	56 (36.6%)
Odds ratio (95% CI)	1.145 (0.716, 1.833)	
P-value for Odds Ratio	0.5721	
Relative Risk (95% CI)	1.11 (0.84, 1.46)	
P-value for Relative Risk	0.4806	
Risk difference (95% CI)	3.11 (-7.64, 13.87)	
P-value for Risk Difference	0.5706	
Improvement	35 (23.2%)	35 (22.9%)
Odds ratio (95% CI)	1.021 (0.593, 1.756)	
P-value for Odds Ratio	0.9411	
Relative Risk (95% CI)	1.02 (0.68, 1.52)	
P-value for Relative Risk	0.9407	
Risk difference (95% CI)	0.50 (-8.82, 9.83)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9155	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	51 (37.5%)	45 (36.6%)
Odds ratio (95% CI)	1.068 (0.641, 1.780)	
P-value for Odds Ratio	0.8007	
Relative Risk (95% CI)	1.04 (0.76, 1.43)	
P-value for Relative Risk	0.8028	
Risk difference (95% CI)	1.41 (-10.24, 13.07)	
P-value for Risk Difference	0.8120	
Improvement	35 (25.7%)	32 (26.0%)
Odds ratio (95% CI)	0.961 (0.549, 1.685)	
P-value for Odds Ratio	0.8907	
Relative Risk (95% CI)	0.98 (0.65, 1.47)	
P-value for Relative Risk	0.9116	
Risk difference (95% CI)	-0.84 (-11.53, 9.85)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8772	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	56 (44.1%)	49 (44.5%)
Odds ratio (95% CI)	0.993 (0.586, 1.685)	
P-value for Odds Ratio	0.9803	
Relative Risk (95% CI)	1.01 (0.76, 1.34)	
P-value for Relative Risk	0.9330	
Risk difference (95% CI)	-0.38 (-12.85, 12.10)	
P-value for Risk Difference	0.9525	
Improvement	31 (24.4%)	19 (17.3%)
Odds ratio (95% CI)	1.634 (0.855, 3.125)	
P-value for Odds Ratio	0.1374	
Relative Risk (95% CI)	1.47 (0.88, 2.44)	
P-value for Relative Risk	0.1377	
Risk difference (95% CI)	8.97 (-2.03, 19.98)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1100	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	60 (43.2%)	54 (41.2%)
Odds ratio (95% CI)	1.089 (0.667, 1.777)	
P-value for Odds Ratio	0.7333	
Relative Risk (95% CI)	1.05 (0.80, 1.39)	
P-value for Relative Risk	0.7263	
Risk difference (95% CI)	1.94 (-9.79, 13.68)	
P-value for Risk Difference	0.7458	
Improvement	30 (21.6%)	30 (22.9%)
Odds ratio (95% CI)	0.923 (0.517, 1.648)	
P-value for Odds Ratio	0.7875	
Relative Risk (95% CI)	0.93 (0.59, 1.46)	
P-value for Relative Risk	0.7481	
Risk difference (95% CI)	-0.73 (-10.71, 9.25)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8856	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	38 (34.9%)	27 (36.5%)
Odds ratio (95% CI)	1.054 (0.560, 1.984)	
P-value for Odds Ratio	0.8708	
Relative Risk (95% CI)	1.04 (0.71, 1.54)	
P-value for Relative Risk	0.8284	
Risk difference (95% CI)	-0.95 (-13.64, 11.74)	
P-value for Risk Difference	0.8834	
Improvement	27 (24.8%)	20 (27.0%)
Odds ratio (95% CI)	0.843 (0.424, 1.678)	
P-value for Odds Ratio	0.6276	
Relative Risk (95% CI)	0.90 (0.55, 1.47)	
P-value for Relative Risk	0.6661	
Risk difference (95% CI)	-3.72 (-16.51, 9.07)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5685	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	40 (38.5%)	20 (31.3%)
Odds ratio (95% CI)	1.449 (0.742, 2.828)	
P-value for Odds Ratio	0.2773	
Relative Risk (95% CI)	1.26 (0.82, 1.95)	
P-value for Relative Risk	0.2930	
Risk difference (95% CI)	7.88 (-6.79, 22.55)	
P-value for Risk Difference	0.2924	
Improvement	24 (23.1%)	17 (26.6%)
Odds ratio (95% CI)	0.847 (0.411, 1.745)	
P-value for Odds Ratio	0.6518	
Relative Risk (95% CI)	0.89 (0.52, 1.52)	
P-value for Relative Risk	0.6674	
Risk difference (95% CI)	-3.54 (-17.17, 10.09)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6110	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	36 (42.4%)	18 (32.7%)
Odds ratio (95% CI)	1.560 (0.759, 3.205)	
P-value for Odds Ratio	0.2261	
Relative Risk (95% CI)	1.33 (0.85, 2.09)	
P-value for Relative Risk	0.2123	
Risk difference (95% CI)	9.70 (-6.32, 25.72)	
P-value for Risk Difference	0.2353	
Improvement	24 (28.2%)	10 (18.2%)
Odds ratio (95% CI)	1.721 (0.745, 3.974)	
P-value for Odds Ratio	0.2034	
Relative Risk (95% CI)	1.55 (0.81, 2.98)	
P-value for Relative Risk	0.1880	
Risk difference (95% CI)	8.57 (-5.97, 23.12)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2481	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	30 (42.3%)	14 (32.6%)
Odds ratio (95% CI)	1.533 (0.686, 3.425)	
P-value for Odds Ratio	0.2972	
Relative Risk (95% CI)	1.31 (0.79, 2.18)	
P-value for Relative Risk	0.3010	
Risk difference (95% CI)	9.83 (-8.31, 27.97)	
P-value for Risk Difference	0.2883	
Improvement	18 (25.4%)	9 (20.9%)
Odds ratio (95% CI)	1.275 (0.505, 3.221)	
P-value for Odds Ratio	0.6070	
Relative Risk (95% CI)	1.24 (0.61, 2.50)	
P-value for Relative Risk	0.5513	
Risk difference (95% CI)	1.30 (-15.15, 17.75)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8769	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	20 (36.4%)	7 (21.9%)
Odds ratio (95% CI)	2.064 (0.747, 5.705)	
P-value for Odds Ratio	0.1625	
Relative Risk (95% CI)	1.66 (0.80, 3.47)	
P-value for Relative Risk	0.1760	
Risk difference (95% CI)	13.67 (-5.20, 32.54)	
P-value for Risk Difference	0.1556	
Improvement	13 (23.6%)	5 (15.6%)
Odds ratio (95% CI)	1.886 (0.582, 6.111)	
P-value for Odds Ratio	0.2901	
Relative Risk (95% CI)	1.58 (0.63, 3.95)	
P-value for Relative Risk	0.3247	
Risk difference (95% CI)	7.70 (-13.73, 29.14)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4812	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	15 (36.6%)	11 (39.3%)
Odds ratio (95% CI)	0.842 (0.306, 2.312)	
P-value for Odds Ratio	0.7383	
Relative Risk (95% CI)	0.85 (0.46, 1.57)	
P-value for Relative Risk	0.6088	
Risk difference (95% CI)	-3.23 (-26.39, 19.93)	
P-value for Risk Difference	0.7844	
Improvement	9 (22.0%)	5 (17.9%)
Odds ratio (95% CI)	1.590 (0.430, 5.876)	
P-value for Odds Ratio	0.4870	
Relative Risk (95% CI)	1.39 (0.55, 3.49)	
P-value for Relative Risk	0.4828	
Risk difference (95% CI)	2.55 (-23.34, 28.44)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8470	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	13 (50.0%)	7 (31.8%)
Odds ratio (95% CI)	1.733 (0.506, 5.927)	
P-value for Odds Ratio	0.3811	
Relative Risk (95% CI)	1.39 (0.68, 2.85)	
P-value for Relative Risk	0.3677	
Risk difference (95% CI)	13.15 (13.15, 13.15)*	
Improvement	3 (11.5%)	5 (22.7%)
Odds ratio (95% CI)	0.556 (0.103, 3.013)	
P-value for Odds Ratio	0.4959	
Relative Risk (95% CI)	0.63 (0.17, 2.41)	
P-value for Relative Risk	0.5042	
Risk difference (95% CI)	-5.58 (-34.05, 22.89)	
P-value for Risk Difference	0.7008	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	6 (28.6%)	6 (40.0%)
Odds ratio (95% CI)	0.727 (0.150, 3.525)	
P-value for Odds Ratio	0.6921	
Relative Risk (95% CI)	0.69 (0.22, 2.21)	
P-value for Relative Risk	0.5354	
Risk difference (95% CI)	-6.63 (-6.63, -6.63)*	
Improvement	5 (23.8%)	2 (13.3%)
Odds ratio (95% CI)	2.594 (0.388, 17.327)	
P-value for Odds Ratio	0.3254	
Relative Risk (95% CI)	2.17 (0.48, 9.76)	
P-value for Relative Risk	0.3114	
Risk difference (95% CI)	13.77 (13.77, 13.77)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	1 (14.3%)	5 (50.0%)
Odds ratio (95% CI)	0.306 (0.018, 5.276)	
P-value for Odds Ratio	0.4154	
Relative Risk (95% CI)	0.41 (0.03, 5.71)	
P-value for Relative Risk	0.5081	
Risk difference (95% CI)	-17.08 (-75.13, 40.97)	
P-value for Risk Difference	0.5641	
Improvement	3 (42.9%)	3 (30.0%)
Odds ratio (95% CI)	1.814 (0.162, 20.312)	
P-value for Odds Ratio	0.6291	
Relative Risk (95% CI)	1.02 (1.02, 1.02)*	
Risk difference (95% CI)	15.14 (-47.81, 78.10)	
P-value for Risk Difference	0.6374	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (50.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.04, 7.10)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	14 (9.3%)	23 (15.0%)
Odds ratio (95% CI)	0.599 (0.294, 1.220)	
P-value for Odds Ratio	0.1578	
Relative Risk (95% CI)	0.64 (0.35, 1.20)	
P-value for Relative Risk	0.1667	
Risk difference (95% CI)	-5.47 (-14.36, 3.41)	
P-value for Risk Difference	0.2272	
Improvement	9 (6.0%)	13 (8.5%)
Odds ratio (95% CI)	0.685 (0.283, 1.656)	
P-value for Odds Ratio	0.4006	
Relative Risk (95% CI)	0.70 (0.31, 1.60)	
P-value for Relative Risk	0.4030	
Risk difference (95% CI)	-2.78 (-8.70, 3.14)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3578	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	13 (9.6%)	15 (12.2%)
Odds ratio (95% CI)	0.746 (0.338, 1.648)	
P-value for Odds Ratio	0.4688	
Relative Risk (95% CI)	0.78 (0.38, 1.57)	
P-value for Relative Risk	0.4820	
Risk difference (95% CI)	-3.16 (-10.76, 4.45)	
P-value for Risk Difference	0.4158	
Improvement	11 (8.1%)	10 (8.1%)
Odds ratio (95% CI)	1.023 (0.417, 2.509)	
P-value for Odds Ratio	0.9603	
Relative Risk (95% CI)	1.03 (0.45, 2.35)	
P-value for Relative Risk	0.9373	
Risk difference (95% CI)	-1.13 (-7.81, 5.54)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7392	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	12 (9.4%)	11 (10.0%)
Odds ratio (95% CI)	0.950 (0.396, 2.275)	
P-value for Odds Ratio	0.9076	
Relative Risk (95% CI)	0.96 (0.44, 2.09)	
P-value for Relative Risk	0.9192	
Risk difference (95% CI)	-1.74 (-9.17, 5.68)	
P-value for Risk Difference	0.6450	
Improvement	7 (5.5%)	7 (6.4%)
Odds ratio (95% CI)	0.871 (0.294, 2.586)	
P-value for Odds Ratio	0.8037	
Relative Risk (95% CI)	0.87 (0.32, 2.43)	
P-value for Relative Risk	0.7973	
Risk difference (95% CI)	0.05 (-6.64, 6.73)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9891	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	15 (10.8%)	13 (9.9%)
Odds ratio (95% CI)	1.168 (0.529, 2.577)	
P-value for Odds Ratio	0.7003	
Relative Risk (95% CI)	1.14 (0.56, 2.30)	
P-value for Relative Risk	0.7166	
Risk difference (95% CI)	3.32 (-5.21, 11.84)	
P-value for Risk Difference	0.4456	
Improvement	11 (7.9%)	8 (6.1%)
Odds ratio (95% CI)	1.429 (0.550, 3.709)	
P-value for Odds Ratio	0.4638	
Relative Risk (95% CI)	1.39 (0.58, 3.33)	
P-value for Relative Risk	0.4659	
Risk difference (95% CI)	2.29 (-6.21, 10.80)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5975	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	10 (9.2%)	7 (9.5%)
Odds ratio (95% CI)	1.053 (0.378, 2.936)	
P-value for Odds Ratio	0.9211	
Relative Risk (95% CI)	1.05 (0.42, 2.61)	
P-value for Relative Risk	0.9216	
Risk difference (95% CI)	0.20 (-12.02, 12.41)	
P-value for Risk Difference	0.9746	
Improvement	9 (8.3%)	5 (6.8%)
Odds ratio (95% CI)	1.236 (0.393, 3.893)	
P-value for Odds Ratio	0.7169	
Relative Risk (95% CI)	1.21 (0.42, 3.48)	
P-value for Relative Risk	0.7277	
Risk difference (95% CI)	3.16 (-5.50, 11.82)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4747	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	10 (9.6%)	6 (9.4%)
Odds ratio (95% CI)	1.125 (0.385, 3.291)	
P-value for Odds Ratio	0.8295	
Relative Risk (95% CI)	1.11 (0.43, 2.90)	
P-value for Relative Risk	0.8262	
Risk difference (95% CI)	0.88 (-10.94, 12.69)	
P-value for Risk Difference	0.8844	
Improvement	9 (8.7%)	3 (4.7%)
Odds ratio (95% CI)	1.984 (0.512, 7.695)	
P-value for Odds Ratio	0.3216	
Relative Risk (95% CI)	1.87 (0.53, 6.68)	
P-value for Relative Risk	0.3335	
Risk difference (95% CI)	5.15 (-6.47, 16.76)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3851	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	6 (7.1%)	5 (9.1%)
Odds ratio (95% CI)	0.817 (0.234, 2.860)	
P-value for Odds Ratio	0.7524	
Relative Risk (95% CI)	0.85 (0.27, 2.61)	
P-value for Relative Risk	0.7706	
Risk difference (95% CI)	-1.66 (-14.25, 10.93)	
P-value for Risk Difference	0.7957	
Improvement	6 (7.1%)	5 (9.1%)
Odds ratio (95% CI)	0.733 (0.210, 2.555)	
P-value for Odds Ratio	0.6253	
Relative Risk (95% CI)	0.75 (0.24, 2.35)	
P-value for Relative Risk	0.6160	
Risk difference (95% CI)	-1.87 (-11.17, 7.43)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6934	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	5 (7.0%)	5 (11.6%)
Odds ratio (95% CI)	0.602 (0.160, 2.268)	
P-value for Odds Ratio	0.4528	
Relative Risk (95% CI)	0.62 (0.19, 2.01)	
P-value for Relative Risk	0.4282	
Risk difference (95% CI)	-3.01 (-19.08, 13.07)	
P-value for Risk Difference	0.7139	
Improvement	8 (11.3%)	4 (9.3%)
Odds ratio (95% CI)	1.332 (0.371, 4.777)	
P-value for Odds Ratio	0.6605	
Relative Risk (95% CI)	1.31 (0.42, 4.10)	
P-value for Relative Risk	0.6386	
Risk difference (95% CI)	-0.05 (-14.82, 14.71)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9943	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	4 (7.3%)	4 (12.5%)
Odds ratio (95% CI)	0.522 (0.118, 2.313)	
P-value for Odds Ratio	0.3917	
Relative Risk (95% CI)	0.58 (0.16, 2.13)	
P-value for Relative Risk	0.4131	
Risk difference (95% CI)	-5.34 (-22.88, 12.21)	
P-value for Risk Difference	0.5510	
Improvement	4 (7.3%)	1 (3.1%)
Odds ratio (95% CI)	2.615 (0.277, 24.662)	
P-value for Odds Ratio	0.4012	
Relative Risk (95% CI)	2.47 (0.29, 21.06)	
P-value for Relative Risk	0.4074	
Risk difference (95% CI)	3.97 (-13.23, 21.17)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6510	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	4 (9.8%)	1 (3.6%)
Odds ratio (95% CI)	2.970 (0.307, 28.730)	
P-value for Odds Ratio	0.3471	
Relative Risk (95% CI)	2.85 (0.34, 23.57)	
P-value for Relative Risk	0.3316	
Risk difference (95% CI)	5.02 (-22.17, 32.20)	
P-value for Risk Difference	0.7176	
Improvement	3 (7.3%)	1 (3.6%)
Odds ratio (95% CI)	2.154 (0.211, 22.034)	
P-value for Odds Ratio	0.5177	
Relative Risk (95% CI)	1.82 (1.82, 1.82)*	
Risk difference (95% CI)	3.65 (-29.75, 37.04)	
P-value for Risk Difference	0.8306	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	4 (15.4%)	1 (4.5%)
Odds ratio (95% CI)	3.058 (0.302, 30.981)	
P-value for Odds Ratio	0.3441	
Relative Risk (95% CI)	1.44 (1.44, 1.44)*	
Risk difference (95% CI)	9.20 (9.20, 9.20)*	
Improvement	3 (11.5%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.62 (0.46, 14.88)	
P-value for Relative Risk	0.2667	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	2 (9.5%)	2 (13.3%)
Odds ratio (95% CI)	0.433 (0.030, 6.251)	
P-value for Odds Ratio	0.5389	
Relative Risk (95% CI)	0.18 (0.18, 0.18)*	
Risk difference (95% CI)	-9.20 (-9.20, -9.20)*	
Improvement	2 (9.5%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.58 (0.25, 85.33)	
P-value for Relative Risk	0.2572	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	34 (22.5%)	38 (24.8%)
Odds ratio (95% CI)	0.890 (0.521, 1.519)	
P-value for Odds Ratio	0.6684	
Relative Risk (95% CI)	0.91 (0.61, 1.36)	
P-value for Relative Risk	0.6322	
Risk difference (95% CI)	-2.13 (-11.44, 7.18)	
P-value for Risk Difference	0.6541	
Improvement	41 (27.2%)	31 (20.3%)
Odds ratio (95% CI)	1.510 (0.883, 2.584)	
P-value for Odds Ratio	0.1324	
Relative Risk (95% CI)	1.35 (0.90, 2.04)	
P-value for Relative Risk	0.1441	
Risk difference (95% CI)	7.77 (-1.62, 17.16)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1050	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	34 (25.0%)	25 (20.3%)
Odds ratio (95% CI)	1.333 (0.736, 2.413)	
P-value for Odds Ratio	0.3432	
Relative Risk (95% CI)	1.21 (0.77, 1.91)	
P-value for Relative Risk	0.4050	
Risk difference (95% CI)	5.37 (-4.61, 15.35)	
P-value for Risk Difference	0.2917	
Improvement	33 (24.3%)	30 (24.4%)
Odds ratio (95% CI)	1.006 (0.566, 1.787)	
P-value for Odds Ratio	0.9844	
Relative Risk (95% CI)	1.00 (0.65, 1.53)	
P-value for Relative Risk	0.9854	
Risk difference (95% CI)	0.07 (-10.35, 10.49)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9897	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	36 (28.3%)	25 (22.7%)
Odds ratio (95% CI)	1.502 (0.817, 2.761)	
P-value for Odds Ratio	0.1900	
Relative Risk (95% CI)	1.32 (0.86, 2.03)	
P-value for Relative Risk	0.2066	
Risk difference (95% CI)	5.73 (-4.84, 16.30)	
P-value for Risk Difference	0.2877	
Improvement	28 (22.0%)	25 (22.7%)
Odds ratio (95% CI)	1.022 (0.548, 1.907)	
P-value for Odds Ratio	0.9451	
Relative Risk (95% CI)	1.04 (0.65, 1.67)	
P-value for Relative Risk	0.8595	
Risk difference (95% CI)	-1.75 (-12.66, 9.15)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7525	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	45 (32.4%)	34 (26.0%)
Odds ratio (95% CI)	1.361 (0.798, 2.319)	
P-value for Odds Ratio	0.2577	
Relative Risk (95% CI)	1.24 (0.85, 1.81)	
P-value for Relative Risk	0.2621	
Risk difference (95% CI)	6.13 (-4.63, 16.89)	
P-value for Risk Difference	0.2641	
Improvement	32 (23.0%)	26 (19.8%)
Odds ratio (95% CI)	1.315 (0.722, 2.396)	
P-value for Odds Ratio	0.3702	
Relative Risk (95% CI)	1.24 (0.79, 1.94)	
P-value for Relative Risk	0.3475	
Risk difference (95% CI)	3.38 (-6.20, 12.95)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4895	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	31 (28.4%)	19 (25.7%)
Odds ratio (95% CI)	1.247 (0.629, 2.474)	
P-value for Odds Ratio	0.5275	
Relative Risk (95% CI)	1.07 (0.66, 1.75)	
P-value for Relative Risk	0.7788	
Risk difference (95% CI)	7.89 (-5.83, 21.61)	
P-value for Risk Difference	0.2598	
Improvement	26 (23.9%)	15 (20.3%)
Odds ratio (95% CI)	1.338 (0.641, 2.791)	
P-value for Odds Ratio	0.4380	
Relative Risk (95% CI)	1.22 (0.70, 2.12)	
P-value for Relative Risk	0.4839	
Risk difference (95% CI)	5.86 (-6.07, 17.78)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3359	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	22 (21.2%)	11 (17.2%)
Odds ratio (95% CI)	1.334 (0.595, 2.992)	
P-value for Odds Ratio	0.4844	
Relative Risk (95% CI)	1.24 (0.65, 2.38)	
P-value for Relative Risk	0.5189	
Risk difference (95% CI)	5.93 (-6.74, 18.60)	
P-value for Risk Difference	0.3592	
Improvement	26 (25.0%)	16 (25.0%)
Odds ratio (95% CI)	1.052 (0.508, 2.181)	
P-value for Odds Ratio	0.8910	
Relative Risk (95% CI)	1.05 (0.61, 1.78)	
P-value for Relative Risk	0.8711	
Risk difference (95% CI)	-0.42 (-13.09, 12.25)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9480	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	25 (29.4%)	10 (18.2%)
Odds ratio (95% CI)	1.950 (0.845, 4.499)	
P-value for Odds Ratio	0.1176	
Relative Risk (95% CI)	1.65 (0.86, 3.16)	
P-value for Relative Risk	0.1330	
Risk difference (95% CI)	11.95 (-2.06, 25.97)	
P-value for Risk Difference	0.0946	
Improvement	20 (23.5%)	10 (18.2%)
Odds ratio (95% CI)	1.423 (0.604, 3.356)	
P-value for Odds Ratio	0.4199	
Relative Risk (95% CI)	1.32 (0.67, 2.59)	
P-value for Relative Risk	0.4251	
Risk difference (95% CI)	5.41 (-8.26, 19.07)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4381	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	18 (25.4%)	6 (14.0%)
Odds ratio (95% CI)	2.237 (0.803, 6.234)	
P-value for Odds Ratio	0.1235	
Relative Risk (95% CI)	1.88 (0.81, 4.36)	
P-value for Relative Risk	0.1406	
Risk difference (95% CI)	13.56 (-1.73, 28.85)	
P-value for Risk Difference	0.0821	
Improvement	20 (28.2%)	8 (18.6%)
Odds ratio (95% CI)	1.720 (0.673, 4.393)	
P-value for Odds Ratio	0.2571	
Relative Risk (95% CI)	1.49 (0.72, 3.10)	
P-value for Relative Risk	0.2821	
Risk difference (95% CI)	11.01 (-5.26, 27.28)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1847	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	15 (27.3%)	5 (15.6%)
Odds ratio (95% CI)	2.164 (0.683, 6.857)	
P-value for Odds Ratio	0.1894	
Relative Risk (95% CI)	1.73 (0.71, 4.23)	
P-value for Relative Risk	0.2313	
Risk difference (95% CI)	12.87 (-7.94, 33.68)	
P-value for Risk Difference	0.2254	
Improvement	13 (23.6%)	8 (25.0%)
Odds ratio (95% CI)	0.953 (0.344, 2.641)	
P-value for Odds Ratio	0.9269	
Relative Risk (95% CI)	0.97 (0.45, 2.11)	
P-value for Relative Risk	0.9387	
Risk difference (95% CI)	-1.35 (-21.47, 18.76)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8952	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	14 (34.1%)	5 (17.9%)
Odds ratio (95% CI)	2.382 (0.727, 7.799)	
P-value for Odds Ratio	0.1516	
Relative Risk (95% CI)	1.79 (0.73, 4.38)	
P-value for Relative Risk	0.2052	
Risk difference (95% CI)	18.55 (-1.35, 38.45)	
P-value for Risk Difference	0.0677	
Improvement	11 (26.8%)	3 (10.7%)
Odds ratio (95% CI)	3.122 (0.774, 12.599)	
P-value for Odds Ratio	0.1097	
Relative Risk (95% CI)	2.54 (0.78, 8.28)	
P-value for Relative Risk	0.1217	
Risk difference (95% CI)	13.32 (-10.59, 37.22)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2749	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	8 (30.8%)	4 (18.2%)
Odds ratio (95% CI)	1.633 (0.399, 6.681)	
P-value for Odds Ratio	0.4949	
Relative Risk (95% CI)	1.42 (0.50, 4.05)	
P-value for Relative Risk	0.5109	
Risk difference (95% CI)	10.19 (10.19, 10.19)*	
Improvement	5 (19.2%)	4 (18.2%)
Odds ratio (95% CI)	0.977 (0.219, 4.361)	
P-value for Odds Ratio	0.9754	
Relative Risk (95% CI)	1.05 (0.31, 3.55)	
P-value for Relative Risk	0.9386	
Risk difference (95% CI)	-2.24 (-2.24, -2.24)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	7 (33.3%)	4 (26.7%)
Odds ratio (95% CI)	1.282 (0.243, 6.763)	
P-value for Odds Ratio	0.7694	
Relative Risk (95% CI)	1.25 (0.44, 3.57)	
P-value for Relative Risk	0.6768	
Risk difference (95% CI)	3.24 (-28.43, 34.91)	
P-value for Risk Difference	0.8412	
Improvement	4 (19.0%)	4 (26.7%)
Odds ratio (95% CI)	0.714 (0.127, 4.019)	
P-value for Odds Ratio	0.7020	
Relative Risk (95% CI)	0.99 (0.99, 0.99)*	
Risk difference (95% CI)	-3.53 (-3.53, -3.53)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	1 (14.3%)	3 (30.0%)
Odds ratio (95% CI)	0.581 (0.030, 11.152)	
P-value for Odds Ratio	0.7187	
Relative Risk (95% CI)	0.46 (0.02, 11.74)	
P-value for Relative Risk	0.6379	
Risk difference (95% CI)	-3.47 (-58.34, 51.40)	
P-value for Risk Difference	0.9014	
Improvement	1 (14.3%)	3 (30.0%)
Odds ratio (95% CI)	0.178 (0.008, 4.180)	
P-value for Odds Ratio	0.2835	
Relative Risk (95% CI)	0.18 (0.18, 0.18)*	
Risk difference (95% CI)	-36.75 (-124.40, 50.89)	
P-value for Risk Difference	0.4111	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	17 (11.3%)	22 (14.4%)
Odds ratio (95% CI)	0.753 (0.382, 1.486)	
P-value for Odds Ratio	0.4135	
Relative Risk (95% CI)	0.78 (0.43, 1.42)	
P-value for Relative Risk	0.4176	
Risk difference (95% CI)	-3.36 (-10.93, 4.20)	
P-value for Risk Difference	0.3836	
Improvement	15 (9.9%)	11 (7.2%)
Odds ratio (95% CI)	1.456 (0.642, 3.302)	
P-value for Odds Ratio	0.3685	
Relative Risk (95% CI)	1.39 (0.66, 2.92)	
P-value for Relative Risk	0.3863	
Risk difference (95% CI)	3.08 (-2.95, 9.12)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3168	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	16 (11.8%)	15 (12.2%)
Odds ratio (95% CI)	0.986 (0.460, 2.115)	
P-value for Odds Ratio	0.9708	
Relative Risk (95% CI)	0.99 (0.51, 1.92)	
P-value for Relative Risk	0.9845	
Risk difference (95% CI)	0.03 (-7.58, 7.65)	
P-value for Risk Difference	0.9932	
Improvement	13 (9.6%)	13 (10.6%)
Odds ratio (95% CI)	0.901 (0.395, 2.055)	
P-value for Odds Ratio	0.8038	
Relative Risk (95% CI)	0.90 (0.44, 1.85)	
P-value for Relative Risk	0.7725	
Risk difference (95% CI)	0.08 (-6.70, 6.87)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9805	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	17 (13.4%)	19 (17.3%)
Odds ratio (95% CI)	0.747 (0.364, 1.534)	
P-value for Odds Ratio	0.4269	
Relative Risk (95% CI)	0.78 (0.43, 1.44)	
P-value for Relative Risk	0.4322	
Risk difference (95% CI)	-4.03 (-13.16, 5.10)	
P-value for Risk Difference	0.3869	
Improvement	9 (7.1%)	12 (10.9%)
Odds ratio (95% CI)	0.618 (0.245, 1.559)	
P-value for Odds Ratio	0.3080	
Relative Risk (95% CI)	0.64 (0.28, 1.47)	
P-value for Relative Risk	0.2977	
Risk difference (95% CI)	-2.59 (-9.51, 4.34)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4641	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	23 (16.5%)	24 (18.3%)
Odds ratio (95% CI)	0.849 (0.450, 1.604)	
P-value for Odds Ratio	0.6147	
Relative Risk (95% CI)	0.87 (0.52, 1.47)	
P-value for Relative Risk	0.6014	
Risk difference (95% CI)	-2.29 (-11.31, 6.72)	
P-value for Risk Difference	0.6181	
Improvement	14 (10.1%)	13 (9.9%)
Odds ratio (95% CI)	1.089 (0.487, 2.433)	
P-value for Odds Ratio	0.8361	
Relative Risk (95% CI)	1.07 (0.52, 2.18)	
P-value for Relative Risk	0.8574	
Risk difference (95% CI)	1.84 (-5.39, 9.06)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6181	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	25 (22.9%)	12 (16.2%)
Odds ratio (95% CI)	1.578 (0.725, 3.432)	
P-value for Odds Ratio	0.2500	
Relative Risk (95% CI)	1.41 (0.76, 2.62)	
P-value for Relative Risk	0.2809	
Risk difference (95% CI)	7.36 (-3.94, 18.67)	
P-value for Risk Difference	0.2018	
Improvement	9 (8.3%)	5 (6.8%)
Odds ratio (95% CI)	1.344 (0.418, 4.315)	
P-value for Odds Ratio	0.6196	
Relative Risk (95% CI)	1.28 (0.45, 3.64)	
P-value for Relative Risk	0.6385	
Risk difference (95% CI)	1.66 (-10.18, 13.51)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7833	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	17 (16.3%)	14 (21.9%)
Odds ratio (95% CI)	0.742 (0.332, 1.656)	
P-value for Odds Ratio	0.4661	
Relative Risk (95% CI)	0.77 (0.42, 1.44)	
P-value for Relative Risk	0.4189	
Risk difference (95% CI)	-2.80 (-16.90, 11.30)	
P-value for Risk Difference	0.6970	
Improvement	8 (7.7%)	6 (9.4%)
Odds ratio (95% CI)	0.719 (0.232, 2.231)	
P-value for Odds Ratio	0.5683	
Relative Risk (95% CI)	0.71 (0.25, 1.98)	
P-value for Relative Risk	0.5119	
Risk difference (95% CI)	0.46 (-8.87, 9.80)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9227	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	14 (16.5%)	10 (18.2%)
Odds ratio (95% CI)	0.946 (0.378, 2.370)	
P-value for Odds Ratio	0.9065	
Relative Risk (95% CI)	0.98 (0.48, 2.01)	
P-value for Relative Risk	0.9551	
Risk difference (95% CI)	-1.97 (-15.04, 11.10)	
P-value for Risk Difference	0.7675	
Improvement	5 (5.9%)	4 (7.3%)
Odds ratio (95% CI)	0.812 (0.205, 3.217)	
P-value for Odds Ratio	0.7667	
Relative Risk (95% CI)	0.81 (0.23, 2.90)	
P-value for Relative Risk	0.7517	
Risk difference (95% CI)	0.07 (-8.37, 8.50)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9875	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	18 (25.4%)	6 (14.0%)
Odds ratio (95% CI)	2.077 (0.740, 5.825)	
P-value for Odds Ratio	0.1649	
Relative Risk (95% CI)	1.80 (0.78, 4.17)	
P-value for Relative Risk	0.1701	
Risk difference (95% CI)	12.39 (-2.61, 27.39)	
P-value for Risk Difference	0.1053	
Improvement	8 (11.3%)	3 (7.0%)
Odds ratio (95% CI)	1.615 (0.396, 6.588)	
P-value for Odds Ratio	0.5041	
Relative Risk (95% CI)	1.50 (0.42, 5.39)	
P-value for Relative Risk	0.5319	
Risk difference (95% CI)	8.26 (-11.02, 27.54)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4012	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	14 (25.5%)	3 (9.4%)
Odds ratio (95% CI)	3.138 (0.817, 12.054)	
P-value for Odds Ratio	0.0958	
Relative Risk (95% CI)	2.50 (0.78, 8.04)	
P-value for Relative Risk	0.1245	
Risk difference (95% CI)	16.10 (1.07, 31.13)	
P-value for Risk Difference	0.0357	
Improvement	6 (10.9%)	2 (6.3%)
Odds ratio (95% CI)	1.759 (0.319, 9.684)	
P-value for Odds Ratio	0.5166	
Relative Risk (95% CI)	1.63 (0.36, 7.39)	
P-value for Relative Risk	0.5263	
Risk difference (95% CI)	3.70 (-16.62, 24.03)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7208	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	11 (26.8%)	6 (21.4%)
Odds ratio (95% CI)	1.266 (0.397, 4.037)	
P-value for Odds Ratio	0.6908	
Relative Risk (95% CI)	1.10 (0.45, 2.73)	
P-value for Relative Risk	0.8309	
Risk difference (95% CI)	8.47 (-13.60, 30.53)	
P-value for Risk Difference	0.4519	
Improvement	2 (4.9%)	1 (3.6%)
Odds ratio (95% CI)	1.143 (0.077, 16.944)	
P-value for Odds Ratio	0.9227	
Relative Risk (95% CI)	1.11 (0.13, 9.42)	
P-value for Relative Risk	0.9230	
Risk difference (95% CI)	1.15 (-30.84, 33.15)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9436	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	13 (50.0%)	5 (22.7%)
Odds ratio (95% CI)	3.656 (0.937, 14.267)	
P-value for Odds Ratio	0.0620	
Relative Risk (95% CI)	2.40 (0.91, 6.31)	
P-value for Relative Risk	0.0756	
Risk difference (95% CI)	29.06 (1.29, 56.83)	
P-value for Risk Difference	0.0402	
Improvement	2 (7.7%)	2 (9.1%)
Odds ratio (95% CI)	0.853 (0.099, 7.338)	
P-value for Odds Ratio	0.8850	
Relative Risk (95% CI)	0.86 (0.14, 5.17)	
P-value for Relative Risk	0.8670	
Risk difference (95% CI)	1.43 (-34.05, 36.92)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9368	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	8 (38.1%)	2 (13.3%)
Odds ratio (95% CI)	4.959 (0.747, 32.939)	
P-value for Odds Ratio	0.0974	
Relative Risk (95% CI)	3.12 (0.75, 12.91)	
P-value for Relative Risk	0.1168	
Risk difference (95% CI)	29.07 (-1.82, 59.96)	
P-value for Risk Difference	0.0651	
Improvement	0	1 (6.7%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.56 (0.03, 9.73)	
P-value for Relative Risk	0.6933	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	0	1 (10.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.03, 9.46)	
P-value for Relative Risk	0.6460	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (14.3%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	26 (17.2%)	29 (19.0%)
Odds ratio (95% CI)	0.897 (0.498, 1.613)	
P-value for Odds Ratio	0.7159	
Relative Risk (95% CI)	0.90 (0.56, 1.46)	
P-value for Relative Risk	0.6825	
Risk difference (95% CI)	-1.25 (-9.89, 7.39)	
P-value for Risk Difference	0.7774	
Improvement	28 (18.5%)	31 (20.3%)
Odds ratio (95% CI)	0.898 (0.507, 1.592)	
P-value for Odds Ratio	0.7124	
Relative Risk (95% CI)	0.92 (0.58, 1.45)	
P-value for Relative Risk	0.7108	
Risk difference (95% CI)	-1.47 (-10.46, 7.53)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7495	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	36 (26.5%)	22 (17.9%)
Odds ratio (95% CI)	1.773 (0.965, 3.258)	
P-value for Odds Ratio	0.0652	
Relative Risk (95% CI)	1.58 (1.00, 2.52)	
P-value for Relative Risk	0.0522	
Risk difference (95% CI)	7.43 (-2.40, 17.26)	
P-value for Risk Difference	0.1383	
Improvement	28 (20.6%)	18 (14.6%)
Odds ratio (95% CI)	1.447 (0.751, 2.788)	
P-value for Odds Ratio	0.2701	
Relative Risk (95% CI)	1.38 (0.81, 2.37)	
P-value for Relative Risk	0.2375	
Risk difference (95% CI)	4.27 (-5.60, 14.14)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

/home/pingping.xu/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/Generated/t_14_2_6_1_c30_binary.sas
(pingping.xu 11AUG2025 12:07 SAS Linux 9.4)

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3966	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	28 (22.0%)	31 (28.2%)
Odds ratio (95% CI)	0.699 (0.382, 1.280)	
P-value for Odds Ratio	0.2458	
Relative Risk (95% CI)	0.79 (0.51, 1.23)	
P-value for Relative Risk	0.2933	
Risk difference (95% CI)	-6.80 (-17.67, 4.06)	
P-value for Risk Difference	0.2197	
Improvement	23 (18.1%)	18 (16.4%)
Odds ratio (95% CI)	1.090 (0.547, 2.174)	
P-value for Odds Ratio	0.8064	
Relative Risk (95% CI)	1.07 (0.61, 1.86)	
P-value for Relative Risk	0.8223	
Risk difference (95% CI)	4.48 (-6.25, 15.20)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4133	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	37 (26.6%)	34 (26.0%)
Odds ratio (95% CI)	0.978 (0.561, 1.703)	
P-value for Odds Ratio	0.9366	
Relative Risk (95% CI)	0.99 (0.67, 1.47)	
P-value for Relative Risk	0.9734	
Risk difference (95% CI)	-0.43 (-10.70, 9.83)	
P-value for Risk Difference	0.9338	
Improvement	23 (16.5%)	20 (15.3%)
Odds ratio (95% CI)	1.102 (0.568, 2.138)	
P-value for Odds Ratio	0.7745	
Relative Risk (95% CI)	1.07 (0.62, 1.84)	
P-value for Relative Risk	0.8164	
Risk difference (95% CI)	2.97 (-5.96, 11.89)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5146	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	23 (21.1%)	18 (24.3%)
Odds ratio (95% CI)	0.821 (0.403, 1.673)	
P-value for Odds Ratio	0.5870	
Relative Risk (95% CI)	0.86 (0.50, 1.48)	
P-value for Relative Risk	0.5851	
Risk difference (95% CI)	-3.47 (-15.97, 9.03)	
P-value for Risk Difference	0.5864	
Improvement	22 (20.2%)	9 (12.2%)
Odds ratio (95% CI)	1.837 (0.786, 4.297)	
P-value for Odds Ratio	0.1606	
Relative Risk (95% CI)	1.63 (0.79, 3.34)	
P-value for Relative Risk	0.1854	
Risk difference (95% CI)	9.78 (-2.09, 21.66)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1063	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	21 (20.2%)	10 (15.6%)
Odds ratio (95% CI)	1.395 (0.597, 3.258)	
P-value for Odds Ratio	0.4422	
Relative Risk (95% CI)	1.27 (0.65, 2.50)	
P-value for Relative Risk	0.4789	
Risk difference (95% CI)	4.45 (-7.83, 16.73)	
P-value for Risk Difference	0.4775	
Improvement	19 (18.3%)	13 (20.3%)
Odds ratio (95% CI)	0.877 (0.397, 1.938)	
P-value for Odds Ratio	0.7460	
Relative Risk (95% CI)	0.89 (0.47, 1.69)	
P-value for Relative Risk	0.7255	
Risk difference (95% CI)	-1.41 (-14.69, 11.87)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8355	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	15 (17.6%)	12 (21.8%)
Odds ratio (95% CI)	0.788 (0.334, 1.861)	
P-value for Odds Ratio	0.5876	
Relative Risk (95% CI)	0.85 (0.43, 1.66)	
P-value for Relative Risk	0.6277	
Risk difference (95% CI)	-4.35 (-17.58, 8.87)	
P-value for Risk Difference	0.5186	
Improvement	19 (22.4%)	8 (14.5%)
Odds ratio (95% CI)	1.606 (0.639, 4.037)	
P-value for Odds Ratio	0.3142	
Relative Risk (95% CI)	1.44 (0.69, 3.04)	
P-value for Relative Risk	0.3322	
Risk difference (95% CI)	7.17 (-7.60, 21.94)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3416	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	8 (11.3%)	6 (14.0%)
Odds ratio (95% CI)	0.786 (0.245, 2.524)	
P-value for Odds Ratio	0.6862	
Relative Risk (95% CI)	0.84 (0.31, 2.22)	
P-value for Relative Risk	0.7186	
Risk difference (95% CI)	-3.78 (-16.31, 8.75)	
P-value for Risk Difference	0.5541	
Improvement	14 (19.7%)	5 (11.6%)
Odds ratio (95% CI)	1.834 (0.603, 5.577)	
P-value for Odds Ratio	0.2849	
Relative Risk (95% CI)	1.66 (0.64, 4.30)	
P-value for Relative Risk	0.2954	
Risk difference (95% CI)	8.14 (-5.63, 21.92)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2467	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	7 (12.7%)	4 (12.5%)
Odds ratio (95% CI)	0.984 (0.246, 3.946)	
P-value for Odds Ratio	0.9824	
Relative Risk (95% CI)	0.96 (0.32, 2.86)	
P-value for Relative Risk	0.9406	
Risk difference (95% CI)	3.74 (-20.33, 27.81)	
P-value for Risk Difference	0.7608	
Improvement	11 (20.0%)	2 (6.3%)
Odds ratio (95% CI)	3.946 (0.809, 19.258)	
P-value for Odds Ratio	0.0896	
Relative Risk (95% CI)	3.27 (0.77, 13.82)	
P-value for Relative Risk	0.1071	
Risk difference (95% CI)	14.24 (-4.54, 33.02)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1372	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	6 (14.6%)	7 (25.0%)
Odds ratio (95% CI)	0.496 (0.143, 1.718)	
P-value for Odds Ratio	0.2684	
Relative Risk (95% CI)	0.56 (0.22, 1.47)	
P-value for Relative Risk	0.2407	
Risk difference (95% CI)	-9.05 (-29.09, 10.99)	
P-value for Risk Difference	0.3759	
Improvement	5 (12.2%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.49 (0.61, 33.27)	
P-value for Relative Risk	0.1001	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	4 (15.4%)	7 (31.8%)
Odds ratio (95% CI)	0.273 (0.061, 1.217)	
P-value for Odds Ratio	0.0887	
Relative Risk (95% CI)	0.35 (0.12, 1.05)	
P-value for Relative Risk	0.0601	
Risk difference (95% CI)	-21.51 (-21.51, -21.51)*	
Improvement	4 (15.4%)	1 (4.5%)
Odds ratio (95% CI)	120217.3 (0.000, 6.01E145)	
P-value for Odds Ratio	0.9436	
Relative Risk (95% CI)	72650.09 (0.00, 1.89E134)	
P-value for Relative Risk	0.9413	
Risk difference (95% CI)	12.49 (12.49, 12.49)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	3 (14.3%)	4 (26.7%)
Odds ratio (95% CI)	0.368 (0.053, 2.569)	
P-value for Odds Ratio	0.3133	
Relative Risk (95% CI)	0.93 (0.93, 0.93)*	
Risk difference (95% CI)	-13.13 (-13.13, -13.13)*	
Improvement	4 (19.0%)	1 (6.7%)
Odds ratio (95% CI)	2.000 (0.153, 26.187)	
P-value for Odds Ratio	0.5974	
Relative Risk (95% CI)	1.82 (0.19, 17.12)	
P-value for Relative Risk	0.6013	
Risk difference (95% CI)	4.64 (-29.08, 38.35)	
P-value for Risk Difference	0.7876	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	4 (57.1%)	2 (20.0%)
Odds ratio (95% CI)	6.159 (0.352, 107.780)	
P-value for Odds Ratio	0.2132	
Relative Risk (95% CI)	2.11 (0.52, 8.65)	
P-value for Relative Risk	0.2986	
Risk difference (95% CI)	24.28 (-37.79, 86.35)	
P-value for Risk Difference	0.4432	
Improvement	1 (14.3%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.00 (0.14, 28.42)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.50 (0.32, 63.94)	
P-value for Relative Risk	0.2433	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	18 (11.9%)	24 (15.7%)
Odds ratio (95% CI)	0.748 (0.386, 1.452)	
P-value for Odds Ratio	0.3912	
Relative Risk (95% CI)	0.79 (0.45, 1.39)	
P-value for Relative Risk	0.4209	
Risk difference (95% CI)	-5.50 (-14.06, 3.06)	
P-value for Risk Difference	0.2083	
Improvement	21 (13.9%)	30 (19.6%)
Odds ratio (95% CI)	0.670 (0.362, 1.241)	
P-value for Odds Ratio	0.2033	
Relative Risk (95% CI)	0.72 (0.44, 1.20)	
P-value for Relative Risk	0.2098	
Risk difference (95% CI)	-5.58 (-14.06, 2.89)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1967	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	18 (13.2%)	9 (7.3%)
Odds ratio (95% CI)	2.067 (0.870, 4.910)	
P-value for Odds Ratio	0.0999	
Relative Risk (95% CI)	1.89 (0.89, 3.98)	
P-value for Relative Risk	0.0960	
Risk difference (95% CI)	5.24 (-2.37, 12.85)	
P-value for Risk Difference	0.1774	
Improvement	27 (19.9%)	22 (17.9%)
Odds ratio (95% CI)	1.151 (0.611, 2.170)	
P-value for Odds Ratio	0.6634	
Relative Risk (95% CI)	1.10 (0.67, 1.82)	
P-value for Relative Risk	0.7071	
Risk difference (95% CI)	5.19 (-5.38, 15.76)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3359	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	16 (12.6%)	14 (12.7%)
Odds ratio (95% CI)	1.054 (0.483, 2.302)	
P-value for Odds Ratio	0.8941	
Relative Risk (95% CI)	1.06 (0.54, 2.07)	
P-value for Relative Risk	0.8626	
Risk difference (95% CI)	-2.22 (-11.77, 7.33)	
P-value for Risk Difference	0.6485	
Improvement	28 (22.0%)	22 (20.0%)
Odds ratio (95% CI)	1.124 (0.590, 2.141)	
P-value for Odds Ratio	0.7227	
Relative Risk (95% CI)	1.10 (0.68, 1.79)	
P-value for Relative Risk	0.6924	
Risk difference (95% CI)	2.12 (-9.92, 14.16)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7303	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	24 (17.3%)	11 (8.4%)
Odds ratio (95% CI)	2.293 (1.057, 4.972)	
P-value for Odds Ratio	0.0356	
Relative Risk (95% CI)	1.99 (1.02, 3.88)	
P-value for Relative Risk	0.0437	
Risk difference (95% CI)	7.82 (0.23, 15.41)	
P-value for Risk Difference	0.0434	
Improvement	33 (23.7%)	26 (19.8%)
Odds ratio (95% CI)	1.316 (0.722, 2.397)	
P-value for Odds Ratio	0.3699	
Relative Risk (95% CI)	1.21 (0.78, 1.89)	
P-value for Relative Risk	0.3916	
Risk difference (95% CI)	4.32 (-7.10, 15.74)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4587	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	11 (10.1%)	5 (6.8%)
Odds ratio (95% CI)	1.729 (0.553, 5.409)	
P-value for Odds Ratio	0.3468	
Relative Risk (95% CI)	1.25 (1.25, 1.25)*	
Risk difference (95% CI)	3.29 (-10.82, 17.39)	
P-value for Risk Difference	0.6480	
Improvement	28 (25.7%)	16 (21.6%)
Odds ratio (95% CI)	1.194 (0.580, 2.456)	
P-value for Odds Ratio	0.6303	
Relative Risk (95% CI)	1.14 (0.67, 1.94)	
P-value for Relative Risk	0.6170	
Risk difference (95% CI)	4.94 (-8.74, 18.62)	
P-value for Risk Difference	0.4789	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	11 (10.6%)	5 (7.8%)
Odds ratio (95% CI)	1.316 (0.430, 4.028)	
P-value for Odds Ratio	0.6307	
Relative Risk (95% CI)	1.26 (0.45, 3.48)	
P-value for Relative Risk	0.6589	
Risk difference (95% CI)	3.05 (-5.86, 11.96)	
P-value for Risk Difference	0.5026	
Improvement	22 (21.2%)	14 (21.9%)
Odds ratio (95% CI)	1.042 (0.481, 2.259)	
P-value for Odds Ratio	0.9161	
Relative Risk (95% CI)	1.02 (0.57, 1.82)	
P-value for Relative Risk	0.9501	
Risk difference (95% CI)	2.06 (-11.74, 15.86)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7700	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	10 (11.8%)	3 (5.5%)
Odds ratio (95% CI)	2.359 (0.614, 9.067)	
P-value for Odds Ratio	0.2115	
Relative Risk (95% CI)	2.24 (0.65, 7.76)	
P-value for Relative Risk	0.2019	
Risk difference (95% CI)	5.04 (-8.43, 18.51)	
P-value for Risk Difference	0.4632	
Improvement	19 (22.4%)	12 (21.8%)
Odds ratio (95% CI)	1.053 (0.455, 2.436)	
P-value for Odds Ratio	0.9034	
Relative Risk (95% CI)	1.04 (0.56, 1.95)	
P-value for Relative Risk	0.8964	
Risk difference (95% CI)	2.25 (-13.07, 17.56)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

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Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7738	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	7 (9.9%)	3 (7.0%)
Odds ratio (95% CI)	1.255 (0.283, 5.562)	
P-value for Odds Ratio	0.7651	
Relative Risk (95% CI)	1.08 (0.27, 4.25)	
P-value for Relative Risk	0.9140	
Risk difference (95% CI)	0.25 (-10.25, 10.74)	
P-value for Risk Difference	0.9630	
Improvement	22 (31.0%)	12 (27.9%)
Odds ratio (95% CI)	1.224 (0.514, 2.911)	
P-value for Odds Ratio	0.6480	
Relative Risk (95% CI)	1.14 (0.64, 2.04)	
P-value for Relative Risk	0.6541	
Risk difference (95% CI)	3.11 (-15.81, 22.04)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7472	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	1 (1.8%)	3 (9.4%)
Odds ratio (95% CI)	0.177 (0.017, 1.871)	
P-value for Odds Ratio	0.1499	
Relative Risk (95% CI)	0.19 (0.02, 1.69)	
P-value for Relative Risk	0.1367	
Risk difference (95% CI)	-4.77 (-34.74, 25.20)	
P-value for Risk Difference	0.7553	
Improvement	16 (29.1%)	8 (25.0%)
Odds ratio (95% CI)	1.283 (0.464, 3.542)	
P-value for Odds Ratio	0.6312	
Relative Risk (95% CI)	1.18 (0.58, 2.40)	
P-value for Relative Risk	0.6579	
Risk difference (95% CI)	8.78 (-12.22, 29.79)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4125	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	3 (7.3%)	2 (7.1%)
Odds ratio (95% CI)	0.846 (0.116, 6.163)	
P-value for Odds Ratio	0.8687	
Relative Risk (95% CI)	1.46 (1.46, 1.46)*	
Risk difference (95% CI)	1.34 (-25.50, 28.19)	
P-value for Risk Difference	0.9218	
Improvement	11 (26.8%)	5 (17.9%)
Odds ratio (95% CI)	1.906 (0.552, 6.585)	
P-value for Odds Ratio	0.3080	
Relative Risk (95% CI)	1.56 (0.63, 3.87)	
P-value for Relative Risk	0.3356	
Risk difference (95% CI)	8.66 (-16.28, 33.60)	
P-value for Risk Difference	0.4961	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	2 (7.7%)	1 (4.5%)
Odds ratio (95% CI)	0.736 (0.041, 13.237)	
P-value for Odds Ratio	0.8350	
Relative Risk (95% CI)	0.69 (0.05, 10.20)	
P-value for Relative Risk	0.7845	
Risk difference (95% CI)	1.09 (-41.70, 43.89)	
P-value for Risk Difference	0.9600	
Improvement	9 (34.6%)	6 (27.3%)
Odds ratio (95% CI)	1.691 (0.410, 6.981)	
P-value for Odds Ratio	0.4675	
Relative Risk (95% CI)	1.37 (0.58, 3.21)	
P-value for Relative Risk	0.4746	
Risk difference (95% CI)	6.20 (-25.34, 37.74)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6999	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	1 (4.8%)	1 (6.7%)
Odds ratio (95% CI)	0.000 (0.000, 4.6E212)	
P-value for Odds Ratio	0.9648	
Relative Risk (95% CI)	0.00 (0.00, 4.36E197)	
P-value for Relative Risk	0.9630	
Risk difference (95% CI)	-4.57 (-56.95, 47.80)	
P-value for Risk Difference	0.8641	
Improvement	8 (38.1%)	3 (20.0%)
Odds ratio (95% CI)	2.800 (0.463, 16.929)	
P-value for Odds Ratio	0.2621	
Relative Risk (95% CI)	1.82 (0.61, 5.41)	
P-value for Relative Risk	0.2822	
Risk difference (95% CI)	14.00 (14.00, 14.00)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	2 (28.6%)	3 (30.0%)
Odds ratio (95% CI)	1.426 (0.110, 18.477)	
P-value for Odds Ratio	0.7862	
Relative Risk (95% CI)	1.21 (0.25, 5.78)	
P-value for Relative Risk	0.8092	
Risk difference (95% CI)	5.27 (-56.67, 67.20)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8676	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (50.0%)	1 (50.0%)
Odds ratio (95% CI)	0.000 (0.000, 1.42E147)	
P-value for Odds Ratio	0.9536	
Relative Risk (95% CI)	0.06 (0.00, 1149.07)	
P-value for Relative Risk	0.5772	
Risk difference (95% CI)	-47.50 (-250.77, 155.77)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6470	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	15 (9.9%)	18 (11.8%)
Odds ratio (95% CI)	0.838 (0.405, 1.735)	
P-value for Odds Ratio	0.6349	
Relative Risk (95% CI)	0.86 (0.45, 1.64)	
P-value for Relative Risk	0.6404	
Risk difference (95% CI)	-1.83 (-8.80, 5.14)	
P-value for Risk Difference	0.6067	
Improvement	24 (15.9%)	20 (13.1%)
Odds ratio (95% CI)	1.253 (0.659, 2.384)	
P-value for Odds Ratio	0.4917	
Relative Risk (95% CI)	1.20 (0.69, 2.08)	
P-value for Relative Risk	0.5243	
Risk difference (95% CI)	4.46 (-3.97, 12.90)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2999	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	18 (13.2%)	19 (15.4%)
Odds ratio (95% CI)	0.845 (0.420, 1.701)	
P-value for Odds Ratio	0.6377	
Relative Risk (95% CI)	0.87 (0.48, 1.58)	
P-value for Relative Risk	0.6475	
Risk difference (95% CI)	-2.37 (-10.89, 6.14)	
P-value for Risk Difference	0.5846	
Improvement	25 (18.4%)	8 (6.5%)
Odds ratio (95% CI)	3.432 (1.475, 7.984)	
P-value for Odds Ratio	0.0042	
Relative Risk (95% CI)	2.95 (1.39, 6.28)	
P-value for Relative Risk	0.0050	
Risk difference (95% CI)	11.10 (2.94, 19.26)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0077	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	13 (10.2%)	14 (12.7%)
Odds ratio (95% CI)	0.808 (0.357, 1.830)	
P-value for Odds Ratio	0.6099	
Relative Risk (95% CI)	0.83 (0.41, 1.68)	
P-value for Relative Risk	0.6067	
Risk difference (95% CI)	-2.68 (-11.53, 6.16)	
P-value for Risk Difference	0.5525	
Improvement	21 (16.5%)	8 (7.3%)
Odds ratio (95% CI)	2.549 (1.072, 6.064)	
P-value for Odds Ratio	0.0343	
Relative Risk (95% CI)	2.26 (1.04, 4.92)	
P-value for Relative Risk	0.0392	
Risk difference (95% CI)	10.00 (2.04, 17.96)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0138	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	22 (15.8%)	18 (13.7%)
Odds ratio (95% CI)	1.194 (0.604, 2.361)	
P-value for Odds Ratio	0.6093	
Relative Risk (95% CI)	1.16 (0.65, 2.07)	
P-value for Relative Risk	0.6064	
Risk difference (95% CI)	2.12 (-6.57, 10.82)	
P-value for Risk Difference	0.6320	
Improvement	22 (15.8%)	17 (13.0%)
Odds ratio (95% CI)	1.252 (0.628, 2.497)	
P-value for Odds Ratio	0.5228	
Relative Risk (95% CI)	1.20 (0.66, 2.17)	
P-value for Relative Risk	0.5443	
Risk difference (95% CI)	3.27 (-5.11, 11.64)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4445	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	9 (8.3%)	9 (12.2%)
Odds ratio (95% CI)	0.615 (0.228, 1.659)	
P-value for Odds Ratio	0.3371	
Relative Risk (95% CI)	0.65 (0.27, 1.56)	
P-value for Relative Risk	0.3308	
Risk difference (95% CI)	-4.66 (-13.93, 4.60)	
P-value for Risk Difference	0.3240	
Improvement	22 (20.2%)	6 (8.1%)
Odds ratio (95% CI)	2.988 (1.138, 7.843)	
P-value for Odds Ratio	0.0262	
Relative Risk (95% CI)	2.59 (1.10, 6.10)	
P-value for Relative Risk	0.0288	
Risk difference (95% CI)	11.21 (1.24, 21.18)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0275	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	10 (9.6%)	6 (9.4%)
Odds ratio (95% CI)	1.062 (0.364, 3.103)	
P-value for Odds Ratio	0.9119	
Relative Risk (95% CI)	1.07 (0.41, 2.79)	
P-value for Relative Risk	0.8961	
Risk difference (95% CI)	-1.21 (-12.32, 9.91)	
P-value for Risk Difference	0.8317	
Improvement	16 (15.4%)	6 (9.4%)
Odds ratio (95% CI)	1.826 (0.666, 5.003)	
P-value for Odds Ratio	0.2416	
Relative Risk (95% CI)	1.68 (0.70, 4.04)	
P-value for Relative Risk	0.2469	
Risk difference (95% CI)	5.37 (-6.87, 17.60)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3898	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	14 (16.5%)	6 (10.9%)
Odds ratio (95% CI)	1.491 (0.516, 4.308)	
P-value for Odds Ratio	0.4611	
Relative Risk (95% CI)	1.34 (0.56, 3.19)	
P-value for Relative Risk	0.5076	
Risk difference (95% CI)	3.77 (-13.07, 20.62)	
P-value for Risk Difference	0.6606	
Improvement	15 (17.6%)	6 (10.9%)
Odds ratio (95% CI)	1.813 (0.650, 5.057)	
P-value for Odds Ratio	0.2558	
Relative Risk (95% CI)	1.64 (0.68, 3.96)	
P-value for Relative Risk	0.2703	
Risk difference (95% CI)	7.83 (-4.34, 19.99)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2072	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	12 (16.9%)	6 (14.0%)
Odds ratio (95% CI)	1.270 (0.427, 3.782)	
P-value for Odds Ratio	0.6676	
Relative Risk (95% CI)	1.17 (0.48, 2.84)	
P-value for Relative Risk	0.7301	
Risk difference (95% CI)	3.32 (-14.59, 21.23)	
P-value for Risk Difference	0.7166	
Improvement	12 (16.9%)	4 (9.3%)
Odds ratio (95% CI)	2.112 (0.627, 7.111)	
P-value for Odds Ratio	0.2274	
Relative Risk (95% CI)	1.92 (0.66, 5.57)	
P-value for Relative Risk	0.2309	
Risk difference (95% CI)	8.01 (-5.76, 21.78)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2541	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	7 (12.7%)	3 (9.4%)
Odds ratio (95% CI)	1.353 (0.307, 5.953)	
P-value for Odds Ratio	0.6894	
Relative Risk (95% CI)	1.28 (0.37, 4.47)	
P-value for Relative Risk	0.6988	
Risk difference (95% CI)	2.13 (-18.34, 22.60)	
P-value for Risk Difference	0.8382	
Improvement	11 (20.0%)	4 (12.5%)
Odds ratio (95% CI)	1.964 (0.554, 6.969)	
P-value for Odds Ratio	0.2961	
Relative Risk (95% CI)	1.78 (0.63, 5.04)	
P-value for Relative Risk	0.2758	
Risk difference (95% CI)	6.02 (-15.17, 27.22)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5776	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	3 (7.3%)	2 (7.1%)
Odds ratio (95% CI)	0.981 (0.139, 6.900)	
P-value for Odds Ratio	0.9845	
Relative Risk (95% CI)	0.85 (0.16, 4.54)	
P-value for Relative Risk	0.8507	
Risk difference (95% CI)	1.46 (-28.09, 31.00)	
P-value for Risk Difference	0.9230	
Improvement	9 (22.0%)	3 (10.7%)
Odds ratio (95% CI)	2.313 (0.556, 9.617)	
P-value for Odds Ratio	0.2489	
Relative Risk (95% CI)	1.99 (0.59, 6.67)	
P-value for Relative Risk	0.2665	
Risk difference (95% CI)	9.41 (-12.04, 30.85)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3898	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	4 (15.4%)	3 (13.6%)
Odds ratio (95% CI)	1.224 (0.216, 6.934)	
P-value for Odds Ratio	0.8195	
Relative Risk (95% CI)	1.05 (0.29, 3.80)	
P-value for Relative Risk	0.9454	
Risk difference (95% CI)	4.30 (-26.94, 35.54)	
P-value for Risk Difference	0.7872	
Improvement	6 (23.1%)	1 (4.5%)
Odds ratio (95% CI)	3.615 (0.358, 36.510)	
P-value for Odds Ratio	0.2761	
Relative Risk (95% CI)	2.90 (0.35, 24.04)	
P-value for Relative Risk	0.3226	
Risk difference (95% CI)	9.95 (-30.03, 49.93)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6256	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	5 (23.8%)	2 (13.3%)
Odds ratio (95% CI)	3.075 (0.457, 20.702)	
P-value for Odds Ratio	0.2482	
Relative Risk (95% CI)	1.22 (1.22, 1.22)*	
Risk difference (95% CI)	19.21 (19.21, 19.21)*	
Improvement	6 (28.6%)	1 (6.7%)
Odds ratio (95% CI)	2.705 (0.232, 31.484)	
P-value for Odds Ratio	0.4269	
Relative Risk (95% CI)	2.48 (0.27, 22.57)	
P-value for Relative Risk	0.4208	
Risk difference (95% CI)	8.51 (-21.89, 38.90)	
P-value for Risk Difference	0.5832	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	2 (28.6%)	1 (10.0%)
Odds ratio (95% CI)	8.000 (0.310, 206.363)	
P-value for Odds Ratio	0.2099	
Relative Risk (95% CI)	3.33 (0.49, 22.90)	
P-value for Relative Risk	0.2207	
Risk difference (95% CI)	22.92 (22.92, 22.92)*	
Improvement	4 (57.1%)	1 (10.0%)
Odds ratio (95% CI)	6.608E14 (0.000, I)	
P-value for Odds Ratio	0.9529	
Relative Risk (95% CI)	2.62 (0.00, 2871.38)	
P-value for Relative Risk	0.7869	
Risk difference (95% CI)	30.22 (30.22, 30.22)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	1 (50.0%)
Odds ratio (95% CI)	31738.10 (0.000, 1.43E156)	
P-value for Odds Ratio	0.9536	
Relative Risk (95% CI)	1.63 (0.00, 29878.71)	
P-value for Relative Risk	0.9225	
Risk difference (95% CI)	50.00 (50.00, 50.00)*	
Improvement	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (100.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	153
Deterioration	16 (10.6%)	21 (13.7%)
Odds ratio (95% CI)	0.740 (0.369, 1.483)	
P-value for Odds Ratio	0.3959	
Relative Risk (95% CI)	0.77 (0.42, 1.43)	
P-value for Relative Risk	0.4093	
Risk difference (95% CI)	-4.13 (-11.70, 3.43)	
P-value for Risk Difference	0.2841	
Improvement	8 (5.3%)	11 (7.2%)
Odds ratio (95% CI)	0.743 (0.287, 1.922)	
P-value for Odds Ratio	0.5397	
Relative Risk (95% CI)	0.76 (0.32, 1.82)	
P-value for Relative Risk	0.5414	
Risk difference (95% CI)	-1.48 (-9.81, 6.86)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7287	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	123
Deterioration	13 (9.6%)	11 (8.9%)
Odds ratio (95% CI)	1.019 (0.429, 2.419)	
P-value for Odds Ratio	0.9667	
Relative Risk (95% CI)	1.04 (0.48, 2.23)	
P-value for Relative Risk	0.9230	
Risk difference (95% CI)	-1.11 (-7.68, 5.47)	
P-value for Risk Difference	0.7412	
Improvement	7 (5.1%)	8 (6.5%)
Odds ratio (95% CI)	0.787 (0.271, 2.281)	
P-value for Odds Ratio	0.6589	
Relative Risk (95% CI)	0.80 (0.30, 2.13)	
P-value for Relative Risk	0.6541	
Risk difference (95% CI)	-0.42 (-5.81, 4.97)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8789	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	110
Deterioration	21 (16.5%)	14 (12.7%)
Odds ratio (95% CI)	1.346 (0.644, 2.813)	
P-value for Odds Ratio	0.4301	
Relative Risk (95% CI)	1.27 (0.68, 2.38)	
P-value for Relative Risk	0.4574	
Risk difference (95% CI)	4.89 (-3.95, 13.74)	
P-value for Risk Difference	0.2783	
Improvement	8 (6.3%)	6 (5.5%)
Odds ratio (95% CI)	1.143 (0.378, 3.454)	
P-value for Odds Ratio	0.8133	
Relative Risk (95% CI)	1.14 (0.40, 3.18)	
P-value for Relative Risk	0.8092	
Risk difference (95% CI)	0.71 (-5.51, 6.93)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8234	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	139	131
Deterioration	16 (11.5%)	13 (9.9%)
Odds ratio (95% CI)	1.163 (0.532, 2.542)	
P-value for Odds Ratio	0.7045	
Relative Risk (95% CI)	1.13 (0.56, 2.26)	
P-value for Relative Risk	0.7367	
Risk difference (95% CI)	2.15 (-5.04, 9.33)	
P-value for Risk Difference	0.5582	
Improvement	7 (5.0%)	8 (6.1%)
Odds ratio (95% CI)	0.841 (0.293, 2.413)	
P-value for Odds Ratio	0.7481	
Relative Risk (95% CI)	0.84 (0.31, 2.26)	
P-value for Relative Risk	0.7346	
Risk difference (95% CI)	-0.13 (-5.68, 5.43)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9647	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	11 (10.1%)	6 (8.1%)
Odds ratio (95% CI)	1.318 (0.454, 3.830)	
P-value for Odds Ratio	0.6114	
Relative Risk (95% CI)	1.28 (1.28, 1.28)*	
Risk difference (95% CI)	3.47 (-9.88, 16.83)	
P-value for Risk Difference	0.6104	
Improvement	5 (4.6%)	6 (8.1%)
Odds ratio (95% CI)	0.563 (0.158, 2.009)	
P-value for Odds Ratio	0.3764	
Relative Risk (95% CI)	0.56 (0.18, 1.71)	
P-value for Relative Risk	0.3059	
Risk difference (95% CI)	2.99 (-12.42, 18.39)	
P-value for Risk Difference	0.7039	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	5 (4.8%)	9 (14.1%)
Odds ratio (95% CI)	0.324 (0.102, 1.024)	
P-value for Odds Ratio	0.0548	
Relative Risk (95% CI)	0.37 (0.13, 1.04)	
P-value for Relative Risk	0.0585	
Risk difference (95% CI)	-8.41 (-21.35, 4.54)	
P-value for Risk Difference	0.2032	
Improvement	4 (3.8%)	6 (9.4%)
Odds ratio (95% CI)	0.339 (0.088, 1.297)	
P-value for Odds Ratio	0.1139	
Relative Risk (95% CI)	0.35 (0.10, 1.21)	
P-value for Relative Risk	0.0973	
Risk difference (95% CI)	-2.38 (-13.60, 8.84)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6775	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	10 (11.8%)	9 (16.4%)
Odds ratio (95% CI)	0.711 (0.267, 1.895)	
P-value for Odds Ratio	0.4949	
Relative Risk (95% CI)	0.74 (0.32, 1.70)	
P-value for Relative Risk	0.4809	
Risk difference (95% CI)	-2.21 (-15.15, 10.74)	
P-value for Risk Difference	0.7383	
Improvement	4 (4.7%)	6 (10.9%)
Odds ratio (95% CI)	0.413 (0.106, 1.598)	
P-value for Odds Ratio	0.2001	
Relative Risk (95% CI)	0.45 (0.13, 1.52)	
P-value for Relative Risk	0.1995	
Risk difference (95% CI)	-3.09 (-16.79, 10.62)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6589	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	11 (15.5%)	6 (14.0%)
Odds ratio (95% CI)	1.215 (0.410, 3.602)	
P-value for Odds Ratio	0.7254	
Relative Risk (95% CI)	1.19 (0.47, 2.98)	
P-value for Relative Risk	0.7152	
Risk difference (95% CI)	3.06 (-10.98, 17.11)	
P-value for Risk Difference	0.6690	
Improvement	4 (5.6%)	4 (9.3%)
Odds ratio (95% CI)	0.615 (0.137, 2.766)	
P-value for Odds Ratio	0.5263	
Relative Risk (95% CI)	0.61 (0.17, 2.21)	
P-value for Relative Risk	0.4467	
Risk difference (95% CI)	-1.17 (-19.13, 16.78)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8983	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	7 (12.7%)	3 (9.4%)
Odds ratio (95% CI)	1.312 (0.309, 5.572)	
P-value for Odds Ratio	0.7133	
Relative Risk (95% CI)	1.28 (0.35, 4.62)	
P-value for Relative Risk	0.7088	
Risk difference (95% CI)	3.23 (-11.43, 17.90)	
P-value for Risk Difference	0.6658	
Improvement	4 (7.3%)	5 (15.6%)
Odds ratio (95% CI)	0.366 (0.080, 1.671)	
P-value for Odds Ratio	0.1947	
Relative Risk (95% CI)	0.42 (0.13, 1.33)	
P-value for Relative Risk	0.1399	
Risk difference (95% CI)	2.91 (-17.62, 23.45)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7809	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	3 (7.3%)	2 (7.1%)
Odds ratio (95% CI)	1.177 (0.176, 7.888)	
P-value for Odds Ratio	0.8664	
Relative Risk (95% CI)	1.19 (0.22, 6.55)	
P-value for Relative Risk	0.8384	
Risk difference (95% CI)	0.03 (-23.61, 23.67)	
P-value for Risk Difference	0.9979	
Improvement	2 (4.9%)	2 (7.1%)
Odds ratio (95% CI)	0.618 (0.071, 5.373)	
P-value for Odds Ratio	0.6627	
Relative Risk (95% CI)	0.66 (0.10, 4.20)	
P-value for Relative Risk	0.6583	
Risk difference (95% CI)	-1.48 (-34.35, 31.39)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9297	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	3 (11.5%)	3 (13.6%)
Odds ratio (95% CI)	0.709 (0.122, 4.115)	
P-value for Odds Ratio	0.7018	
Relative Risk (95% CI)	0.76 (0.16, 3.50)	
P-value for Relative Risk	0.7238	
Risk difference (95% CI)	-4.92 (-4.92, -4.92)*	
Improvement	2 (7.7%)	3 (13.6%)
Odds ratio (95% CI)	0.381 (0.037, 3.904)	
P-value for Odds Ratio	0.4164	
Relative Risk (95% CI)	0.44 (0.11, 1.73)	
P-value for Relative Risk	0.2416	
Risk difference (95% CI)	-3.40 (-43.50, 36.70)	
P-value for Risk Difference	0.8681	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	2 (9.5%)	2 (13.3%)
Odds ratio (95% CI)	0.888 (0.091, 8.659)	
P-value for Odds Ratio	0.9188	
Relative Risk (95% CI)	0.80 (0.80, 0.80)*	
Risk difference (95% CI)	-4.34 (-4.34, -4.34)*	
Improvement	1 (4.8%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.00 (0.14, 28.42)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	0	1 (10.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.03, 9.46)	
P-value for Relative Risk	0.6460	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (14.3%)	1 (10.0%)
Odds ratio (95% CI)	0.000 (0.000, 1.66E261)	
P-value for Odds Ratio	0.9458	
Relative Risk (95% CI)	0.11 (0.00, 200906.9)	
P-value for Relative Risk	0.7655	
Risk difference (95% CI)	-7.18 (-99.28, 84.93)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8786	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	151	152
Deterioration	14 (9.3%)	10 (6.6%)
Odds ratio (95% CI)	1.472 (0.629, 3.441)	
P-value for Odds Ratio	0.3726	
Relative Risk (95% CI)	1.45 (0.67, 3.17)	
P-value for Relative Risk	0.3462	
Risk difference (95% CI)	2.06 (-4.76, 8.87)	
P-value for Risk Difference	0.5542	
Improvement	18 (11.9%)	13 (8.6%)
Odds ratio (95% CI)	1.379 (0.641, 2.969)	
P-value for Odds Ratio	0.4110	
Relative Risk (95% CI)	1.40 (0.72, 2.73)	
P-value for Relative Risk	0.3159	
Risk difference (95% CI)	-3.36 (-12.03, 5.30)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4467	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	136	122
Deterioration	16 (11.8%)	9 (7.4%)
Odds ratio (95% CI)	1.720 (0.726, 4.077)	
P-value for Odds Ratio	0.2180	
Relative Risk (95% CI)	1.62 (0.75, 3.53)	
P-value for Relative Risk	0.2213	
Risk difference (95% CI)	5.56 (-1.31, 12.43)	
P-value for Risk Difference	0.1129	
Improvement	16 (11.8%)	13 (10.7%)
Odds ratio (95% CI)	1.098 (0.498, 2.422)	
P-value for Odds Ratio	0.8163	
Relative Risk (95% CI)	1.13 (0.57, 2.25)	
P-value for Relative Risk	0.7199	
Risk difference (95% CI)	-2.79 (-11.69, 6.12)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5400	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	127	109
Deterioration	13 (10.2%)	8 (7.3%)
Odds ratio (95% CI)	1.562 (0.616, 3.960)	
P-value for Odds Ratio	0.3479	
Relative Risk (95% CI)	1.21 (1.21, 1.21)*	
Risk difference (95% CI)	3.38 (-6.44, 13.20)	
P-value for Risk Difference	0.5002	
Improvement	16 (12.6%)	13 (11.9%)
Odds ratio (95% CI)	1.024 (0.458, 2.287)	
P-value for Odds Ratio	0.9539	
Relative Risk (95% CI)	1.05 (0.53, 2.07)	
P-value for Relative Risk	0.8898	
Risk difference (95% CI)	-2.44 (-10.58, 5.71)	
P-value for Risk Difference	0.5580	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	138	130
Deterioration	12 (8.7%)	13 (10.0%)
Odds ratio (95% CI)	0.868 (0.378, 1.993)	
P-value for Odds Ratio	0.7386	
Relative Risk (95% CI)	0.87 (0.41, 1.85)	
P-value for Relative Risk	0.7210	
Risk difference (95% CI)	-0.65 (-7.49, 6.18)	
P-value for Risk Difference	0.8513	
Improvement	19 (13.8%)	20 (15.4%)
Odds ratio (95% CI)	0.821 (0.411, 1.637)	
P-value for Odds Ratio	0.5750	
Relative Risk (95% CI)	0.88 (0.49, 1.56)	
P-value for Relative Risk	0.6507	
Risk difference (95% CI)	-4.47 (-12.66, 3.73)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2852	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	109	74
Deterioration	11 (10.1%)	6 (8.1%)
Odds ratio (95% CI)	1.331 (0.466, 3.804)	
P-value for Odds Ratio	0.5937	
Relative Risk (95% CI)	1.28 (0.50, 3.31)	
P-value for Relative Risk	0.6100	
Risk difference (95% CI)	3.19 (-6.15, 12.52)	
P-value for Risk Difference	0.5034	
Improvement	24 (22.0%)	10 (13.5%)
Odds ratio (95% CI)	1.692 (0.743, 3.850)	
P-value for Odds Ratio	0.2101	
Relative Risk (95% CI)	1.61 (0.83, 3.16)	
P-value for Relative Risk	0.1620	
Risk difference (95% CI)	4.02 (-8.16, 16.21)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5176	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	104	64
Deterioration	10 (9.6%)	2 (3.1%)
Odds ratio (95% CI)	3.578 (0.753, 16.996)	
P-value for Odds Ratio	0.1088	
Relative Risk (95% CI)	3.27 (0.74, 14.37)	
P-value for Relative Risk	0.1169	
Risk difference (95% CI)	5.97 (-6.97, 18.91)	
P-value for Risk Difference	0.3660	
Improvement	14 (13.5%)	10 (15.6%)
Odds ratio (95% CI)	0.732 (0.294, 1.822)	
P-value for Odds Ratio	0.5031	
Relative Risk (95% CI)	0.81 (0.39, 1.69)	
P-value for Relative Risk	0.5784	
Risk difference (95% CI)	-6.44 (-16.99, 4.11)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2318	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	85	55
Deterioration	7 (8.2%)	3 (5.5%)
Odds ratio (95% CI)	1.639 (0.398, 6.759)	
P-value for Odds Ratio	0.4942	
Relative Risk (95% CI)	1.53 (0.42, 5.60)	
P-value for Relative Risk	0.5204	
Risk difference (95% CI)	3.43 (-15.15, 22.00)	
P-value for Risk Difference	0.7178	
Improvement	16 (18.8%)	6 (10.9%)
Odds ratio (95% CI)	2.005 (0.703, 5.722)	
P-value for Odds Ratio	0.1933	
Relative Risk (95% CI)	1.91 (0.82, 4.48)	
P-value for Relative Risk	0.1356	
Risk difference (95% CI)	5.17 (-7.35, 17.69)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4183	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	71	43
Deterioration	8 (11.3%)	1 (2.3%)
Odds ratio (95% CI)	6.275 (0.744, 52.944)	
P-value for Odds Ratio	0.0915	
Relative Risk (95% CI)	2.61 (2.61, 2.61)*	
Risk difference (95% CI)	8.01 (-18.70, 34.72)	
P-value for Risk Difference	0.5567	
Improvement	12 (16.9%)	6 (14.0%)
Odds ratio (95% CI)	1.091 (0.364, 3.271)	
P-value for Odds Ratio	0.8771	
Relative Risk (95% CI)	1.12 (0.45, 2.76)	
P-value for Relative Risk	0.8079	
Risk difference (95% CI)	-2.62 (-18.26, 13.03)	
P-value for Risk Difference	0.7431	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	55	32
Deterioration	7 (12.7%)	2 (6.3%)
Odds ratio (95% CI)	2.226 (0.427, 11.613)	
P-value for Odds Ratio	0.3424	
Relative Risk (95% CI)	1.39 (1.39, 1.39)*	
Risk difference (95% CI)	8.15 (-14.86, 31.17)	
P-value for Risk Difference	0.4873	
Improvement	12 (21.8%)	6 (18.8%)
Odds ratio (95% CI)	1.101 (0.335, 3.617)	
P-value for Odds Ratio	0.8739	
Relative Risk (95% CI)	1.19 (0.57, 2.49)	
P-value for Relative Risk	0.6521	
Risk difference (95% CI)	-3.98 (-21.65, 13.69)	
P-value for Risk Difference	0.6591	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	41	28
Deterioration	9 (22.0%)	1 (3.6%)
Odds ratio (95% CI)	7.877 (0.911, 68.143)	
P-value for Odds Ratio	0.0608	
Relative Risk (95% CI)	5.82 (0.78, 43.61)	
P-value for Relative Risk	0.0864	
Risk difference (95% CI)	15.30 (-15.85, 46.45)	
P-value for Risk Difference	0.3356	
Improvement	8 (19.5%)	5 (17.9%)
Odds ratio (95% CI)	0.998 (0.267, 3.733)	
P-value for Odds Ratio	0.9981	
Relative Risk (95% CI)	1.08 (0.42, 2.78)	
P-value for Relative Risk	0.8660	
Risk difference (95% CI)	-5.41 (-24.38, 13.55)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5758	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	26	22
Deterioration	4 (15.4%)	1 (4.5%)
Odds ratio (95% CI)	2.727 (0.243, 30.661)	
P-value for Odds Ratio	0.4164	
Relative Risk (95% CI)	2.36 (0.28, 19.66)	
P-value for Relative Risk	0.4281	
Risk difference (95% CI)	5.65 (-26.66, 37.96)	
P-value for Risk Difference	0.7317	
Improvement	4 (15.4%)	4 (18.2%)
Odds ratio (95% CI)	0.285 (0.041, 1.980)	
P-value for Odds Ratio	0.2043	
Relative Risk (95% CI)	0.35 (0.08, 1.65)	
P-value for Relative Risk	0.1857	
Risk difference (95% CI)	-7.78 (-37.88, 22.32)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6125	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	21	15
Deterioration	1 (4.8%)	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.75 (0.12, 60.70)	
P-value for Relative Risk	0.5083	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	5 (23.8%)	1 (6.7%)
Odds ratio (95% CI)	2.705 (0.232, 31.484)	
P-value for Odds Ratio	0.4269	
Relative Risk (95% CI)	2.24 (0.25, 20.45)	
P-value for Relative Risk	0.4743	
Risk difference (95% CI)	12.01 (-18.05, 42.07)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4335	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	7	10
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (14.3%)	1 (10.0%)
Odds ratio (95% CI)	0.888 (0.032, 24.396)	
P-value for Odds Ratio	0.9441	
Relative Risk (95% CI)	0.48 (0.48, 0.48)*	
Risk difference (95% CI)	-1.18 (-80.45, 78.10)	
P-value for Risk Difference	0.9768	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (50.0%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.04, 7.10)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Global health status/QoL (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	70 (33.5 %)	53 (25.7 %)
Number of censored cases	n (%)	139 (66.5 %)	153 (74.3 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	0	1 (0.5 %)
No confirmed deterioration	n (%)	112 (53.6 %)	126 (61.2 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	10.78 [5.98, 13.73]	8.31 [5.65, 13.93]
	Median [95% CI]	35.15 [24.74, NC]	50.92 [34.92, NC]
	Q3 [95% CI]	NYR [51.61, NC]	NYR [50.92, NC]
	p-value[b]		0.520
	HR [95 % CI][c]		1.13 [0.78, 1.62]
Physical Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	53 (25.4 %)	47 (22.8 %)
Number of censored cases	n (%)	156 (74.6 %)	159 (77.2 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	1 (0.5 %)	0
No confirmed deterioration	n (%)	128 (61.2 %)	133 (64.6 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	18.40 [11.20, 27.93]	11.63 [8.31, 18.00]
	Median [95% CI]	38.97 [33.87, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.375
	HR [95 % CI][c]		0.83 [0.56, 1.25]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Role Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	78 (37.3 %)	60 (29.1 %)
Number of censored cases	n (%)	131 (62.7 %)	146 (70.9 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	5 (2.4 %)	0
No confirmed deterioration	n (%)	99 (47.4 %)	120 (58.3 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.44 [5.62, 13.14]	8.31 [5.59, 9.95]
	Median [95% CI]	23.46 [17.58, 35.98]	49.74 [23.95, NC]
	Q3 [95% CI]	NYR [40.31, NC]	NYR [NC, NC]
	p-value[b]		0.473
	HR [95 % CI][c]		1.13 [0.80, 1.59]
Emotional Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	54 (25.8 %)	47 (22.8 %)
Number of censored cases	n (%)	155 (74.2 %)	159 (77.2 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	1 (0.5 %)	1 (0.5 %)
No confirmed deterioration	n (%)	127 (60.8 %)	132 (64.1 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	11.47 [10.64, 21.88]	13.50 [8.34, 22.21]
	Median [95% CI]	NYR [40.31, NC]	NYR [30.62, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.817
	HR [95 % CI][c]		0.95 [0.64, 1.41]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Cognitive Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	72 (34.4 %)	56 (27.2 %)
Number of censored cases	n (%)	137 (65.6 %)	150 (72.8 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	0	1 (0.5 %)
No confirmed deterioration	n (%)	110 (52.6 %)	123 (59.7 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.34 [5.62, 13.90]	10.64 [8.31, 14.55]
	Median [95% CI]	31.11 [24.08, 46.03]	34.30 [18.50, NC]
	Q3 [95% CI]	46.95 [46.03, NC]	NYR [51.12, NC]
	p-value[b]		0.529
	HR [95 % CI][c]		1.12 [0.79, 1.59]
Social Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	64 (30.6 %)	49 (23.8 %)
Number of censored cases	n (%)	145 (69.4 %)	157 (76.2 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	0	2 (1.0 %)
No confirmed deterioration	n (%)	118 (56.5 %)	129 (62.6 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.48 [8.34, 18.04]	11.30 [5.78, 23.49]
	Median [95% CI]	40.31 [25.59, NC]	NYR [25.86, NC]
	Q3 [95% CI]	NYR [46.95, NC]	NYR [NC, NC]
	p-value[b]		0.664
	HR [95 % CI][c]		1.09 [0.75, 1.59]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Fatigue (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	97 (46.4 %)	86 (41.7 %)
Number of censored cases	n (%)	112 (53.6 %)	120 (58.3 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	1 (0.5 %)	1 (0.5 %)
No confirmed deterioration	n (%)	84 (40.2 %)	93 (45.1 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	3.12 [2.92, 5.59]	3.88 [2.89, 5.78]
	Median [95% CI]	15.51 [8.51, 24.08]	10.61 [8.31, 13.90]
	Q3 [95% CI]	51.61 [39.46, NC]	NYR [34.07, NC]
	p-value[b]		0.533
	HR [95 % CI][c]		0.91 [0.67, 1.22]
Pain (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	63 (30.1 %)	66 (32.0 %)
Number of censored cases	n (%)	146 (69.9 %)	140 (68.0 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	2 (1.0 %)	2 (1.0 %)
No confirmed deterioration	n (%)	117 (56.0 %)	112 (54.4 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.48 [5.72, 18.00]	6.70 [4.27, 8.41]
	Median [95% CI]	40.31 [26.02, NC]	39.16 [14.98, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [49.74, NC]
	p-value[b]		0.203
	HR [95 % CI][c]		0.80 [0.56, 1.13]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Financial Difficulties (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	33 (15.8 %)	21 (10.2 %)
Number of censored cases	n (%)	176 (84.2 %)	185 (89.8 %)
No baseline score	n (%)	17 (8.1 %)	17 (8.3 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	5 (2.4 %)	2 (1.0 %)
No confirmed deterioration	n (%)	144 (68.9 %)	156 (75.7 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	33.87 [19.38, NC]	NYR [NC, NC]
	Median [95% CI]	NYR [46.49, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.344
	HR [95 % CI][c]		1.31 [0.75, 2.28]
Nausea/Vomiting (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	32 (15.3 %)	21 (10.2 %)
Number of censored cases	n (%)	177 (84.7 %)	185 (89.8 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	0	0
No confirmed deterioration	n (%)	150 (71.8 %)	159 (77.2 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	35.15 [18.30, NC]	NYR [21.65, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.495
	HR [95 % CI][c]		1.21 [0.70, 2.11]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Dyspnoea (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	51 (24.4 %)	40 (19.4 %)
Number of censored cases	n (%)	158 (75.6 %)	166 (80.6 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	3 (1.4 %)	0
No confirmed deterioration	n (%)	128 (61.2 %)	140 (68.0 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	21.88 [13.63, 26.02]	18.53 [10.64, 28.55]
	Median [95% CI]	37.85 [33.91, NC]	NYR [32.26, NC]
	Q3 [95% CI]	NYR [44.65, NC]	NYR [NC, NC]
	p-value[b]		0.880
	HR [95 % CI][c]		0.97 [0.63, 1.48]
Insomnia (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	56 (26.8 %)	59 (28.6 %)
Number of censored cases	n (%)	153 (73.2 %)	147 (71.4 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	5 (2.4 %)	6 (2.9 %)
No confirmed deterioration	n (%)	121 (57.9 %)	115 (55.8 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	10.68 [5.65, 17.58]	8.31 [5.62, 8.51]
	Median [95% CI]	47.08 [45.70, NC]	38.01 [22.28, NC]
	Q3 [95% CI]	NYR [47.08, NC]	NYR [NC, NC]
	p-value[b]		0.151
	HR [95 % CI][c]		0.76 [0.52, 1.10]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Appetite Loss (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	35 (16.7 %)	21 (10.2 %)
Number of censored cases	n (%)	174 (83.3 %)	185 (89.8 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	4 (1.9 %)	5 (2.4 %)
No confirmed deterioration	n (%)	143 (68.4 %)	154 (74.8 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	33.74 [14.52, NC]	NYR [22.67, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.349
	HR [95 % CI][c]		1.29 [0.75, 2.23]
Constipation (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	36 (17.2 %)	39 (18.9 %)
Number of censored cases	n (%)	173 (82.8 %)	167 (81.1 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	1 (0.5 %)	3 (1.5 %)
No confirmed deterioration	n (%)	145 (69.4 %)	138 (67.0 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	39.46 [14.49, NC]	21.75 [10.45, 30.69]
	Median [95% CI]	NYR [46.49, NC]	57.33 [46.72, NC]
	Q3 [95% CI]	NYR [NC, NC]	57.33 [NC, NC]
	p-value[b]		0.326
	HR [95 % CI][c]		0.79 [0.50, 1.26]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Diarrhoea (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	28 (13.4 %)	27 (13.1 %)
Number of censored cases	n (%)	181 (86.6 %)	179 (86.9 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	10 (4.8 %)	10 (4.9 %)
No deterioration possible	n (%)	1 (0.5 %)	0
No confirmed deterioration	n (%)	153 (73.2 %)	153 (74.3 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	41.46 [24.74, NC]	25.66 [14.75, NC]
	Median [95% CI]	NYR [47.31, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.307
	HR [95 % CI][c]		0.76 [0.44, 1.30]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	70 (33.5%)	53 (25.7%)
Number of censored participants, n (%)	139 (66.5%)	153 (74.3%)
Proportionality Test p-value[a][b]	0.0335	
Hazard ratio(interaction)	0.609 (0.386, 0.962)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	53 (25.4%)	47 (22.8%)
Number of censored participants, n (%)	156 (74.6%)	159 (77.2%)
Proportionality Test p-value[a][b]	0.2276	
Hazard ratio(interaction)	0.746 (0.464, 1.201)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	78 (37.3%)	60 (29.1%)
Number of censored participants, n (%)	131 (62.7%)	146 (70.9%)
Proportionality Test p-value[a][b]	0.0185	
Hazard ratio(interaction)	0.590 (0.380, 0.915)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	54 (25.8%)	47 (22.8%)
Number of censored participants, n (%)	155 (74.2%)	159 (77.2%)
Proportionality Test p-value[a][b]	0.5854	
Hazard ratio(interaction)	1.145 (0.704, 1.861)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	72 (34.4%)	56 (27.2%)
Number of censored participants, n (%)	137 (65.6%)	150 (72.8%)
Proportionality Test p-value[a][b]	0.8772	
Hazard ratio(interaction)	1.032 (0.688, 1.549)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	64 (30.6%)	49 (23.8%)
Number of censored participants, n (%)	145 (69.4%)	157 (76.2%)
Proportionality Test p-value[a][b]	0.2879	
Hazard ratio(interaction)	0.797 (0.525, 1.211)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	97 (46.4%)	86 (41.7%)
Number of censored participants, n (%)	112 (53.6%)	120 (58.3%)
Proportionality Test p-value[a][b]	0.6561	
Hazard ratio(interaction)	0.916 (0.623, 1.347)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	32 (15.3%)	21 (10.2%)
Number of censored participants, n (%)	177 (84.7%)	185 (89.8%)
Proportionality Test p-value[a][b]	0.2656	
Hazard ratio(interaction)	0.684 (0.350, 1.335)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Pain (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	63 (30.1%)	66 (32.0%)
Number of censored participants, n (%)	146 (69.9%)	140 (68.0%)
Proportionality Test p-value[a][b]	0.2298	
Hazard ratio(interaction)	0.768 (0.499, 1.182)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	51 (24.4%)	40 (19.4%)
Number of censored participants, n (%)	158 (75.6%)	166 (80.6%)
Proportionality Test p-value[a][b]	0.0463	
Hazard ratio(interaction)	0.626 (0.396, 0.992)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	56 (26.8%)	59 (28.6%)
Number of censored participants, n (%)	153 (73.2%)	147 (71.4%)
Proportionality Test p-value[a][b]	0.5316	
Hazard ratio(interaction)	1.159 (0.729, 1.843)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	35 (16.7%)	21 (10.2%)
Number of censored participants, n (%)	174 (83.3%)	185 (89.8%)
Proportionality Test p-value[a][b]	0.8305	
Hazard ratio(interaction)	1.074 (0.557, 2.072)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Constipation (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	36 (17.2%)	39 (18.9%)
Number of censored participants, n (%)	173 (82.8%)	167 (81.1%)
Proportionality Test p-value[a][b]	0.9986	
Hazard ratio(interaction)	1.000 (0.602, 1.660)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	28 (13.4%)	27 (13.1%)
Number of censored participants, n (%)	181 (86.6%)	179 (86.9%)
Proportionality Test p-value[a][b]	0.4055	
Hazard ratio(interaction)	0.756 (0.391, 1.462)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

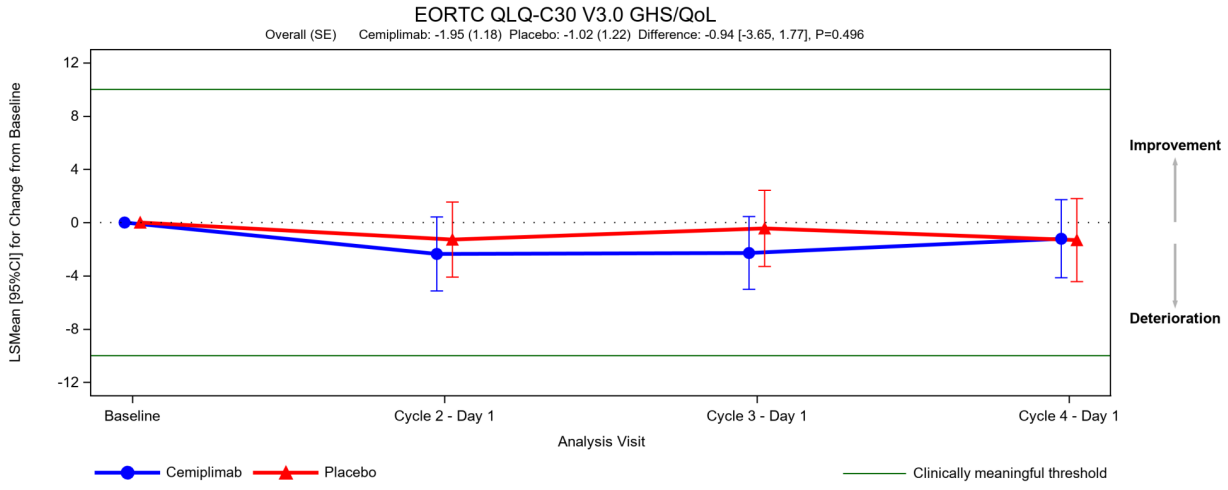
Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	33 (15.8%)	21 (10.2%)
Number of censored participants, n (%)	176 (84.2%)	185 (89.8%)
Proportionality Test p-value[a][b]	0.0793	
Hazard ratio(interaction)	0.553 (0.285, 1.072)	

Data cut-off as of October 4, 2024.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Figure 4.1.1: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 GHS/QoL scale
FAS (N=415)

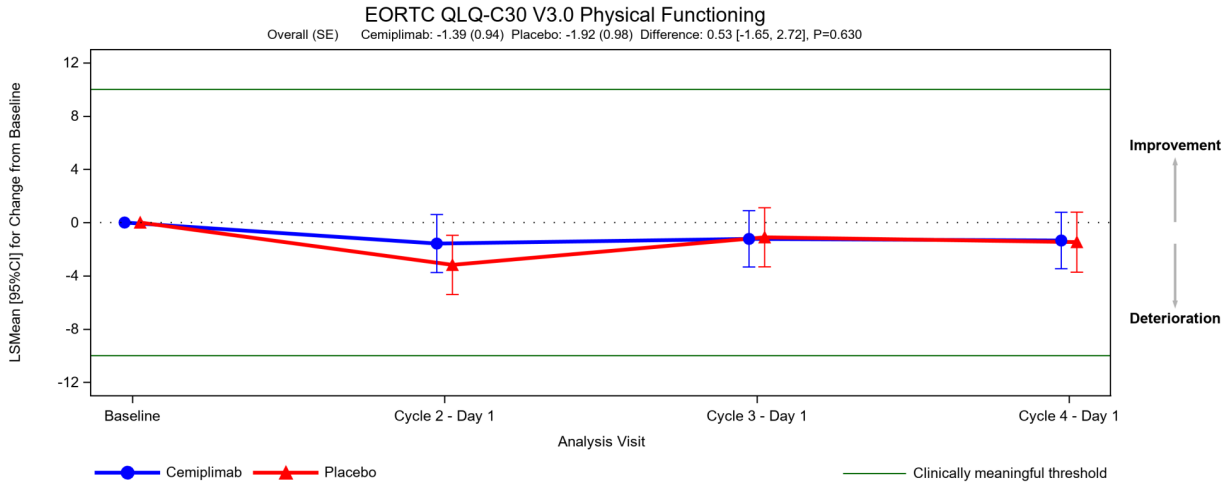


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.2: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Physical Functioning scale
FAS (N=415)

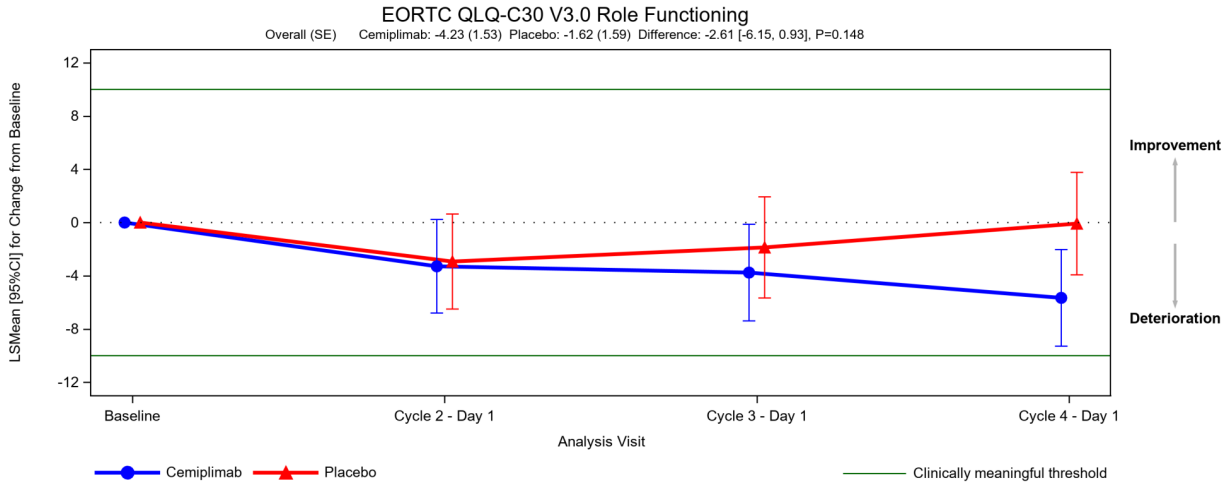


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.3: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Role Functioning scale
FAS (N=415)

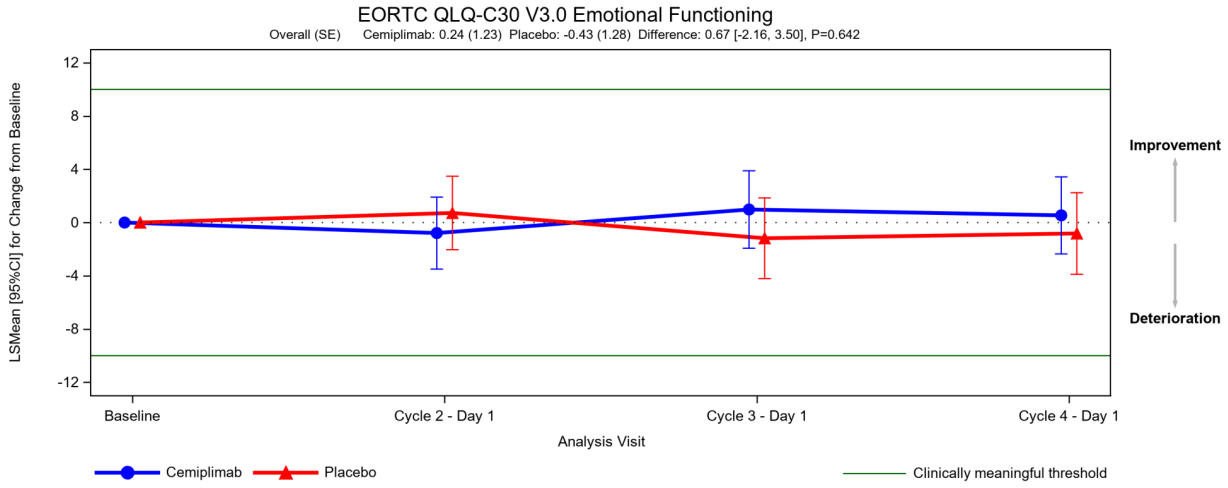


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.4: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Emotional Functioning scale
FAS (N=415)

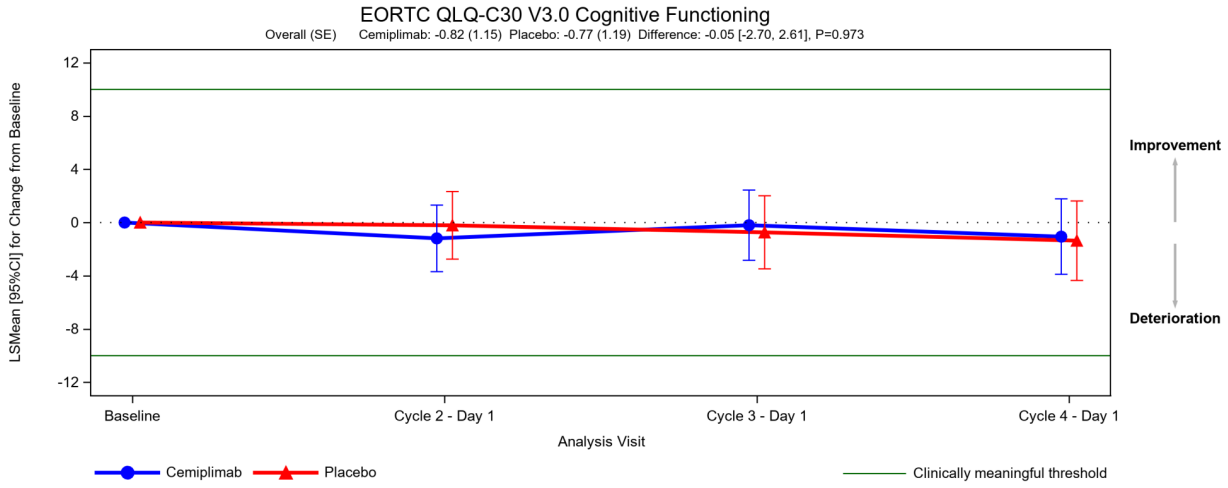


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.5: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Cognitive Functioning scale
FAS (N=415)

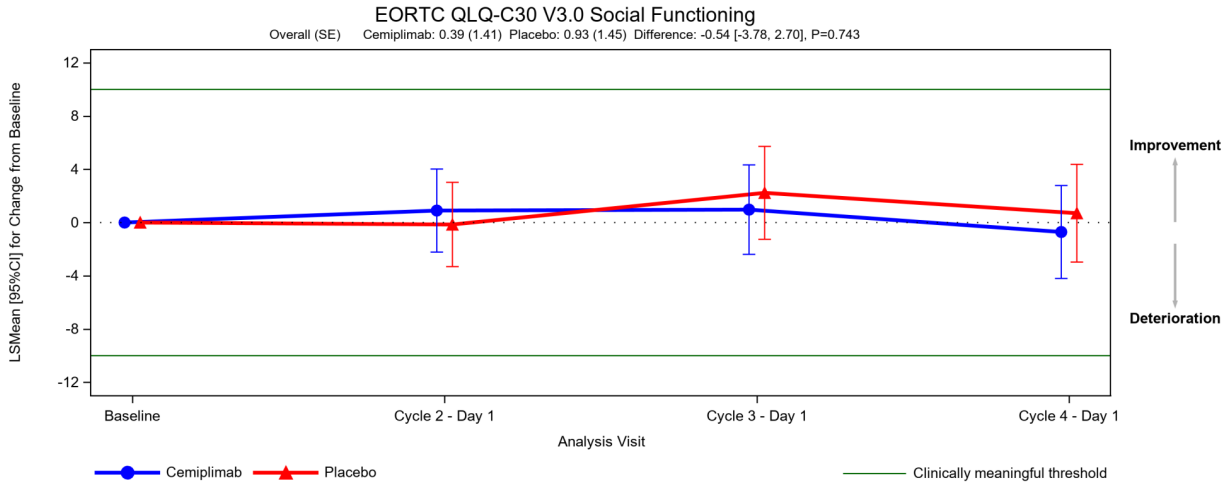


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.6: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Social Functioning scale
FAS (N=415)

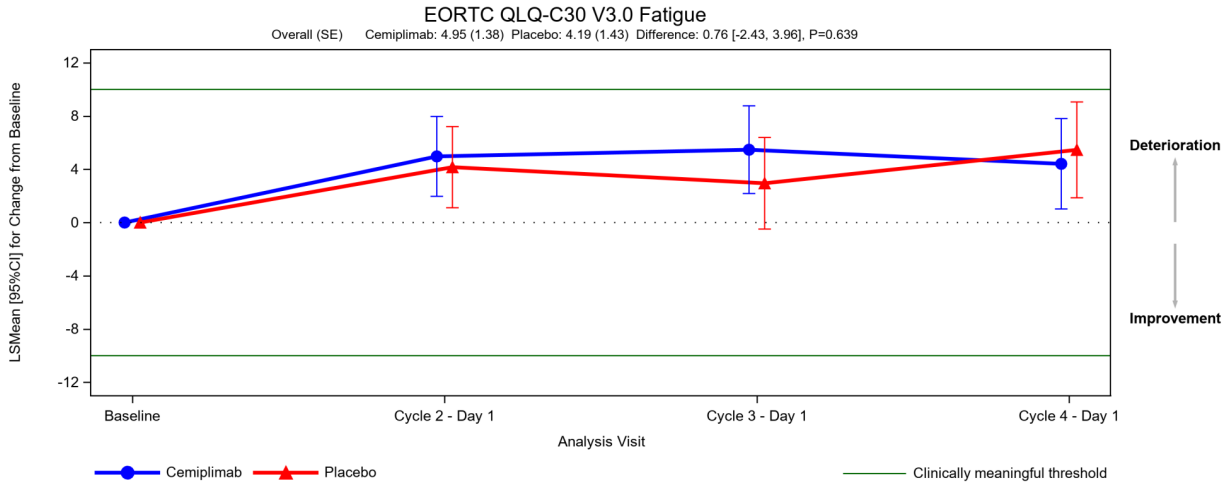


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.7: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Fatigue scale
FAS (N=415)

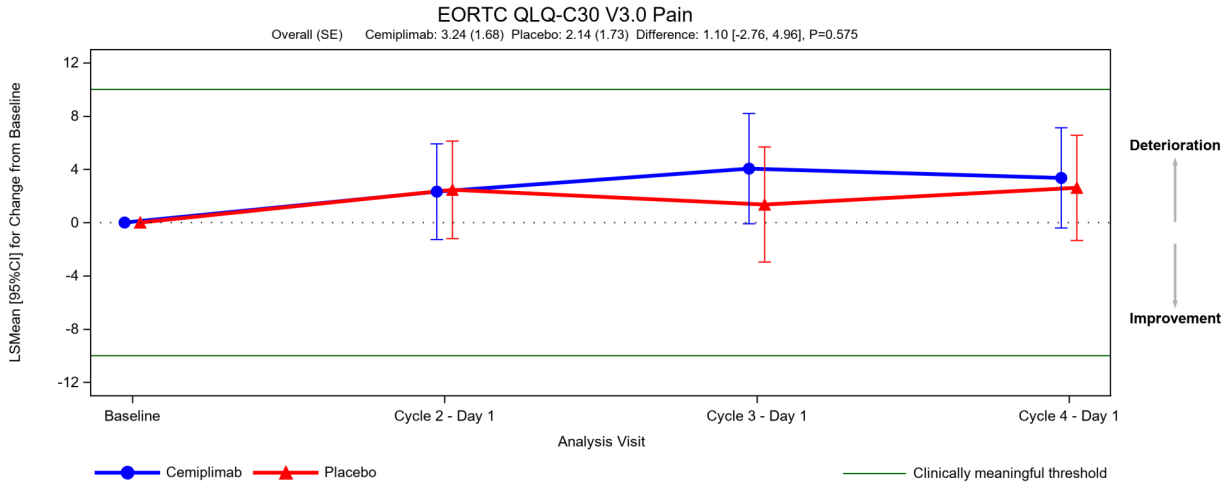


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.8: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Pain scale
FAS (N=415)

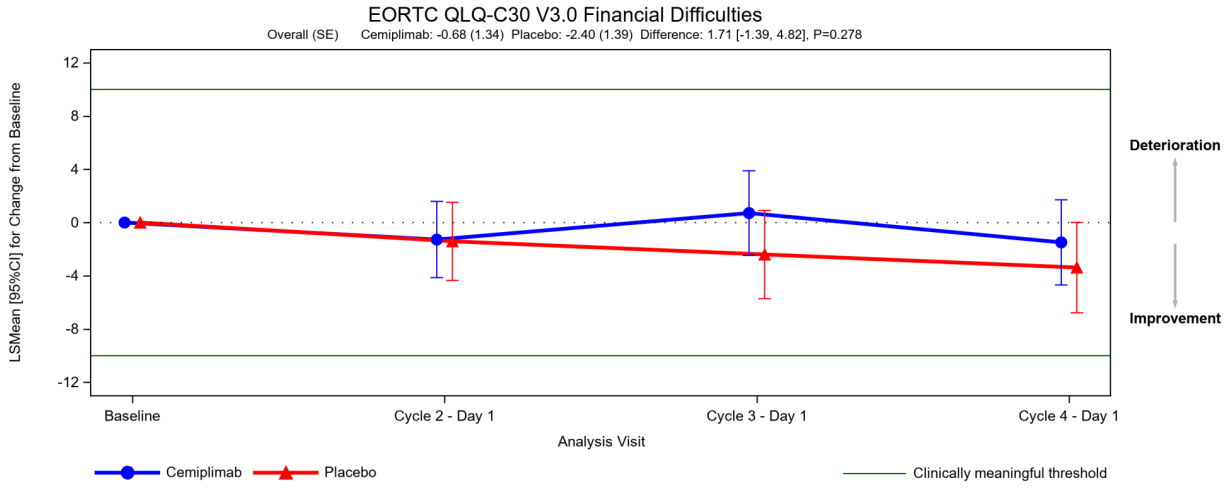


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.9: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Financial Difficulties scale
FAS (N=415)

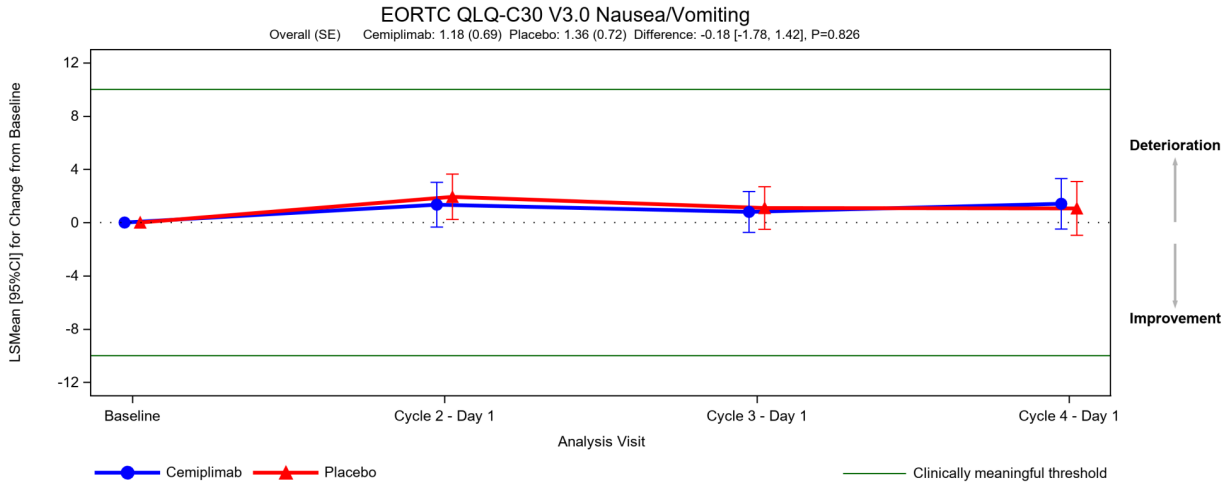


Number of patients

Cemiplimab	151	136	127
Placebo	152	122	109

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.10: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Nausea/Vomiting scale
FAS (N=415)

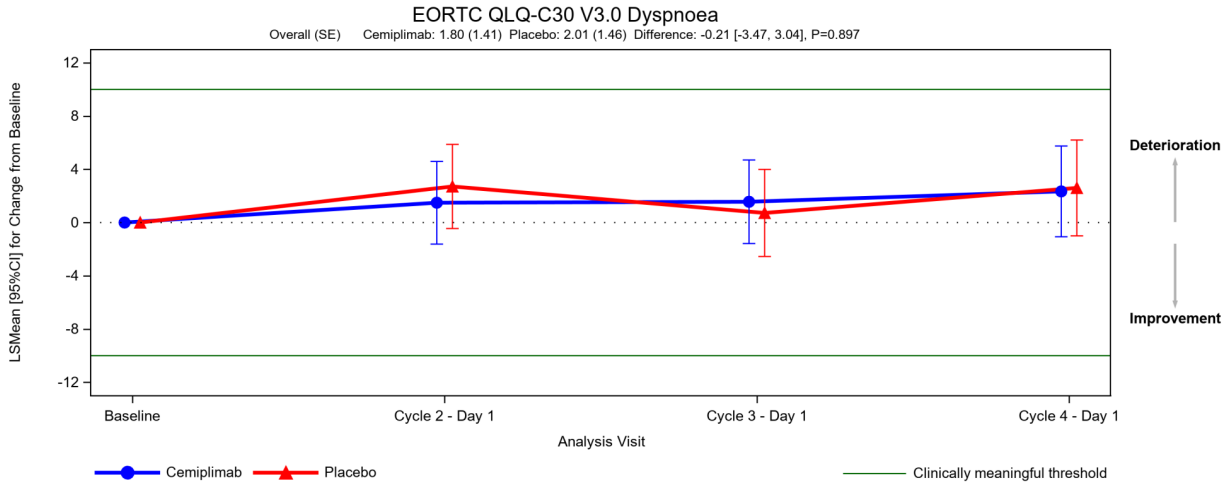


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.11: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Dyspnoea scale
FAS (N=415)

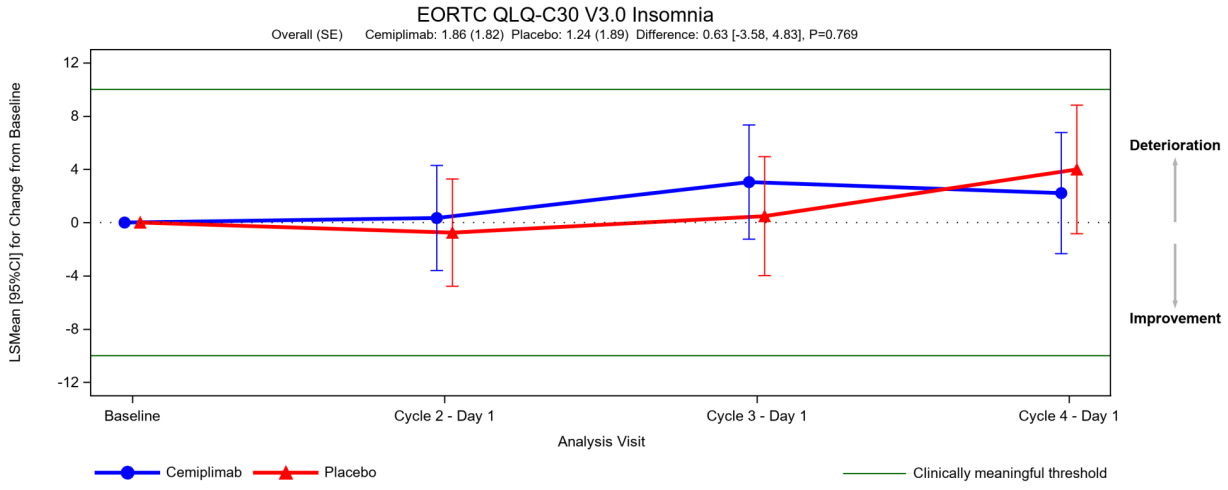


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.12: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Insomnia scale
FAS (N=415)

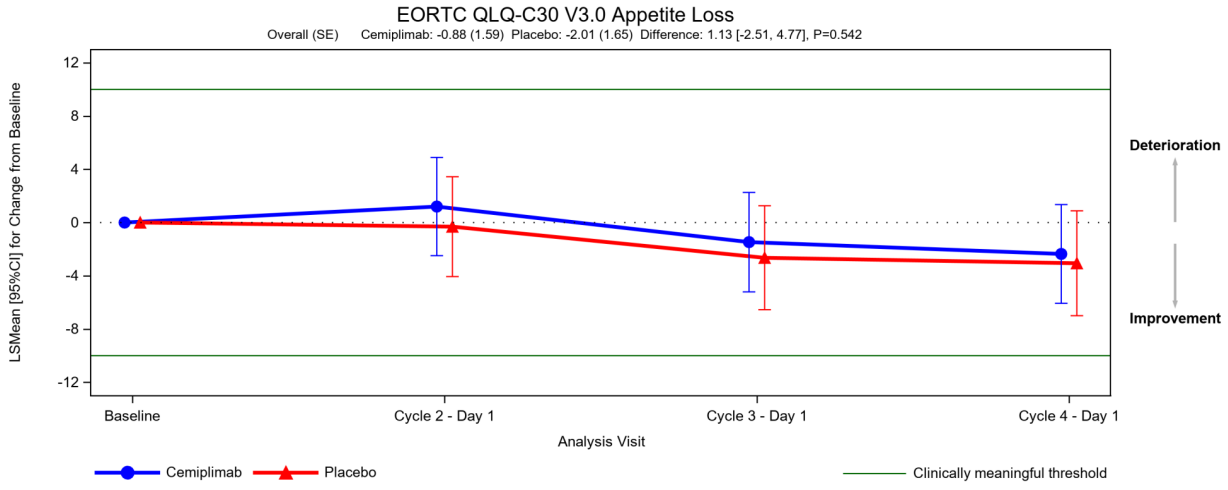


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.13: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Appetite Loss scale
FAS (N=415)

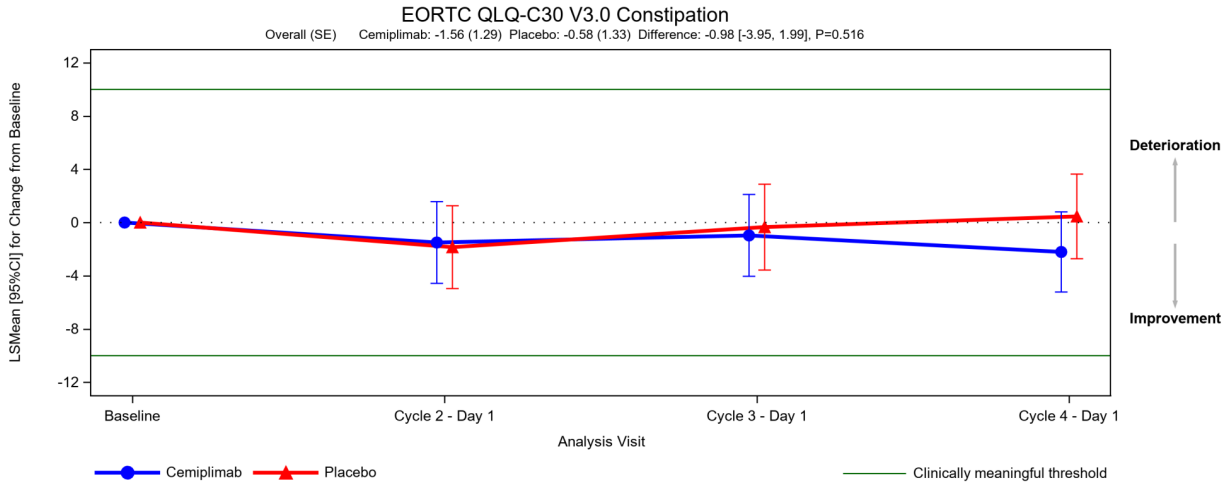


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.14: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Constipation scale
FAS (N=415)

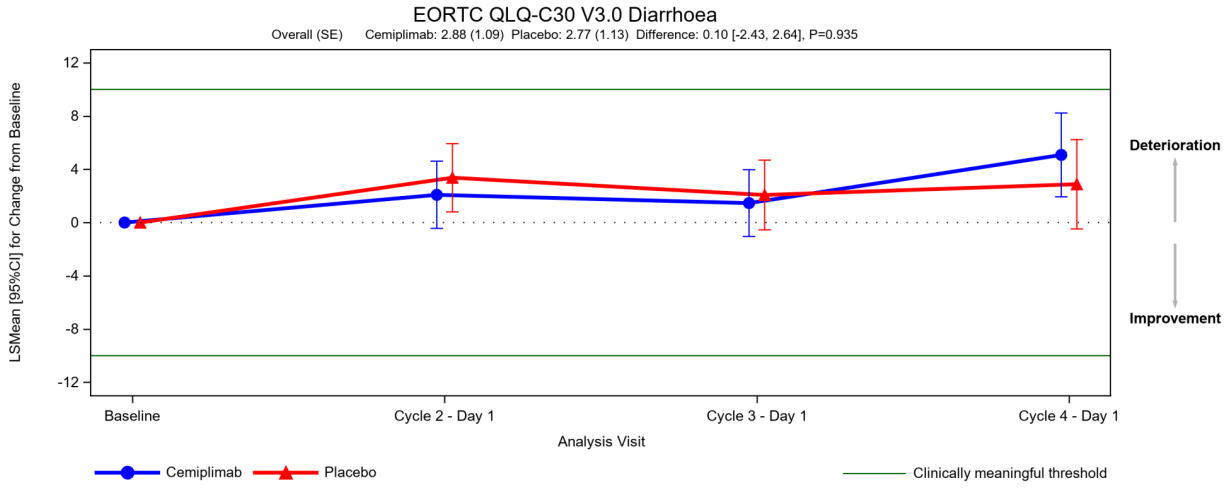


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure 4.1.15: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Diarrhoea scale
FAS (N=415)

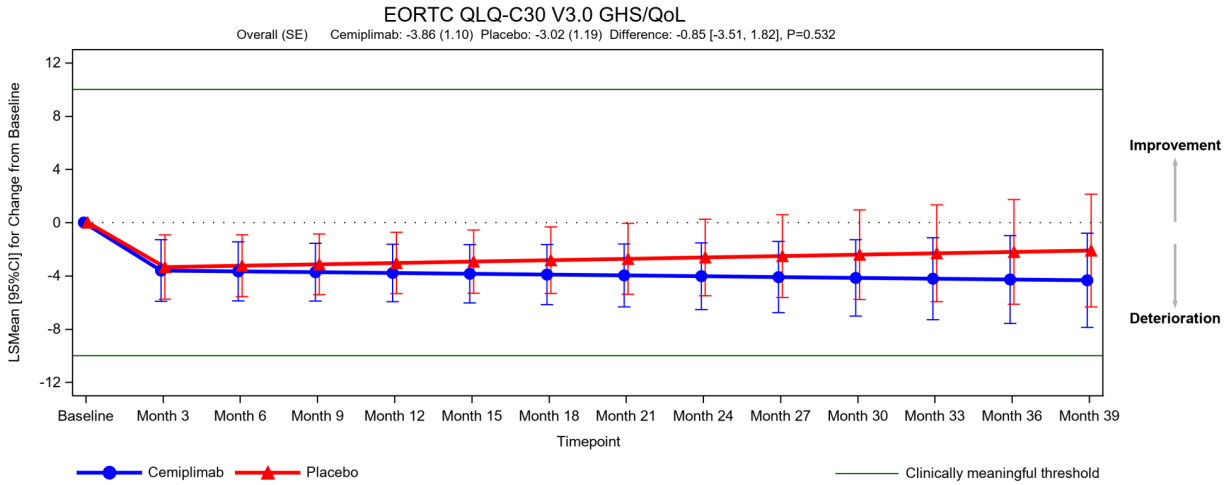


Number of patients

Cemiplimab	151	136	127
Placebo	153	123	110

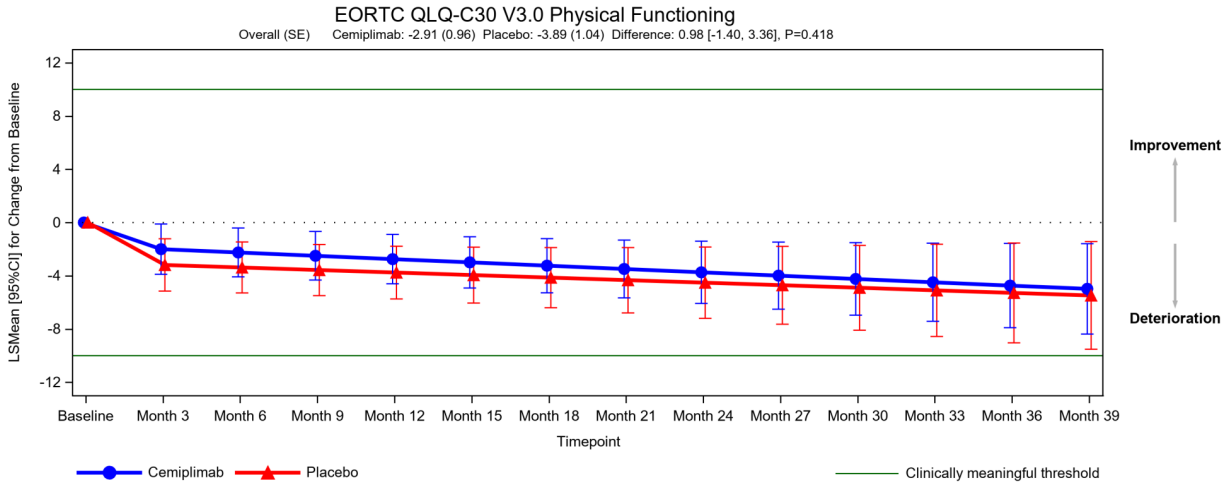
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure A3.1.1: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 GHS/QoL
FAS (N=415)



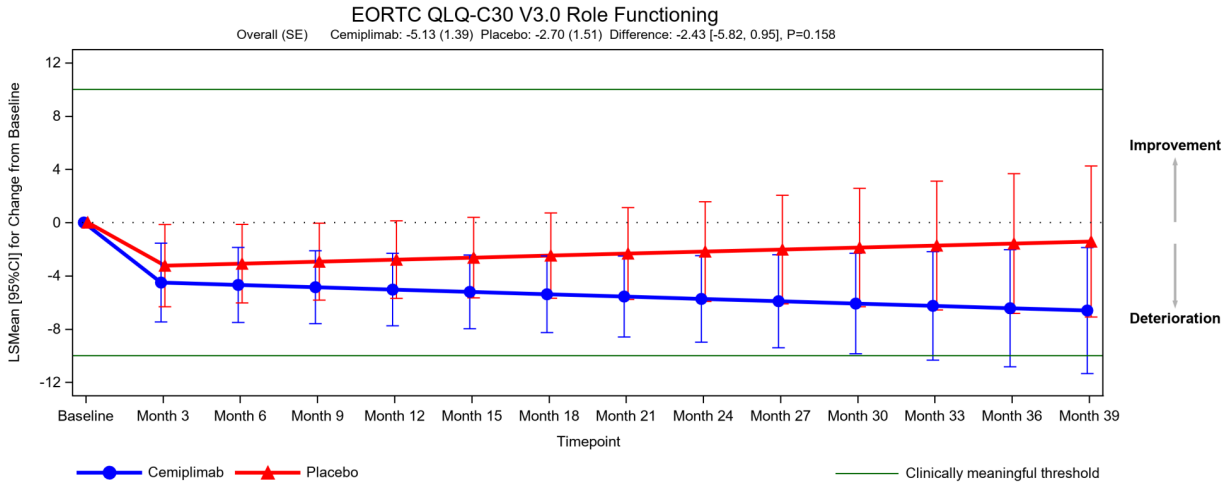
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.2: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Physical Functioning scale
FAS (N=415)



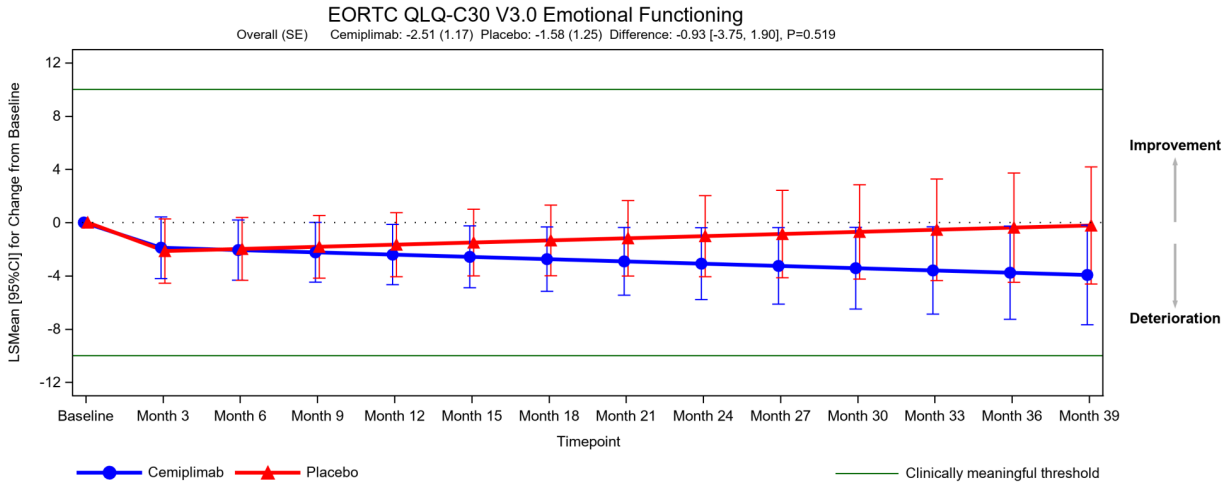
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.3: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Role Functioning scale
FAS (N=415)



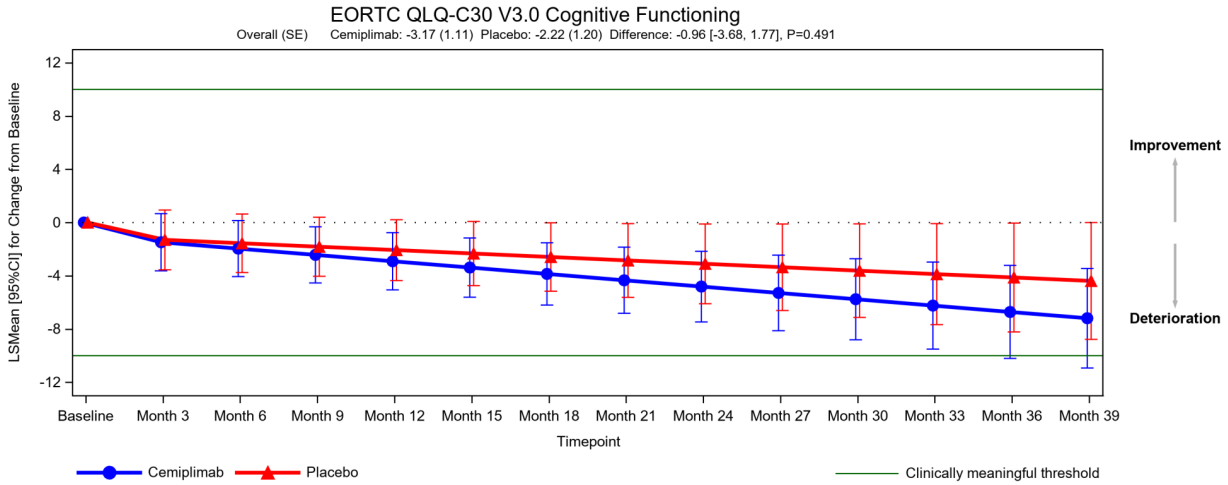
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.4: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Emotional Functioning scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.5: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Cognitive Functioning scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
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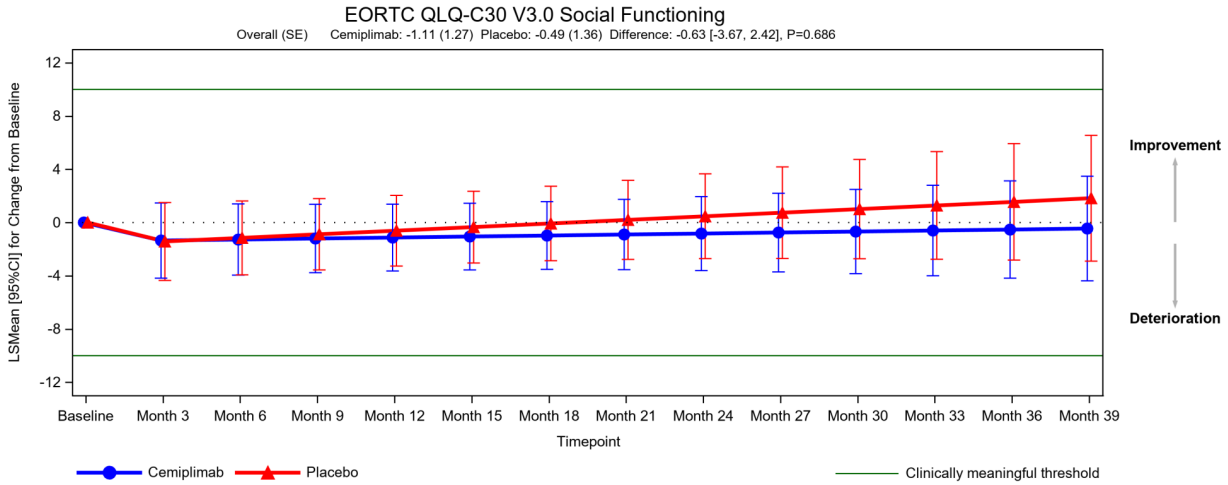
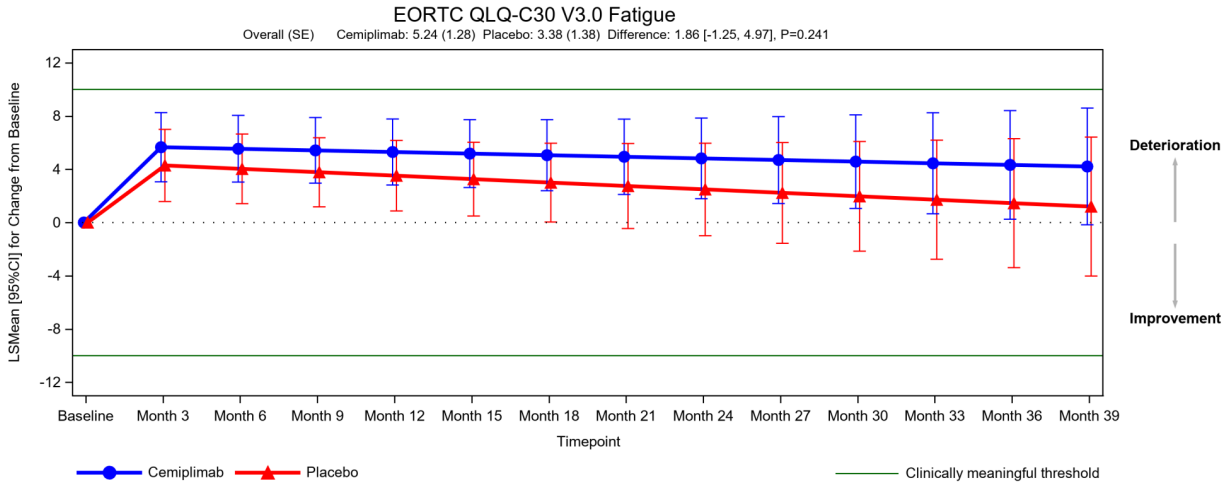
Figure A3.1.6: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Social Functioning scale
FAS (N=415)



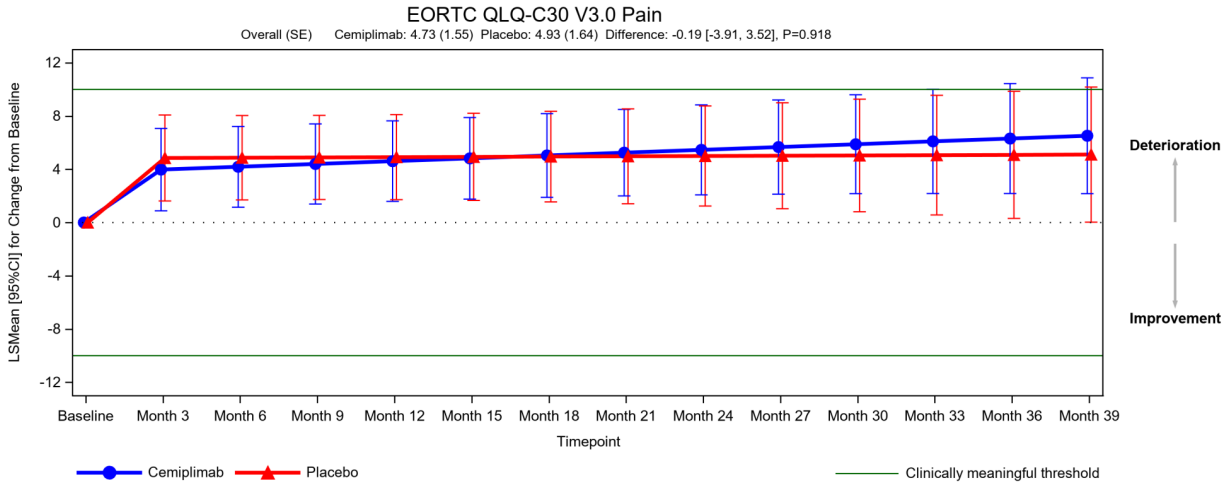
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.7: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Fatigue scale
FAS (N=415)



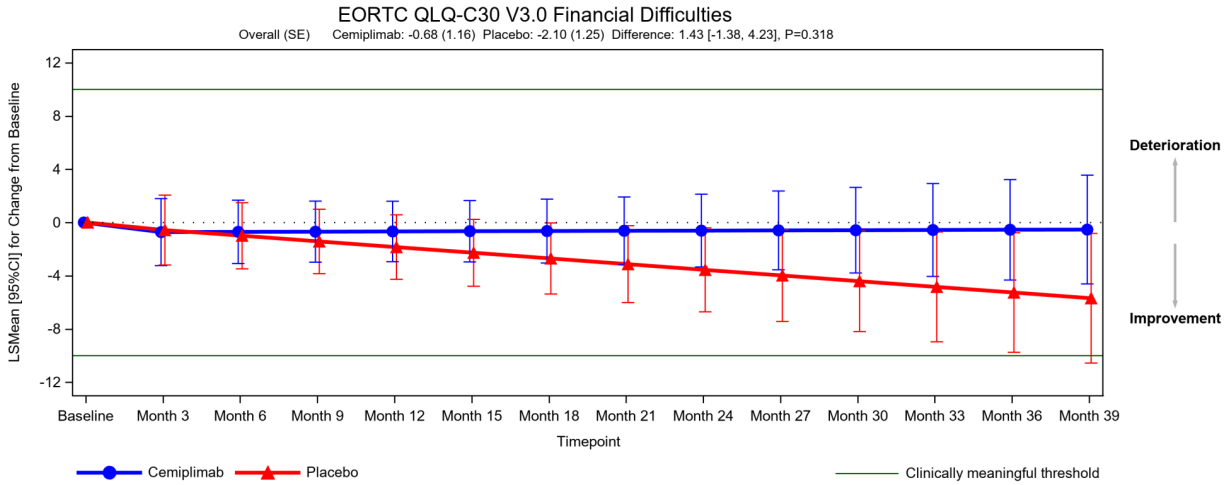
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.8: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Pain scale
FAS (N=415)



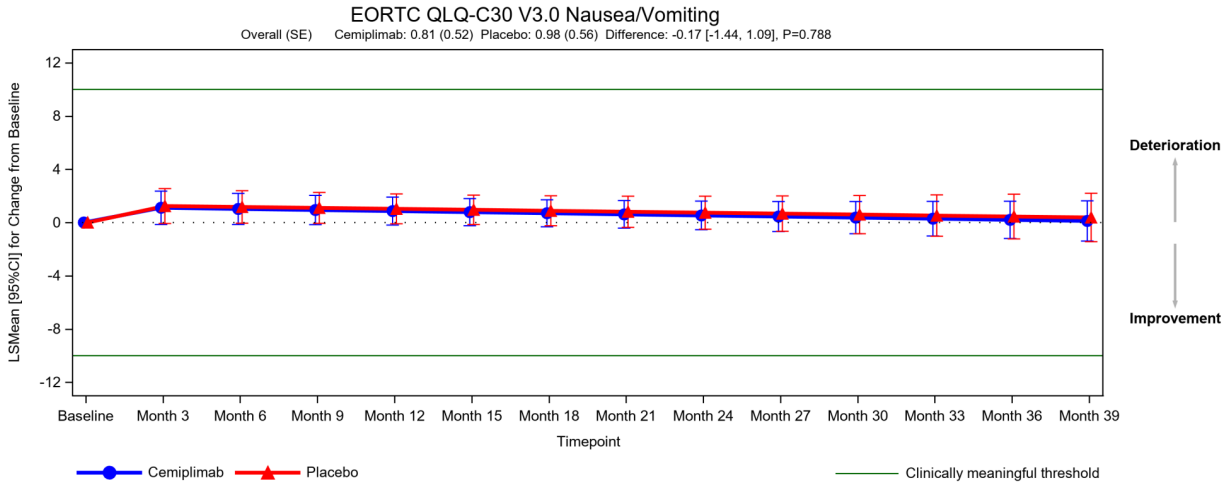
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.9: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Financial Difficulties scale
FAS (N=415)



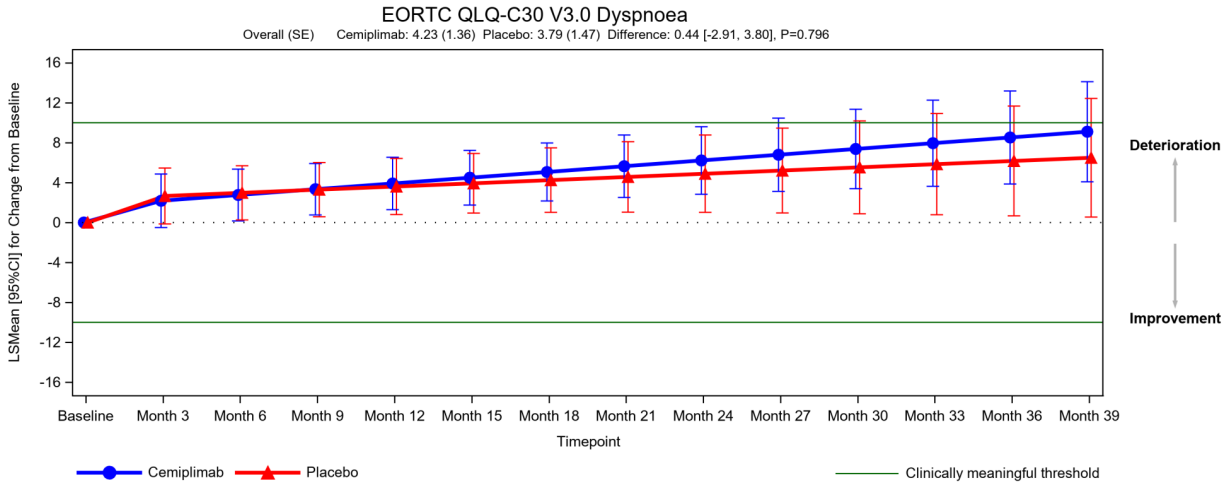
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.10: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Nausea/Vomiting scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.11: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Dyspnoea scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
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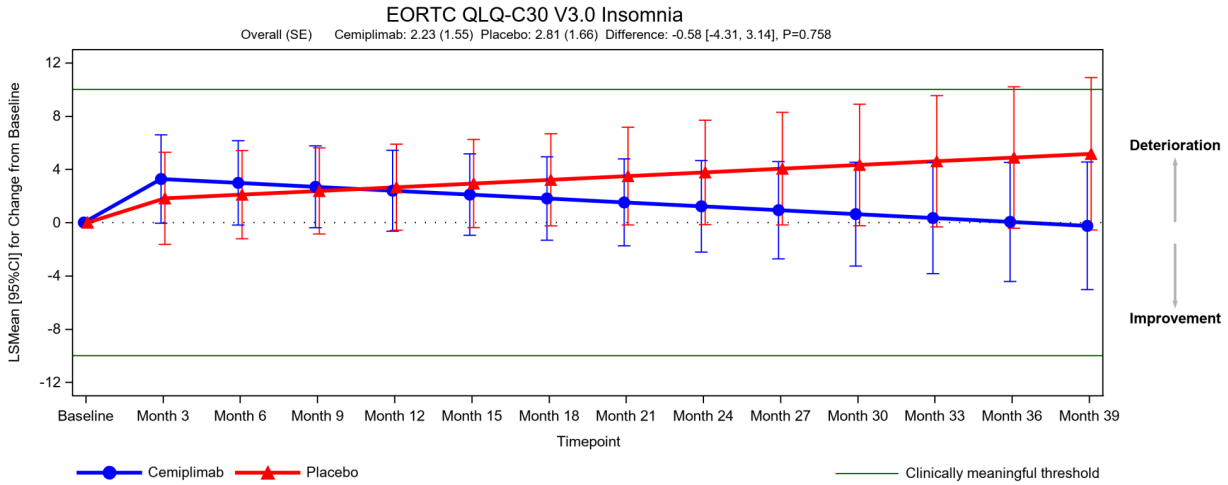
Figure A3.1.12: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Insomnia scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
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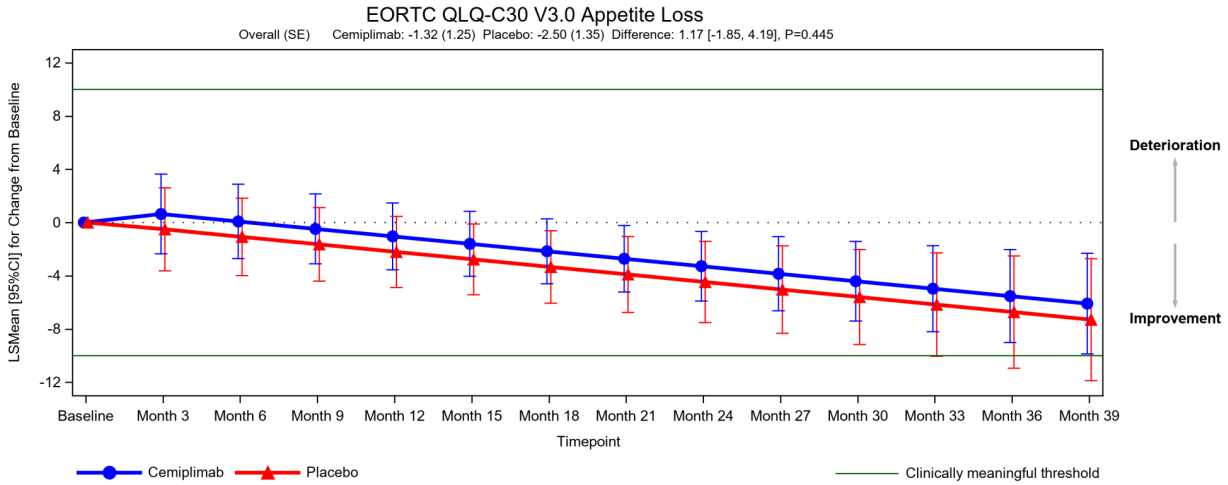
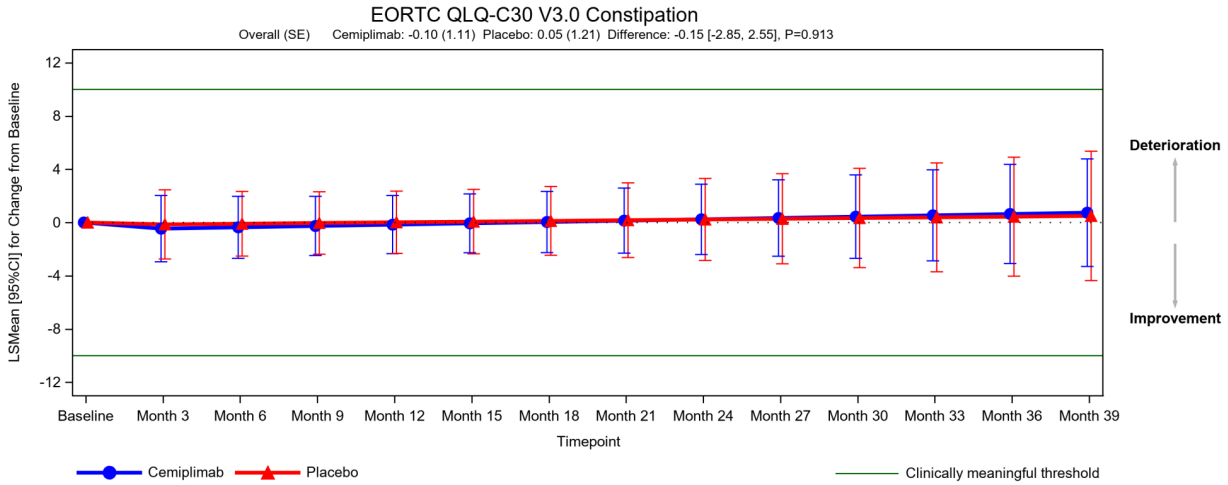
Figure A3.1.13: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Appetite Loss scale
FAS (N=415)



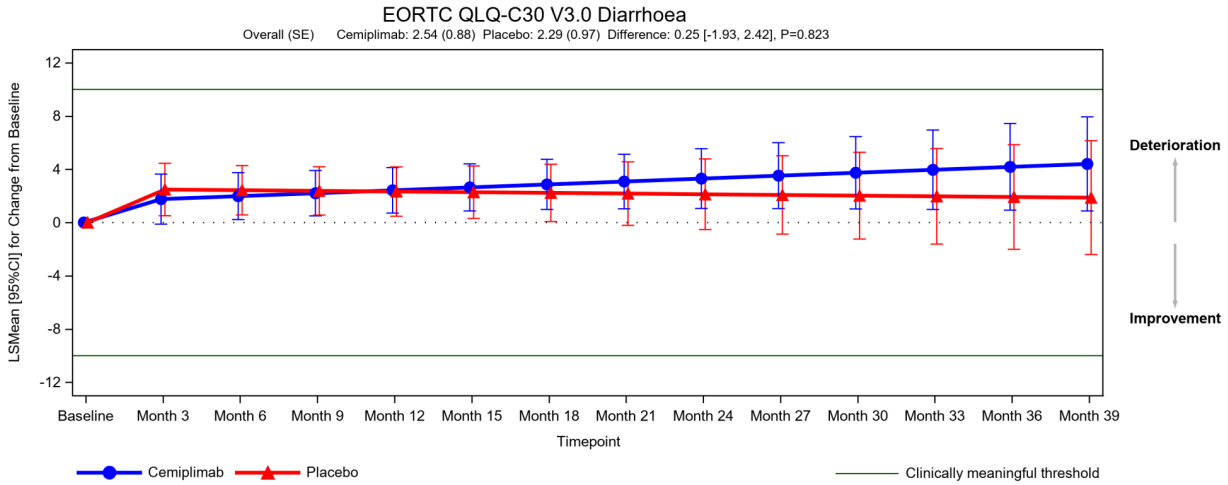
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure A3.1.14: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Constipation scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

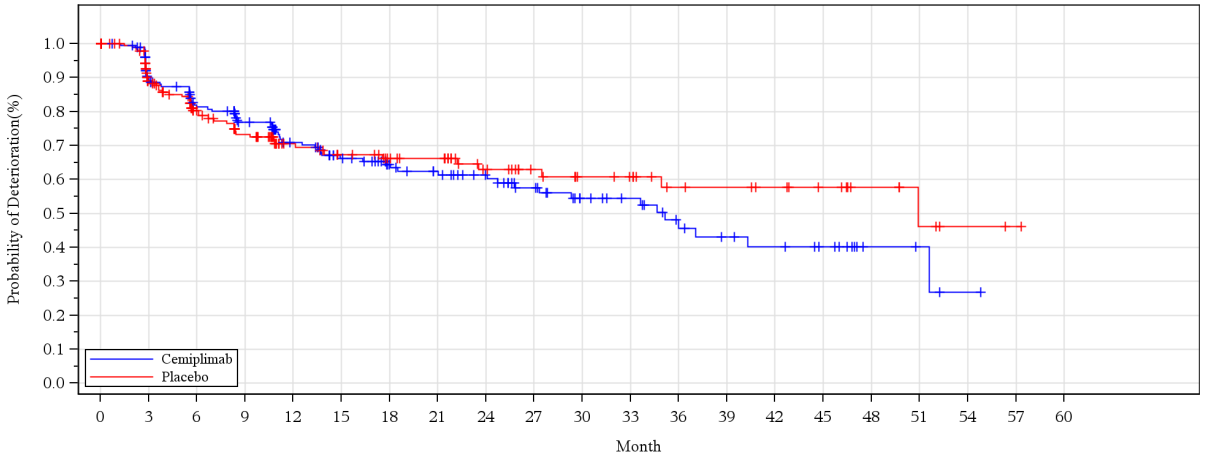
Figure A3.1.15: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Diarrhoea scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

1.1.1.1 Figures KM EORTC

Figure 14.2.11.1 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale
(Full Analysis Set)



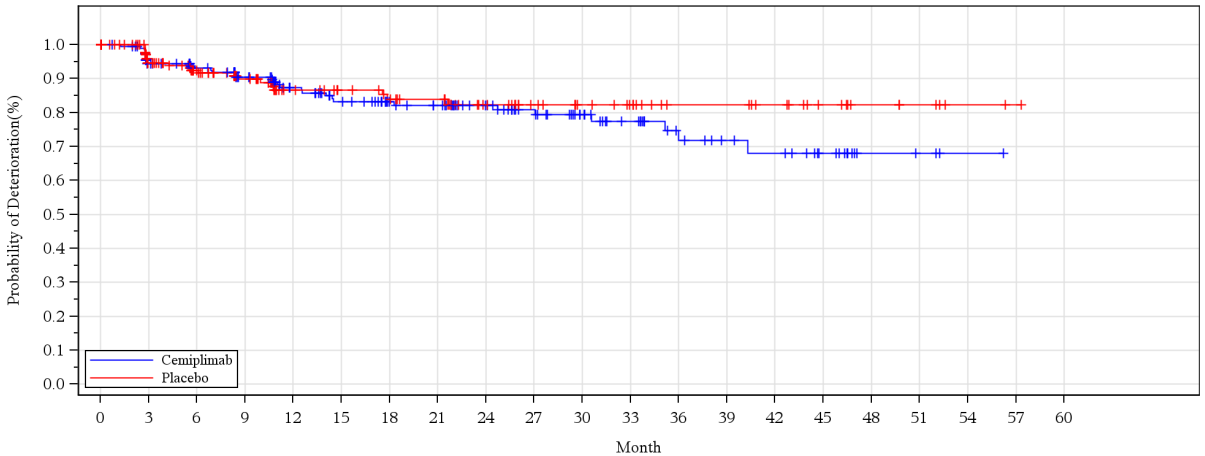
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	154 (37)	131 (46)	114 (56)	92 (70)	79 (77)	65 (89)	59 (93)	51 (100)	41 (107)	31 (115)	27 (119)	19 (123)	16 (125)	14 (126)	11 (129)	4 (136)	3 (137)	1 (138)	0 (139)	0 (139)
Placebo	206 (0)	142 (45)	108 (66)	89 (76)	67 (95)	59 (100)	52 (106)	49 (109)	37 (119)	30 (126)	25 (130)	23 (132)	17 (137)	16 (138)	14 (140)	11 (143)	7 (147)	4 (149)	2 (151)	1 (152)	0 (153)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km2.sas' (wenju.shi 10DEC2025 11:36 SAS Linux 9.4)

Figure 14.2.11.10 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	160 (39)	145 (52)	129 (64)	108 (81)	96 (88)	83 (101)	78 (105)	66 (117)	55 (127)	44 (137)	35 (145)	24 (154)	20 (158)	18 (159)	12 (165)	4 (173)	3 (174)	1 (176)	0 (177)	0 (177)
Placebo	206 (0)	146 (51)	118 (76)	95 (96)	70 (118)	64 (124)	59 (127)	55 (131)	43 (142)	35 (150)	30 (155)	26 (159)	19 (166)	19 (166)	16 (169)	11 (174)	7 (178)	5 (180)	2 (183)	1 (184)	0 (185)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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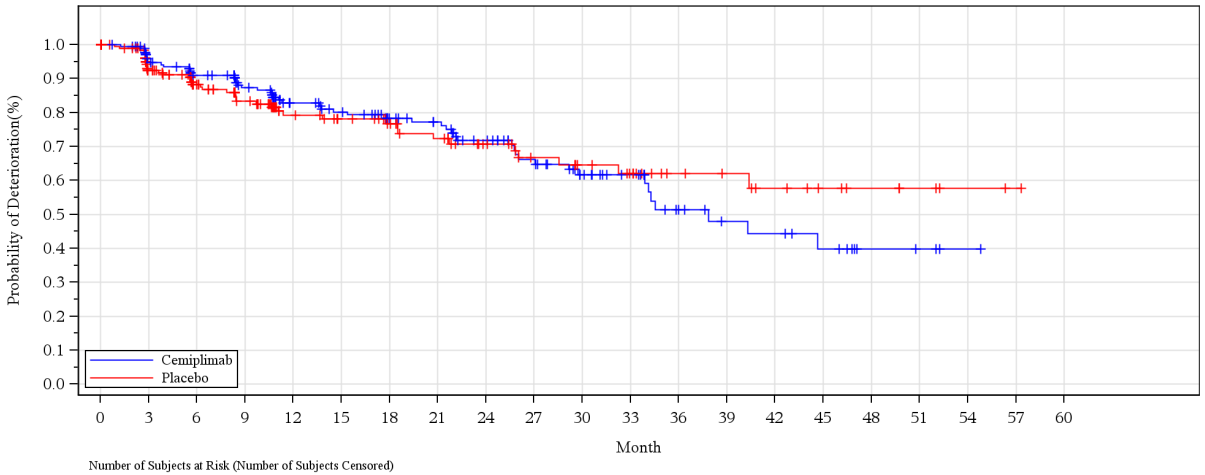
Figure 14.2.11.11 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	156 (44)	139 (55)	121 (68)	98 (85)	90 (90)	77 (101)	71 (106)	59 (113)	48 (120)	36 (129)	29 (136)	17 (144)	13 (147)	12 (147)	9 (149)	4 (154)	3 (155)	1 (157)	0 (158)	0 (158)
Placebo	206 (0)	147 (46)	118 (69)	96 (85)	69 (108)	62 (114)	55 (120)	48 (124)	39 (132)	31 (138)	27 (141)	23 (144)	16 (151)	14 (153)	11 (155)	8 (158)	6 (160)	4 (162)	2 (164)	1 (165)	0 (166)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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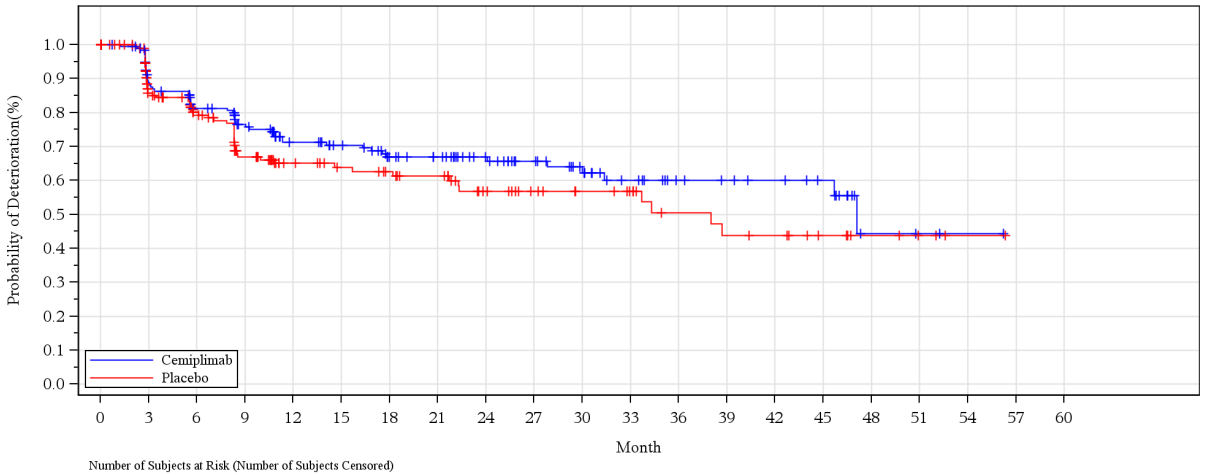
Figure 14.2.11.12 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	145 (45)	125 (53)	108 (63)	89 (75)	82 (81)	69 (90)	64 (95)	53 (106)	44 (114)	35 (121)	27 (128)	20 (135)	18 (137)	16 (139)	13 (142)	3 (150)	2 (151)	1 (152)	0 (153)	0 (153)
Placebo	206 (0)	129 (54)	104 (71)	77 (82)	59 (98)	53 (103)	49 (106)	45 (109)	34 (117)	28 (123)	24 (127)	21 (130)	15 (134)	13 (134)	12 (135)	8 (139)	5 (142)	3 (144)	1 (146)	0 (147)	0 (147)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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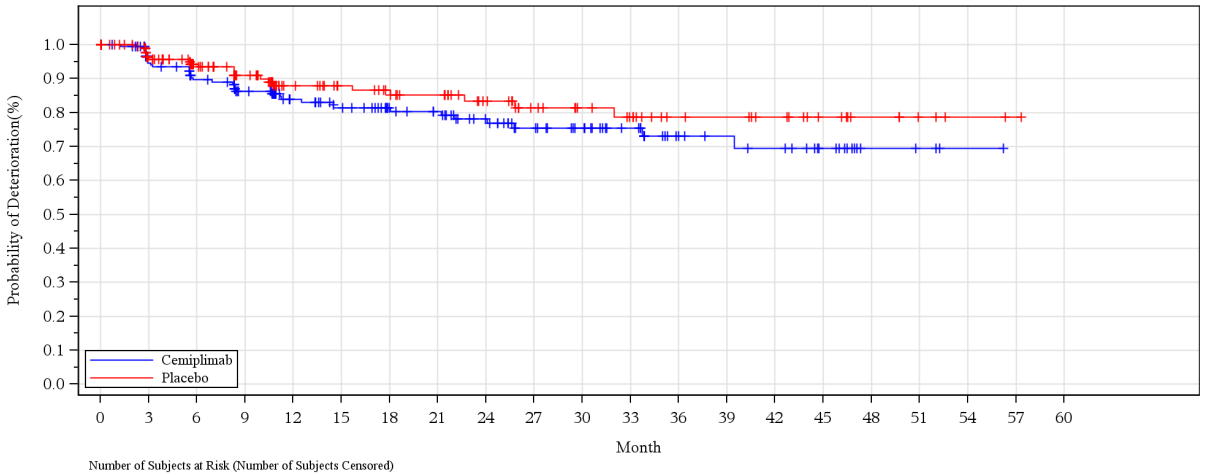
Figure 14.2.11.13 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	154 (46)	138 (54)	121 (66)	101 (83)	92 (89)	79 (102)	74 (106)	62 (116)	51 (125)	44 (132)	35 (141)	22 (153)	20 (155)	18 (156)	12 (162)	4 (170)	3 (171)	1 (173)	0 (174)	0 (174)
Placebo	206 (0)	148 (52)	119 (78)	98 (95)	73 (117)	65 (125)	60 (129)	55 (133)	45 (142)	36 (150)	31 (155)	27 (158)	20 (165)	19 (166)	16 (169)	11 (174)	7 (178)	4 (181)	2 (183)	1 (184)	0 (185)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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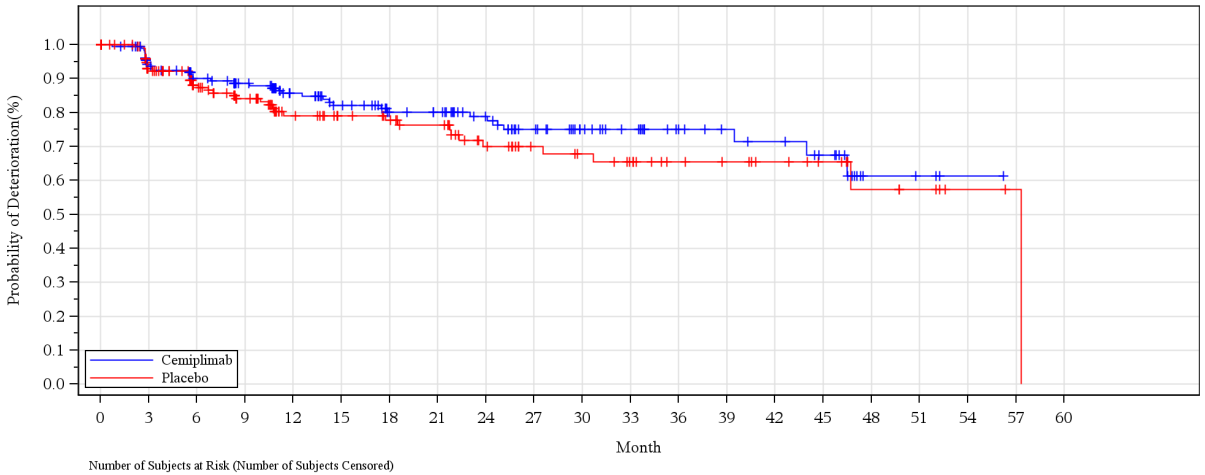
Figure 14.2.11.14 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	157 (41)	140 (52)	126 (64)	103 (83)	91 (91)	77 (103)	74 (106)	62 (117)	50 (126)	40 (136)	34 (142)	24 (152)	21 (155)	19 (156)	15 (159)	4 (169)	3 (170)	1 (172)	0 (173)	0 (173)
Placebo	206 (0)	147 (47)	117 (70)	95 (87)	71 (106)	63 (114)	59 (117)	54 (121)	40 (131)	32 (139)	29 (141)	25 (144)	19 (150)	17 (152)	14 (155)	11 (158)	7 (161)	5 (163)	2 (166)	1 (167)	0 (167)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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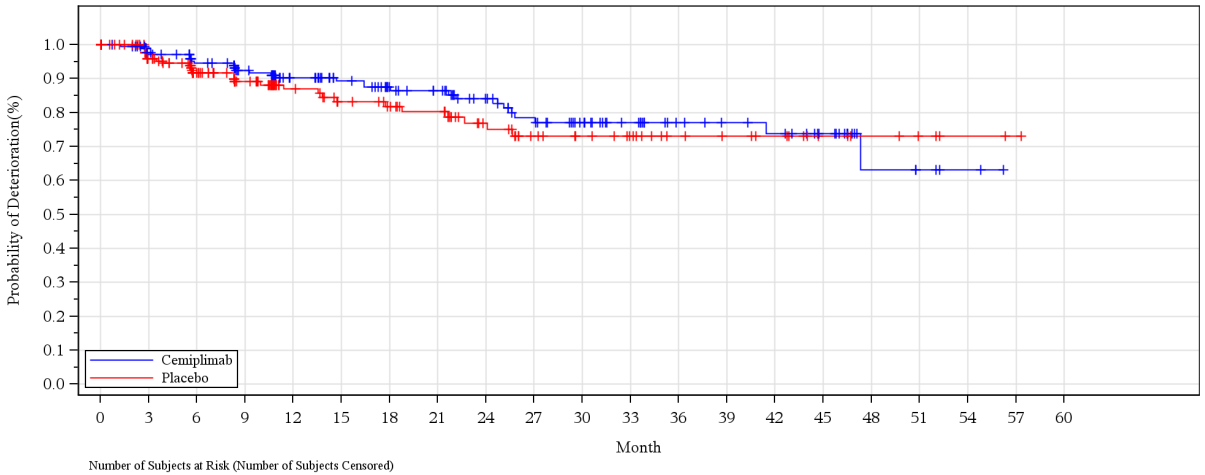
Figure 14.2.11.15 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	162 (43)	145 (55)	129 (68)	108 (86)	97 (96)	84 (107)	78 (112)	65 (123)	55 (129)	45 (138)	36 (147)	27 (156)	24 (159)	22 (160)	16 (166)	6 (175)	4 (177)	2 (179)	0 (181)	0 (181)
Placebo	206 (0)	150 (49)	120 (73)	97 (93)	73 (115)	63 (122)	58 (126)	53 (130)	40 (141)	31 (148)	27 (152)	23 (156)	17 (162)	15 (164)	13 (166)	8 (171)	6 (173)	4 (175)	2 (177)	1 (178)	0 (179)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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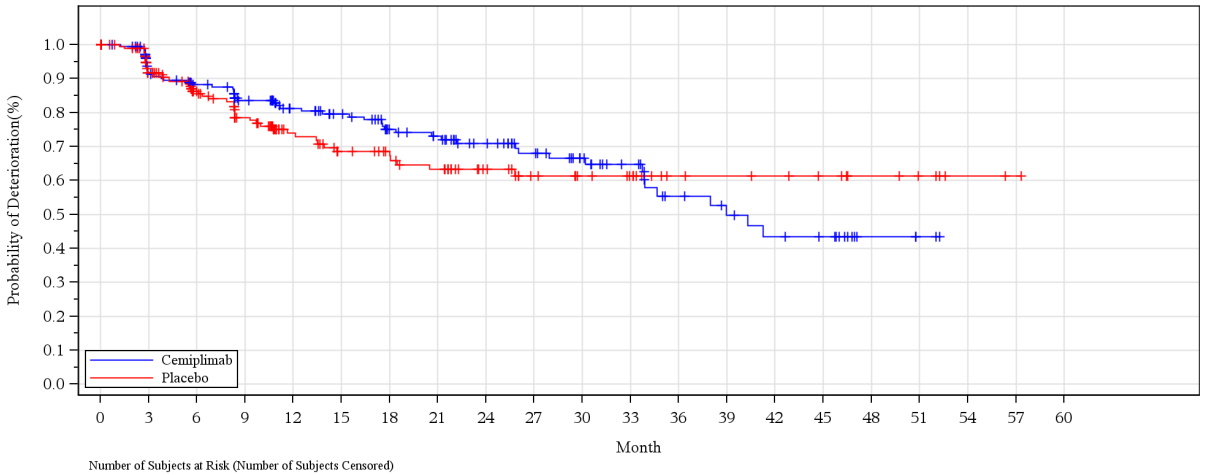
Figure 14.2.11.2 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	154 (41)	137 (52)	119 (63)	101 (78)	92 (85)	76 (96)	70 (100)	58 (110)	48 (118)	39 (126)	31 (133)	21 (139)	17 (141)	14 (142)	12 (144)	4 (152)	2 (154)	0 (156)	0 (156)	0 (156)
Placebo	206 (0)	146 (46)	116 (68)	94 (80)	69 (100)	58 (106)	53 (111)	47 (113)	36 (124)	28 (131)	24 (135)	21 (138)	14 (145)	13 (146)	12 (147)	10 (149)	7 (152)	5 (154)	2 (157)	1 (158)	0 (159)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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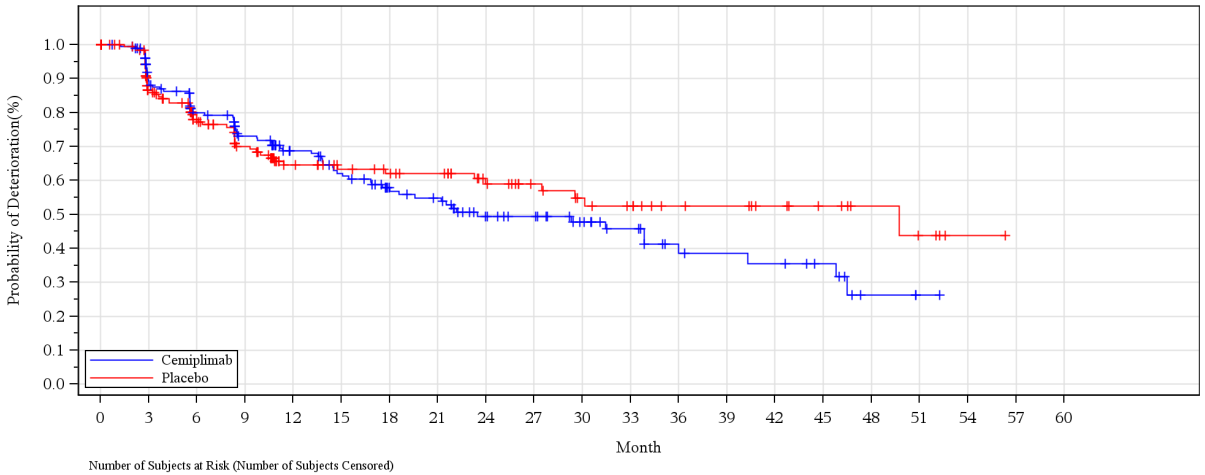
Figure 14.2.11.3 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	147 (44)	122 (54)	103 (63)	85 (75)	74 (78)	59 (88)	54 (90)	40 (99)	36 (103)	28 (110)	22 (115)	14 (120)	13 (121)	12 (121)	9 (124)	3 (128)	1 (130)	0 (131)	0 (131)	0 (131)
Placebo	206 (0)	139 (44)	106 (64)	83 (77)	60 (94)	53 (100)	49 (103)	46 (106)	36 (114)	29 (121)	24 (124)	21 (126)	16 (131)	15 (132)	12 (135)	9 (138)	6 (141)	4 (142)	1 (145)	0 (146)	0 (146)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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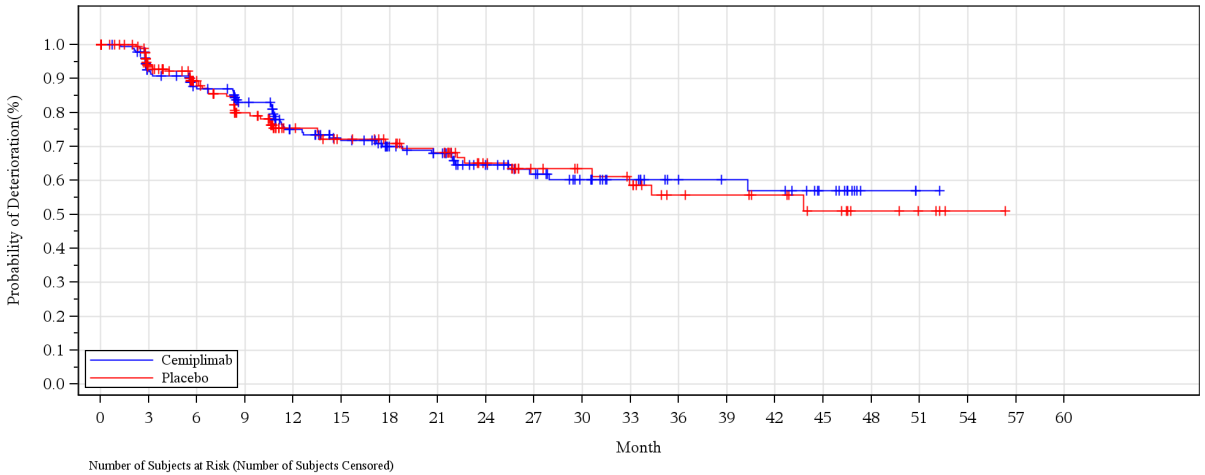
Figure 14.2.11.4 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	155 (41)	136 (51)	119 (62)	96 (74)	85 (81)	72 (92)	66 (96)	51 (108)	43 (114)	34 (122)	27 (129)	20 (136)	19 (137)	18 (137)	12 (143)	3 (152)	1 (154)	0 (155)	0 (155)	0 (155)
Placebo	206 (0)	147 (48)	117 (72)	93 (84)	70 (102)	62 (107)	57 (111)	52 (114)	39 (125)	30 (133)	27 (136)	24 (137)	17 (143)	16 (144)	14 (146)	10 (149)	6 (153)	4 (155)	1 (158)	0 (159)	0 (159)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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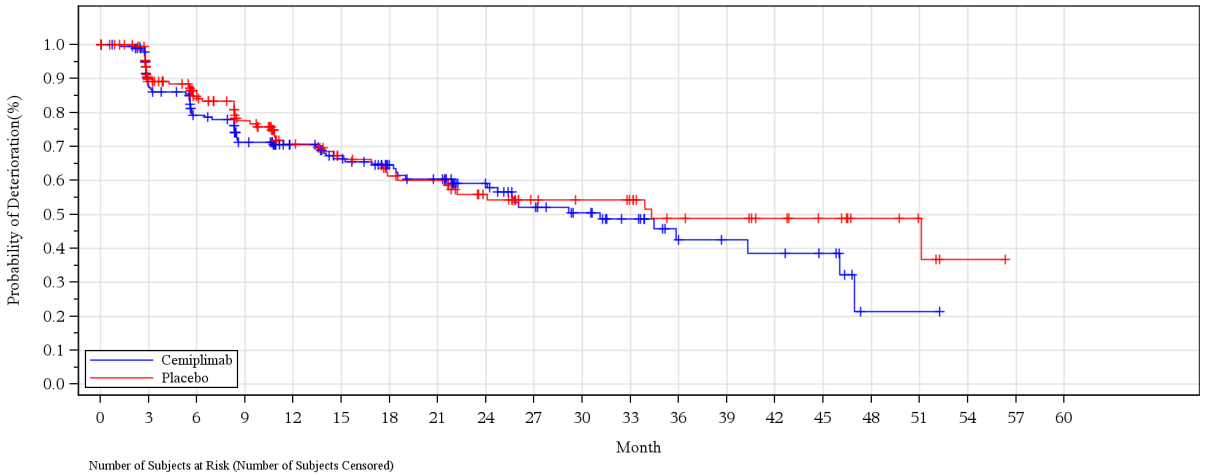
Figure 14.2.11.5 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	148 (40)	124 (50)	102 (60)	87 (74)	76 (80)	62 (92)	56 (94)	45 (104)	35 (109)	29 (114)	22 (120)	12 (128)	11 (129)	10 (129)	8 (131)	1 (136)	1 (136)	0 (137)	0 (137)	0 (137)
Placebo	206 (0)	138 (50)	111 (71)	89 (84)	66 (100)	57 (106)	49 (109)	47 (110)	36 (118)	27 (126)	25 (128)	23 (130)	17 (134)	16 (135)	13 (138)	10 (141)	6 (145)	4 (147)	1 (149)	0 (150)	0 (150)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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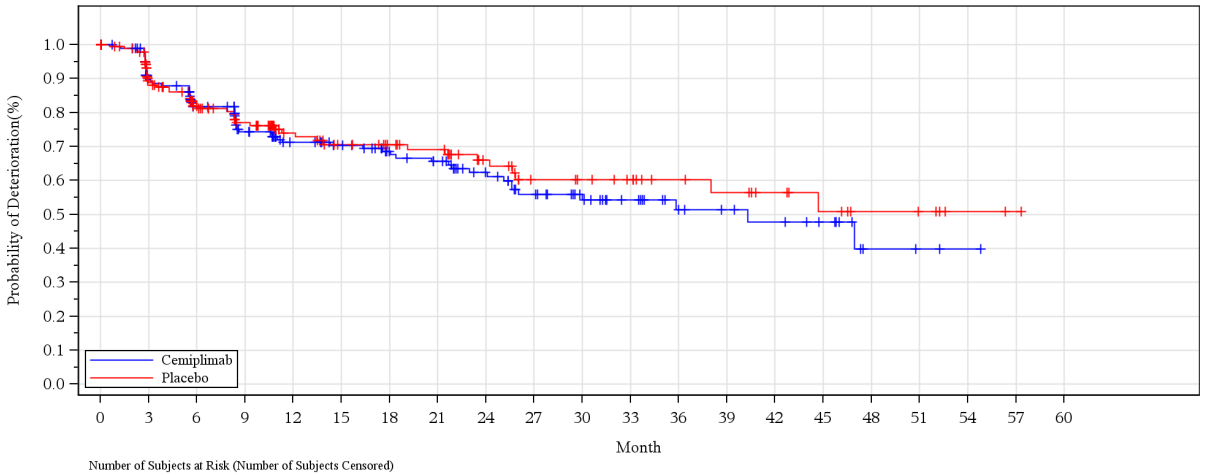
Figure 14.2.11.6 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	150 (41)	127 (51)	106 (61)	88 (75)	82 (80)	70 (90)	64 (93)	51 (103)	41 (108)	32 (116)	25 (123)	17 (130)	15 (132)	13 (133)	10 (136)	3 (142)	2 (143)	1 (144)	0 (145)	0 (145)
Placebo	206 (0)	140 (47)	108 (69)	89 (82)	66 (102)	57 (108)	52 (113)	48 (116)	36 (126)	27 (132)	25 (134)	22 (137)	17 (142)	15 (143)	12 (146)	9 (148)	6 (151)	5 (152)	2 (155)	1 (156)	0 (157)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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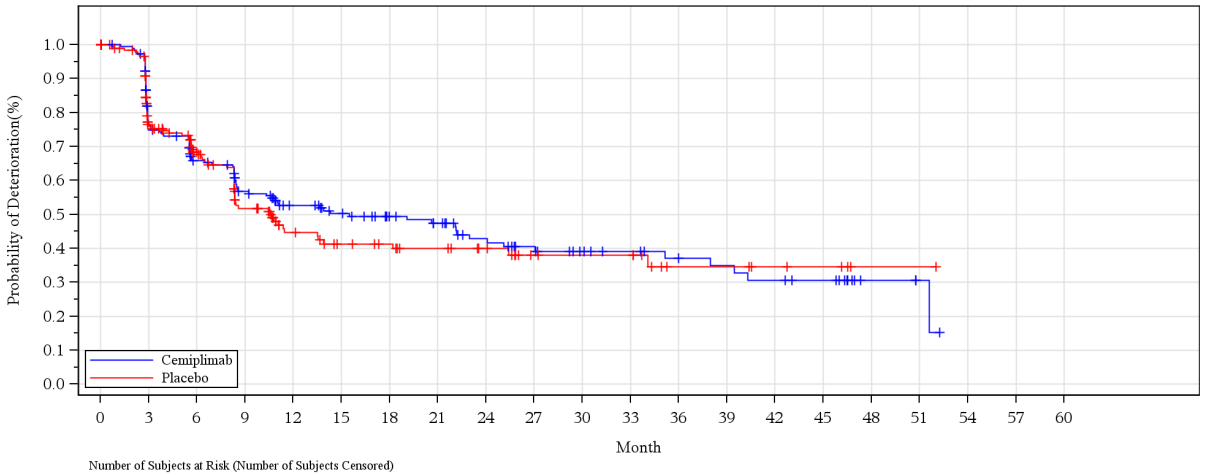
Figure 14.2.11.7 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	131 (37)	105 (45)	85 (51)	69 (61)	61 (66)	51 (75)	46 (78)	36 (84)	30 (88)	24 (93)	21 (96)	17 (99)	16 (99)	14 (99)	12 (101)	4 (109)	2 (111)	0 (112)	0 (112)	0 (112)
Placebo	206 (0)	122 (44)	92 (62)	61 (72)	41 (85)	33 (90)	30 (93)	26 (96)	22 (100)	15 (106)	14 (107)	14 (107)	7 (113)	7 (113)	5 (115)	4 (116)	1 (119)	1 (119)	0 (120)	0 (120)	0 (120)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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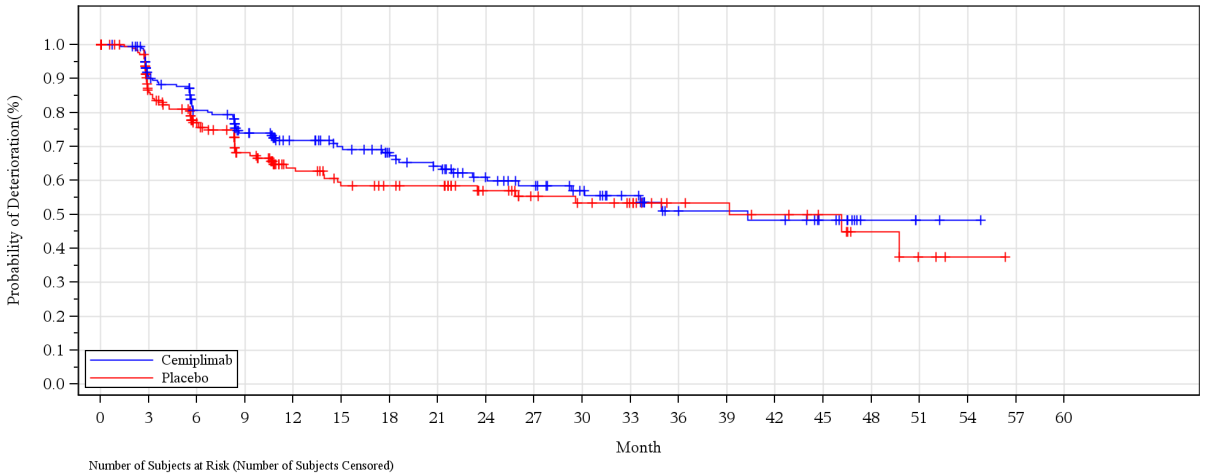
Figure 14.2.11.8 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	150 (43)	124 (53)	104 (63)	88 (76)	80 (82)	70 (90)	63 (93)	51 (102)	45 (106)	37 (113)	30 (119)	18 (129)	18 (129)	17 (129)	12 (134)	4 (142)	2 (144)	1 (145)	0 (146)	0 (146)
Placebo	206 (0)	142 (41)	110 (58)	85 (71)	63 (88)	54 (92)	50 (96)	48 (98)	37 (108)	30 (114)	27 (116)	23 (120)	16 (127)	15 (128)	13 (129)	10 (132)	6 (135)	3 (137)	1 (139)	0 (140)	0 (140)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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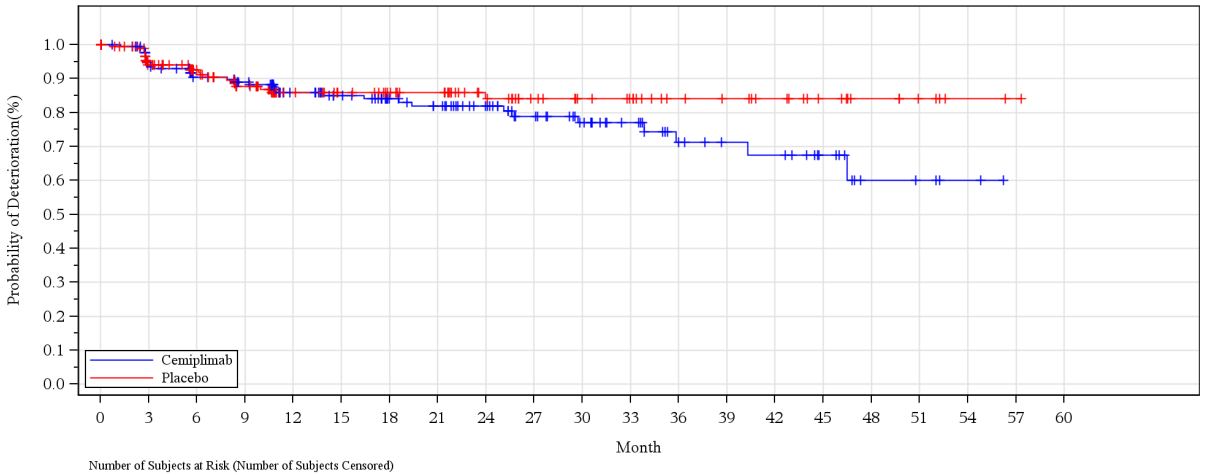
Figure 14.2.11.9 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	154 (44)	138 (55)	125 (66)	101 (86)	92 (94)	78 (107)	72 (111)	61 (122)	49 (132)	40 (140)	32 (148)	22 (156)	19 (159)	18 (159)	12 (165)	5 (171)	4 (172)	2 (174)	0 (176)	0 (176)
Placebo	206 (0)	147 (49)	120 (74)	99 (89)	75 (111)	68 (118)	62 (124)	58 (128)	45 (140)	37 (148)	32 (153)	29 (156)	22 (163)	20 (165)	17 (168)	12 (173)	8 (177)	5 (180)	2 (183)	1 (184)	0 (185)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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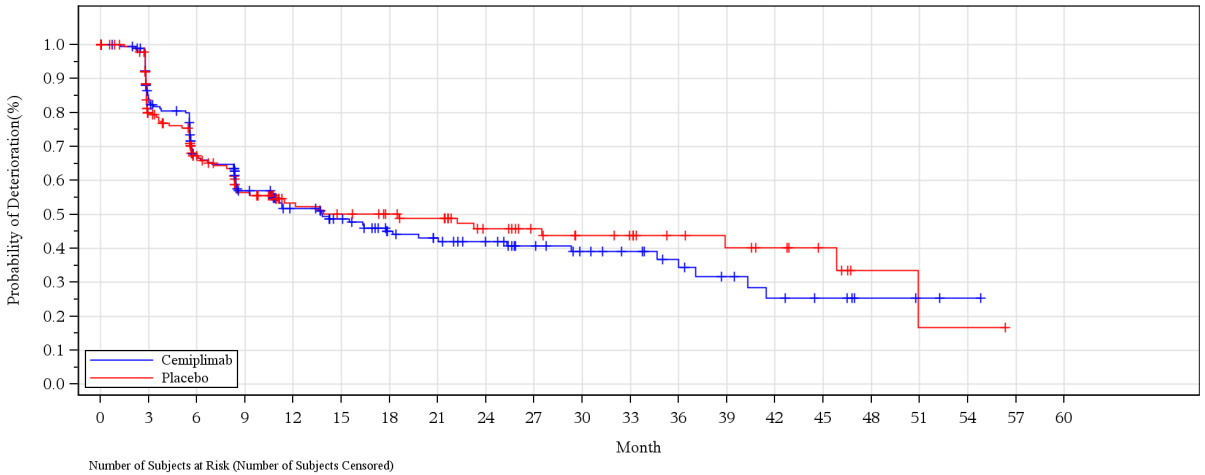
Figure 14.2.8.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	144 (37)	107 (45)	84 (53)	67 (63)	58 (68)	45 (77)	40 (80)	34 (85)	27 (91)	22 (95)	19 (98)	14 (101)	11 (103)	8 (104)	6 (106)	3 (109)	2 (110)	1 (111)	0 (112)	0 (112)
Placebo	206 (0)	127 (45)	91 (62)	68 (71)	49 (87)	44 (89)	40 (93)	37 (95)	28 (102)	23 (107)	19 (110)	17 (112)	13 (116)	11 (117)	9 (119)	6 (122)	2 (125)	1 (125)	1 (125)	0 (126)	0 (126)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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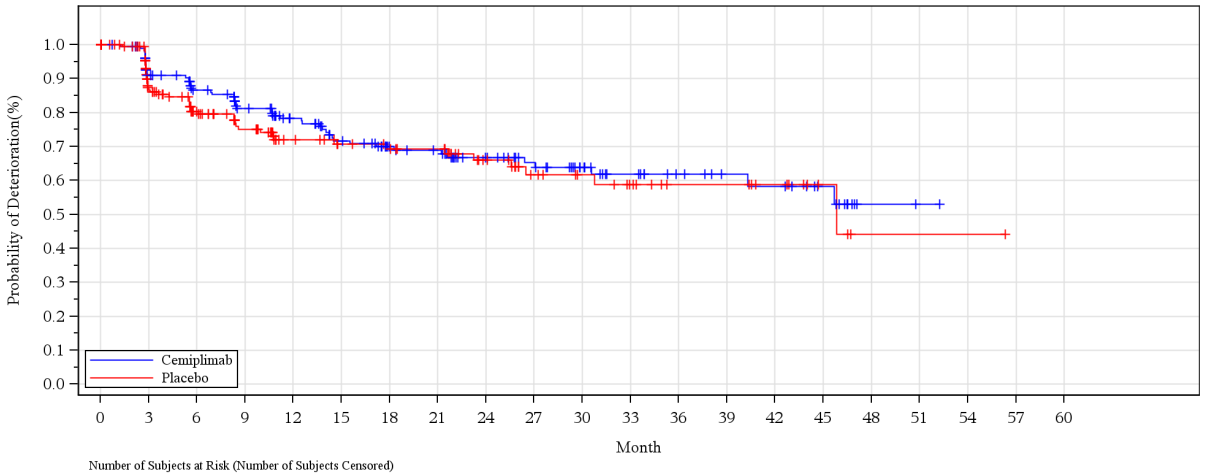
Figure 14.2.8.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	154 (39)	135 (51)	116 (62)	99 (75)	84 (82)	70 (94)	66 (97)	53 (108)	45 (115)	35 (124)	27 (131)	21 (137)	17 (141)	16 (141)	11 (146)	2 (154)	1 (155)	0 (156)	0 (156)	0 (156)
Placebo	206 (0)	134 (51)	103 (72)	82 (87)	61 (105)	54 (111)	51 (113)	48 (116)	35 (127)	25 (135)	21 (139)	17 (142)	12 (147)	12 (147)	9 (150)	4 (155)	1 (157)	1 (157)	1 (157)	0 (158)	0 (158)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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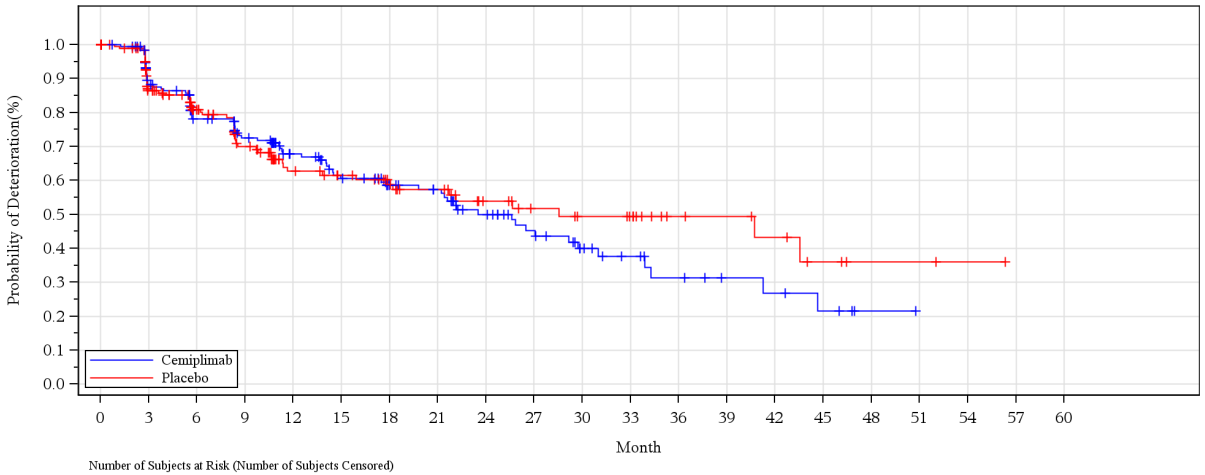
Figure 14.2.8.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	145 (44)	118 (55)	101 (64)	79 (80)	66 (85)	54 (95)	49 (99)	37 (105)	28 (111)	19 (117)	14 (121)	10 (123)	7 (126)	6 (126)	4 (127)	1 (130)	0 (131)	0 (131)	0 (131)	0 (131)
Placebo	206 (0)	137 (46)	106 (69)	78 (84)	55 (100)	49 (105)	41 (111)	36 (115)	27 (122)	22 (126)	19 (128)	17 (130)	10 (137)	9 (138)	7 (139)	4 (141)	2 (143)	2 (143)	1 (144)	0 (145)	0 (145)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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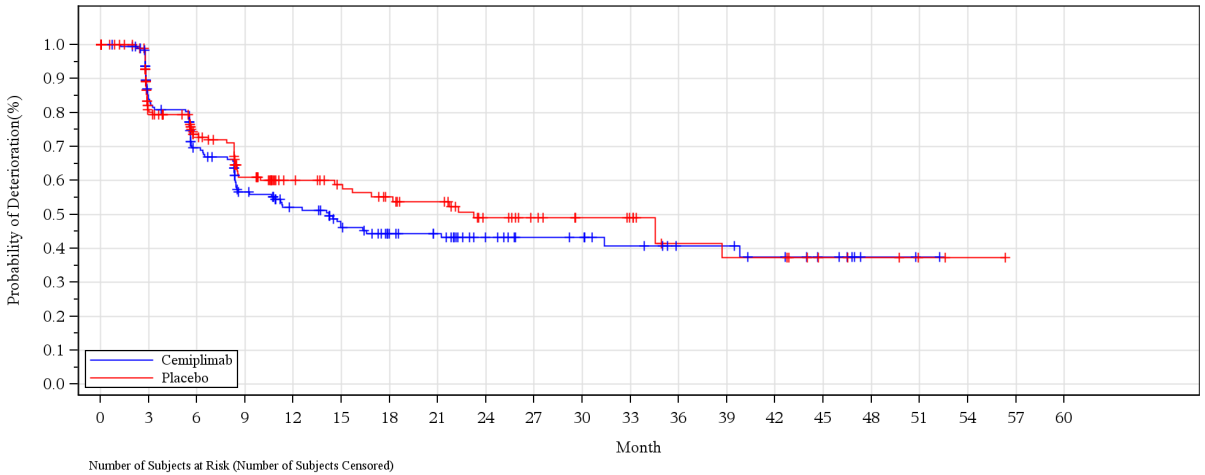
Figure 14.2.8.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	137 (45)	106 (53)	79 (61)	65 (69)	53 (74)	42 (83)	38 (87)	27 (97)	22 (102)	21 (103)	17 (106)	13 (110)	13 (110)	10 (112)	7 (115)	2 (120)	1 (121)	0 (122)	0 (122)	0 (122)
Placebo	206 (0)	121 (54)	94 (71)	69 (81)	53 (96)	47 (101)	41 (104)	37 (107)	27 (114)	22 (119)	18 (123)	16 (125)	10 (129)	9 (129)	9 (129)	5 (133)	4 (134)	2 (136)	1 (137)	0 (138)	0 (138)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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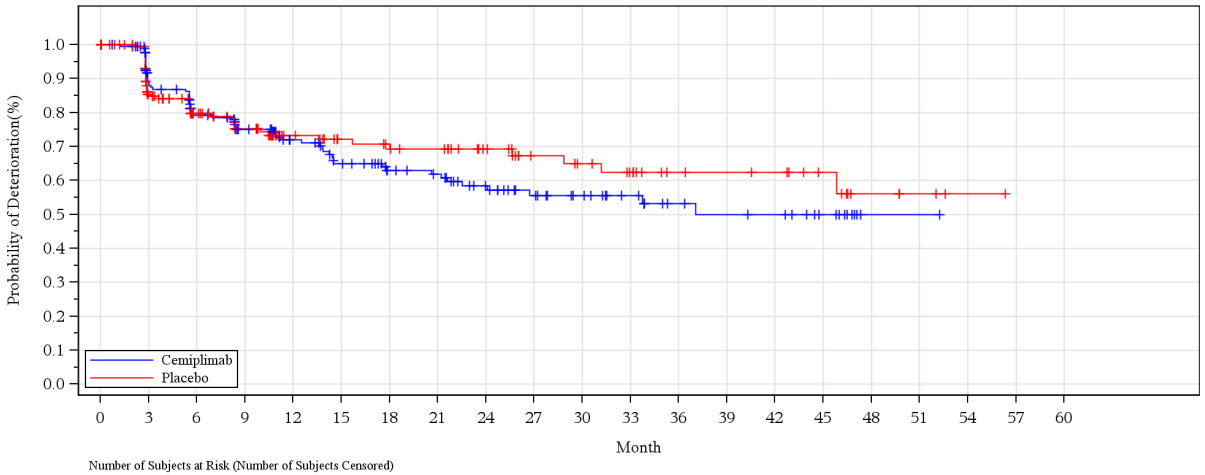
Figure 14.2.8.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	144 (46)	121 (54)	104 (65)	86 (79)	73 (84)	60 (95)	56 (98)	45 (106)	36 (113)	30 (119)	24 (125)	17 (131)	15 (132)	14 (133)	9 (138)	1 (146)	1 (146)	0 (147)	0 (147)	0 (147)
Placebo	206 (0)	130 (52)	98 (76)	80 (89)	60 (107)	52 (114)	49 (116)	46 (118)	38 (126)	29 (134)	26 (136)	22 (139)	16 (145)	15 (146)	14 (147)	10 (151)	5 (155)	3 (157)	1 (159)	0 (160)	0 (160)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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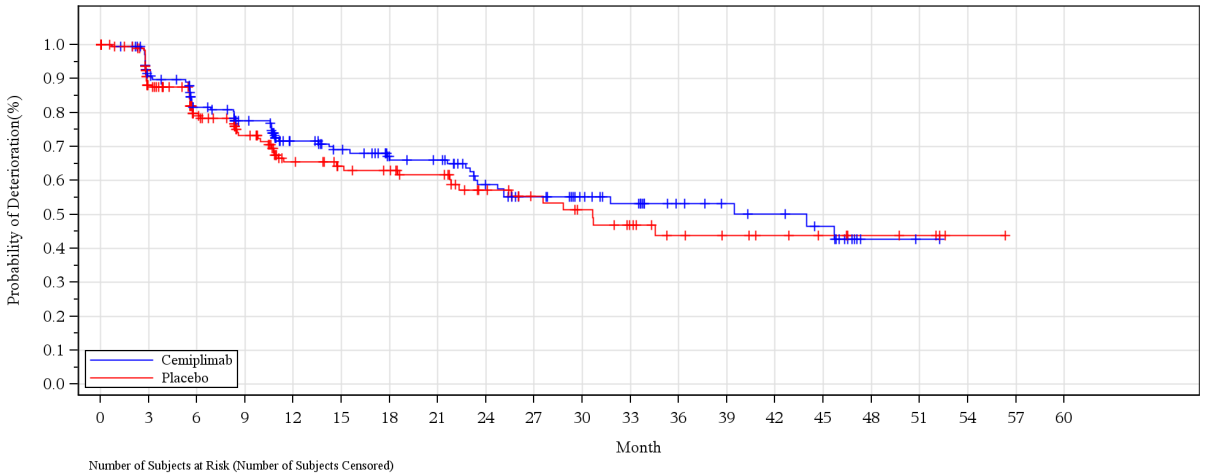
Figure 14.2.8.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	152 (41)	127 (51)	110 (62)	85 (79)	76 (85)	64 (95)	61 (97)	47 (105)	40 (109)	33 (116)	28 (120)	20 (128)	17 (131)	15 (132)	12 (134)	2 (143)	1 (144)	0 (145)	0 (145)	0 (145)
Placebo	206 (0)	139 (47)	106 (68)	83 (83)	60 (98)	53 (104)	50 (106)	45 (110)	34 (118)	27 (124)	23 (126)	18 (129)	13 (133)	11 (135)	9 (137)	7 (139)	5 (141)	4 (142)	1 (145)	0 (146)	0 (146)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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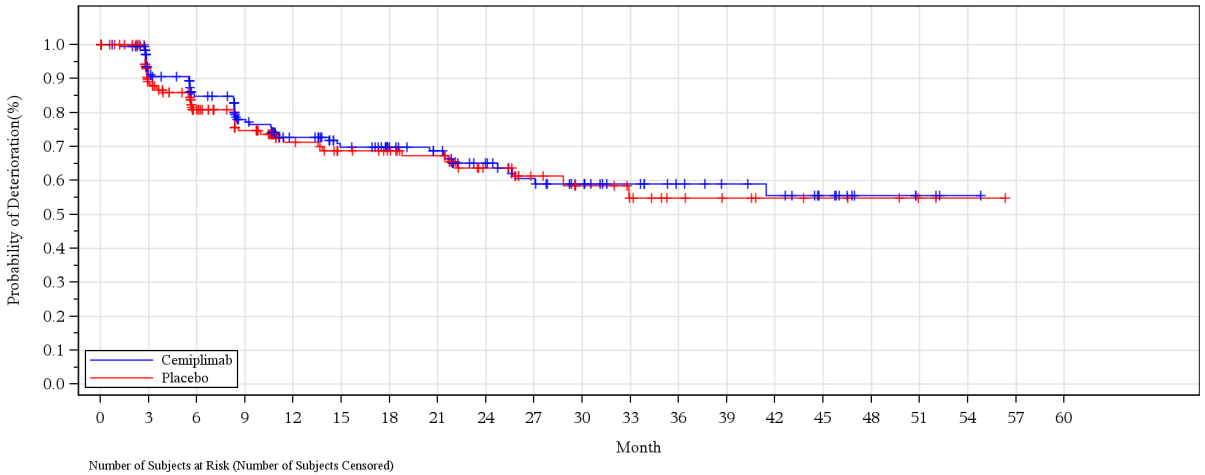
Figure 14.2.8.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	151 (43)	129 (55)	107 (67)	87 (80)	75 (89)	64 (100)	58 (105)	47 (113)	39 (118)	32 (124)	26 (130)	21 (135)	18 (138)	16 (139)	11 (144)	5 (150)	3 (152)	1 (154)	0 (155)	0 (155)
Placebo	206 (0)	139 (49)	104 (72)	79 (90)	59 (107)	51 (113)	47 (117)	42 (121)	30 (131)	22 (138)	18 (141)	14 (144)	10 (148)	8 (150)	6 (152)	5 (153)	4 (154)	2 (156)	1 (157)	0 (158)	0 (158)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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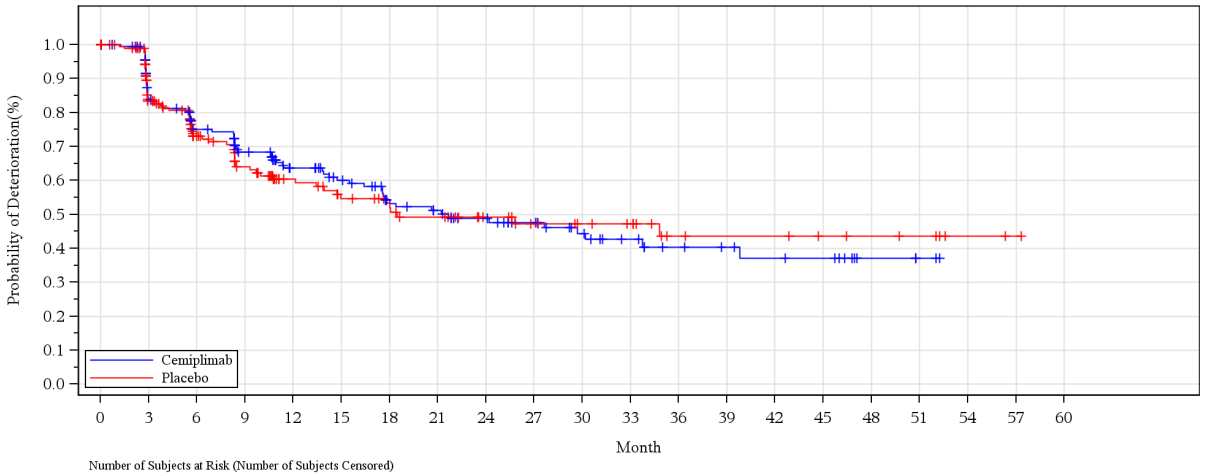
Figure 14.2.8.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	141 (41)	116 (51)	96 (61)	76 (75)	66 (81)	52 (89)	46 (92)	40 (96)	33 (102)	26 (107)	20 (112)	15 (116)	13 (118)	11 (119)	10 (120)	4 (126)	2 (128)	0 (130)	0 (130)	0 (130)
Placebo	206 (0)	132 (46)	96 (67)	74 (78)	54 (94)	45 (98)	40 (102)	35 (104)	27 (112)	22 (116)	19 (119)	17 (121)	10 (127)	9 (128)	9 (128)	7 (130)	6 (131)	5 (132)	2 (135)	1 (136)	0 (137)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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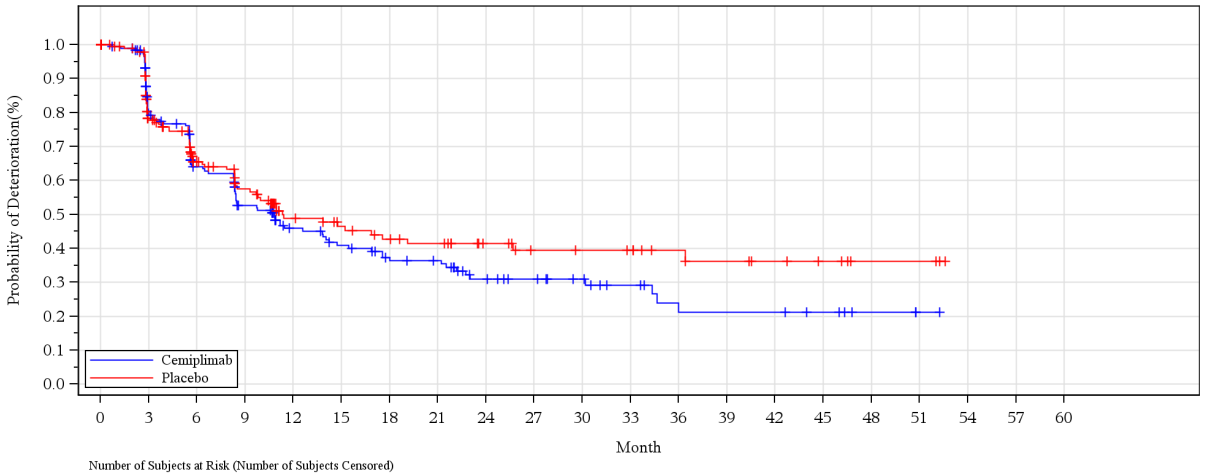
Figure 14.2.8.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	132 (44)	97 (53)	75 (58)	56 (68)	48 (70)	40 (74)	37 (76)	26 (82)	22 (86)	18 (90)	13 (94)	8 (96)	8 (96)	8 (96)	6 (98)	3 (101)	1 (103)	0 (104)	0 (104)	0 (104)
Placebo	206 (0)	125 (44)	87 (63)	68 (72)	44 (87)	38 (91)	33 (93)	30 (95)	23 (102)	18 (106)	17 (107)	16 (108)	12 (112)	10 (113)	8 (115)	6 (117)	3 (120)	3 (120)	0 (123)	0 (123)	0 (123)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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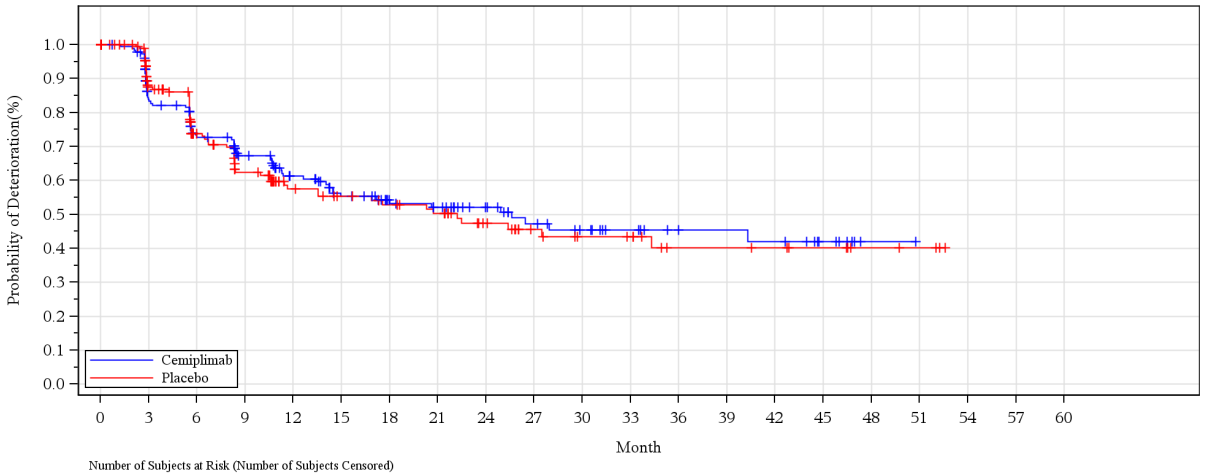
Figure 14.2.8.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	140 (41)	113 (50)	94 (61)	76 (71)	62 (78)	50 (89)	45 (92)	36 (101)	28 (106)	23 (110)	18 (115)	13 (120)	13 (120)	12 (120)	7 (125)	1 (131)	0 (132)	0 (132)	0 (132)	0 (132)
Placebo	206 (0)	137 (48)	95 (70)	73 (78)	53 (93)	47 (97)	43 (99)	39 (101)	29 (109)	21 (116)	17 (119)	16 (120)	10 (125)	10 (125)	9 (126)	7 (128)	4 (131)	3 (132)	0 (135)	0 (135)	0 (135)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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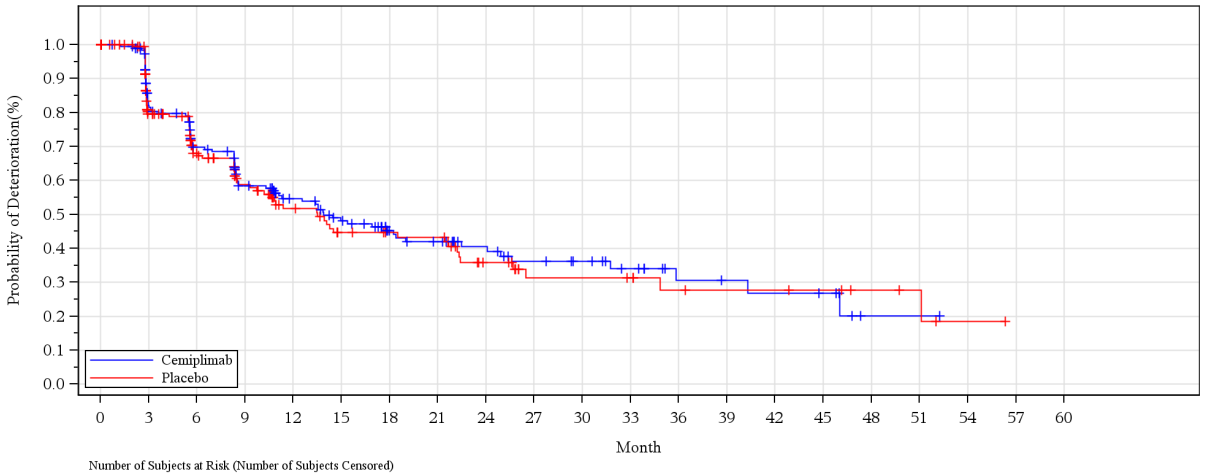
Figure 14.2.8.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	138 (40)	109 (49)	84 (57)	68 (68)	56 (72)	41 (84)	36 (86)	29 (92)	23 (95)	20 (98)	15 (102)	9 (107)	8 (108)	7 (108)	6 (109)	1 (113)	1 (113)	0 (114)	0 (114)	0 (114)
Placebo	206 (0)	122 (50)	88 (68)	65 (80)	46 (92)	36 (96)	33 (99)	32 (99)	20 (106)	12 (112)	12 (112)	11 (113)	8 (115)	7 (116)	7 (116)	6 (117)	4 (119)	3 (120)	1 (121)	0 (122)	0 (122)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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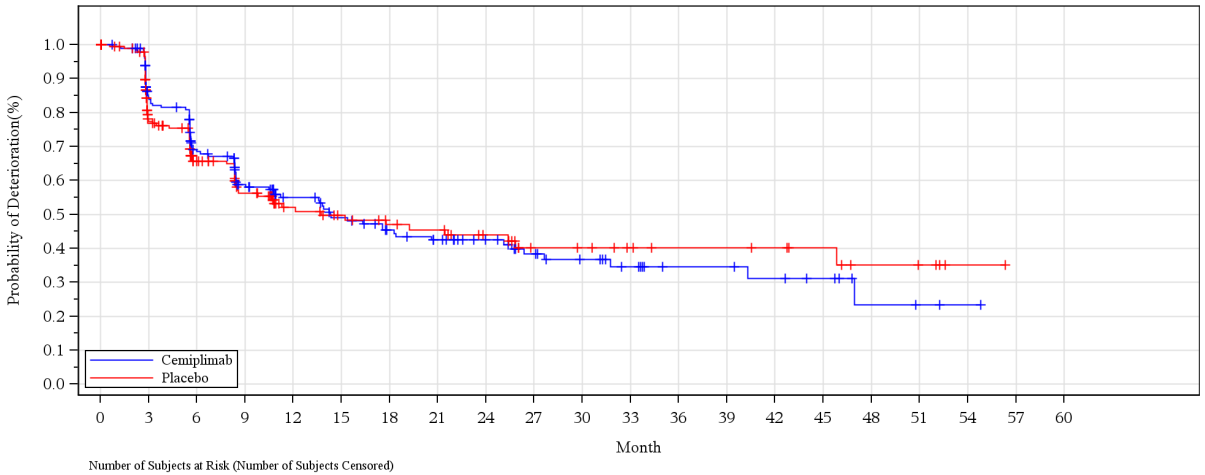
Figure 14.2.8.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	141 (41)	105 (51)	81 (61)	66 (71)	56 (74)	47 (79)	41 (82)	33 (90)	26 (94)	21 (98)	16 (102)	11 (107)	11 (107)	9 (108)	7 (110)	3 (113)	2 (114)	1 (115)	0 (116)	0 (116)
Placebo	206 (0)	121 (47)	84 (67)	63 (77)	44 (92)	38 (96)	33 (99)	31 (100)	25 (105)	17 (111)	16 (112)	13 (115)	11 (117)	11 (117)	10 (118)	8 (120)	5 (122)	4 (123)	1 (126)	0 (127)	0 (127)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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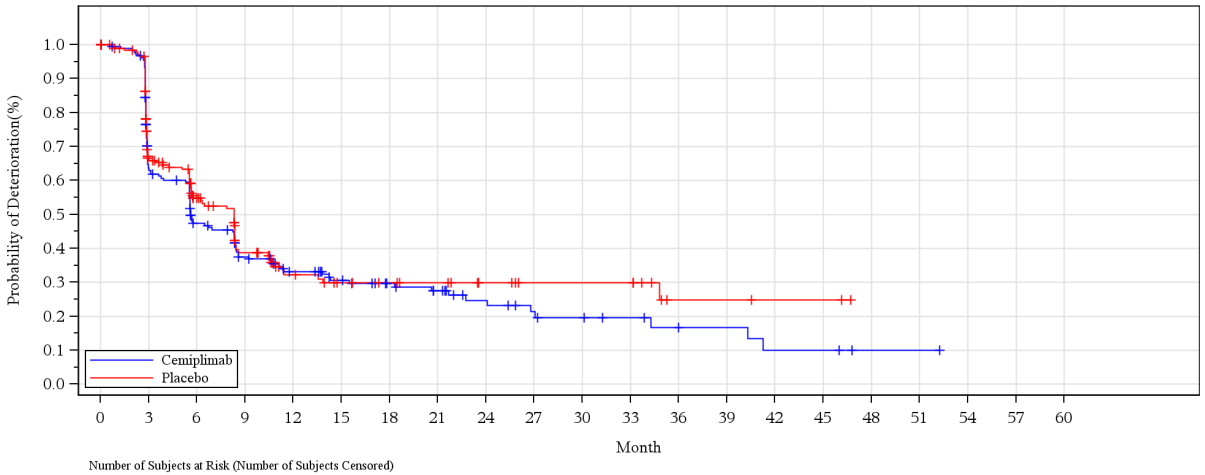
Figure 14.2.8.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	108 (37)	75 (43)	55 (48)	43 (54)	35 (59)	28 (65)	23 (68)	16 (73)	12 (75)	10 (76)	8 (78)	5 (80)	5 (80)	3 (80)	3 (80)	1 (82)	1 (82)	0 (83)	0 (83)	0 (83)
Placebo	206 (0)	105 (44)	72 (60)	43 (70)	27 (80)	21 (84)	19 (86)	17 (88)	13 (92)	10 (95)	10 (95)	10 (95)	3 (101)	3 (101)	2 (102)	2 (102)	0 (104)	0 (104)	0 (104)	0 (104)	0 (104)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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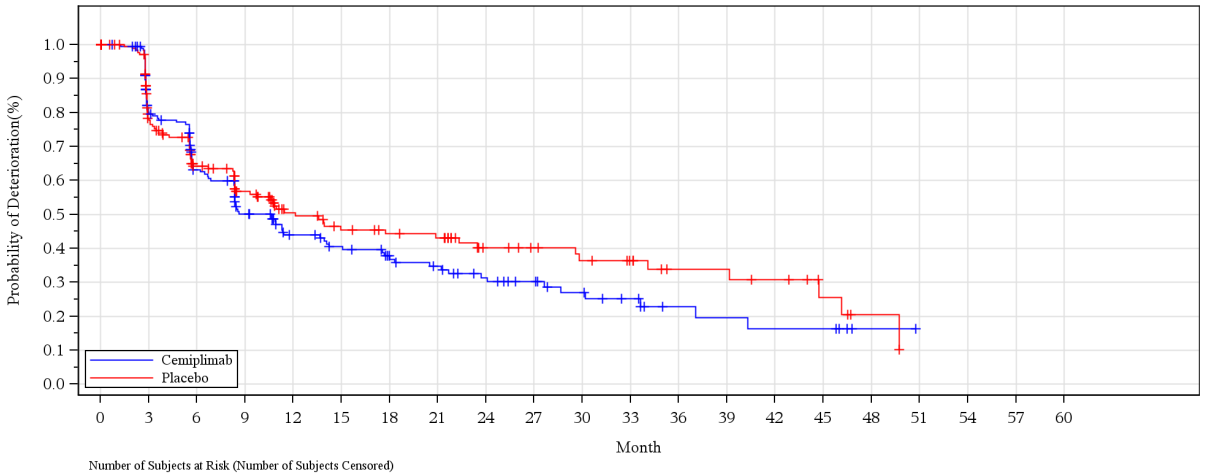
Figure 14.2.8.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	132 (43)	96 (52)	70 (59)	53 (68)	46 (71)	38 (76)	33 (78)	26 (82)	21 (86)	16 (89)	12 (92)	7 (96)	6 (96)	5 (96)	5 (96)	1 (100)	0 (101)	0 (101)	0 (101)	0 (101)
Placebo	206 (0)	128 (41)	91 (56)	71 (66)	51 (79)	43 (82)	39 (85)	37 (86)	25 (96)	22 (99)	19 (100)	16 (103)	11 (107)	11 (107)	9 (108)	5 (111)	2 (113)	0 (114)	0 (114)	0 (114)	0 (114)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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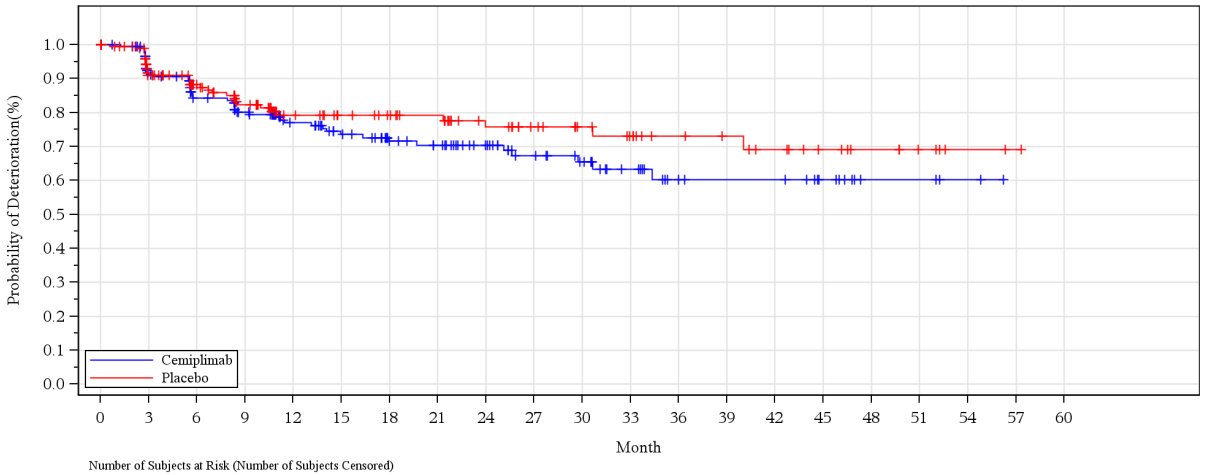
Figure 14.2.8.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	150 (44)	128 (55)	114 (63)	93 (80)	81 (88)	67 (100)	62 (104)	51 (115)	40 (124)	34 (129)	25 (137)	16 (145)	15 (146)	15 (146)	10 (151)	4 (157)	4 (157)	2 (159)	0 (161)	0 (161)
Placebo	206 (0)	142 (49)	113 (74)	91 (89)	66 (111)	59 (118)	55 (122)	51 (126)	40 (135)	34 (141)	29 (146)	25 (149)	20 (154)	18 (156)	15 (158)	11 (162)	8 (165)	5 (168)	2 (171)	1 (172)	0 (173)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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1.1.2 2. Datenschnitt

Table 2.1.1: Completion rate at instrument level-EORTC QLQ-C30
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

[a] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.2: Completion rate at scale level-EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.3: Completion rate at scale level-EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.4: Completion rate at scale level-EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.5: Completion rate at scale level-EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.6: Completion rate at scale level-EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.7: Completion rate at scale level-EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.8: Completion rate at scale level-EORTC QLQ-C30 Fatigue scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.9: Completion rate at scale level-EORTC QLQ-C30 Pain scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.10: Completion rate at scale level-EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	190 (93.6%)	190 (92.2%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.11: Completion rate at scale level-EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.12: Completion rate at scale level-EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

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Table 2.1.13: Completion rate at scale level-EORTC QLQ-C30 Insomnia scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.14: Completion rate at scale level-EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.15: Completion rate at scale level-EORTC QLQ-C30 Constipation scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table 2.1.16: Completion rate at scale level-EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	192 (92.3%)	192 (91.9%)
Cycle 2 - Day 1	182	163 (89.6%)	163 (78.0%)
Cycle 3 - Day 1	173	159 (91.9%)	159 (76.1%)
Cycle 4 - Day 1	158	145 (91.8%)	145 (69.4%)
Placebo (N=206)			
Baseline	203	191 (94.1%)	191 (92.7%)
Cycle 2 - Day 1	185	165 (89.2%)	165 (80.1%)
Cycle 3 - Day 1	162	147 (90.7%)	147 (71.4%)
Cycle 4 - Day 1	142	133 (93.7%)	133 (64.6%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table A2.1.1: Completion rate at instrument level-EORTC QLQ-C30
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

[a] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.2: Completion rate at scale level-EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	165 (85.5%)	165 (78.9%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.

[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.3: Completion rate at scale level-EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	139 (81.8%)	139 (66.5%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
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Table A2.1.4: Completion rate at scale level-EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
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Table A2.1.5: Completion rate at scale level-EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
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Table A2.1.6: Completion rate at scale level-EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.7: Completion rate at scale level-EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	164 (85.0%)	164 (78.5%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

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Table A2.1.8: Completion rate at scale level-EORTC QLQ-C30 Fatigue scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
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Table A2.1.9: Completion rate at scale level-EORTC QLQ-C30 Pain scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.10: Completion rate at scale level-EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	165 (85.5%)	165 (78.9%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.11: Completion rate at scale level-EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.12: Completion rate at scale level-EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.13: Completion rate at scale level-EORTC QLQ-C30 Insomnia scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.14: Completion rate at scale level-EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.15: Completion rate at scale level-EORTC QLQ-C30 Constipation scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table A2.1.16: Completion rate at scale level-EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	166 (86.0%)	166 (79.4%)
FOLLOW-UP VISIT 1	170	140 (82.4%)	140 (67.0%)
FOLLOW-UP VISIT 2	151	121 (80.1%)	121 (57.9%)
FOLLOW-UP VISIT 3	134	103 (76.9%)	103 (49.3%)
FOLLOW-UP VISIT 4	116	90 (77.6%)	90 (43.1%)
FOLLOW-UP VISIT 5	107	79 (73.8%)	79 (37.8%)
FOLLOW-UP VISIT 6	86	61 (70.9%)	61 (29.2%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	30 (73.2%)	30 (14.4%)
FOLLOW-UP VISIT 9	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	159 (82.0%)	159 (77.2%)
FOLLOW-UP VISIT 1	170	105 (61.8%)	105 (51.0%)
FOLLOW-UP VISIT 2	147	89 (60.5%)	89 (43.2%)
FOLLOW-UP VISIT 3	122	69 (56.6%)	69 (33.5%)
FOLLOW-UP VISIT 4	108	59 (54.6%)	59 (28.6%)
FOLLOW-UP VISIT 5	94	47 (50.0%)	47 (22.8%)
FOLLOW-UP VISIT 6	79	38 (48.1%)	38 (18.4%)
FOLLOW-UP VISIT 7	55	31 (56.4%)	31 (15.0%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as at least half of the items within the scale with non-missing values.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table 4.1.1: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	75.88 (17.15)	74.33 (16.51)	-2.12 (1.10), [-4.29, 0.05]	169	76.04 (16.67)	75.56 (16.30)	-0.57 (1.16), [-2.86, 1.71]	-1.07	-1.54 [-4.12, 1.03], 0.240	-0.13 [-0.34, 0.09]
Cycle 2 - Day 1	158	76.69 (16.53)	75.16 (19.96)	-1.93 (1.34), [-4.57, 0.71]	159	75.58 (16.80)	75.31 (17.74)	-0.96 (1.38), [-3.68, 1.76]	-1.27	-0.97 [-4.29, 2.36], 0.567	-0.06 [-0.28, 0.16]
Cycle 3 - Day 1	152	75.44 (17.31)	74.12 (17.58)	-2.18 (1.29), [-4.72, 0.36]	138	77.42 (15.38)	78.02 (16.20)	0.27 (1.37), [-2.41, 2.96]	-1.92	-2.45 [-5.68, 0.78], 0.136	-0.17 [-0.41, 0.06]
Cycle 4 - Day 1	144	76.39 (17.04)	74.77 (19.41)	-2.25 (1.42), [-5.03, 0.54]	127	77.23 (15.80)	76.25 (17.51)	-1.04 (1.51), [-4.01, 1.94]	-0.64	-1.21 [-4.86, 2.44], 0.515	-0.08 [-0.32, 0.16]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 4.1.2: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	87.56 (15.69)	87.47 (14.26)	-1.93 (0.91), [-3.72, -0.15]	169	91.05 (13.01)	89.47 (12.40)	-1.75 (0.96), [-3.64, 0.14]	1.47	-0.19 [-2.32, 1.95], 0.865	-0.02 [-0.23, 0.19]
Cycle 2 - Day 1	158	88.31 (14.13)	88.06 (15.49)	-1.53 (1.06), [-3.61, 0.55]	159	90.61 (13.27)	88.26 (14.36)	-3.14 (1.09), [-5.29, -0.99]	2.09	1.61 [-0.98, 4.20], 0.222	0.14 [-0.08, 0.36]
Cycle 3 - Day 1	152	87.28 (15.66)	87.46 (15.70)	-1.81 (1.05), [-3.87, 0.25]	138	93.00 (11.43)	91.45 (11.53)	-0.82 (1.11), [-3.01, 1.37]	1.72	-0.99 [-3.63, 1.65], 0.460	-0.09 [-0.32, 0.14]
Cycle 4 - Day 1	144	87.69 (14.52)	87.13 (15.24)	-2.47 (1.06), [-4.56, -0.37]	127	93.12 (10.52)	91.18 (11.04)	-1.29 (1.14), [-3.53, 0.95]	1.39	-1.18 [-3.88, 1.53], 0.392	-0.10 [-0.34, 0.14]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 4.1.3: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	84.21 (24.80)	81.51 (20.72)	-4.86 (1.45), [-7.70, -2.01]	169	84.62 (20.41)	84.76 (19.65)	-1.67 (1.53), [-4.68, 1.33]	-2.84	-3.18 [-6.57, 0.20], 0.065	-0.20 [-0.41, 0.01]
Cycle 2 - Day 1	158	85.44 (23.40)	83.76 (23.64)	-3.42 (1.71), [-6.77, -0.06]	159	84.17 (20.69)	83.44 (22.31)	-2.98 (1.76), [-6.44, 0.48]	-0.95	-0.44 [-4.62, 3.74], 0.836	-0.02 [-0.24, 0.20]
Cycle 3 - Day 1	152	83.66 (24.75)	82.02 (24.15)	-4.18 (1.71), [-7.54, -0.81]	138	87.32 (18.73)	85.87 (20.92)	-1.79 (1.81), [-5.35, 1.77]	-0.20	-2.39 [-6.68, 1.90], 0.274	-0.13 [-0.36, 0.10]
Cycle 4 - Day 1	144	84.72 (23.86)	79.86 (23.48)	-6.98 (1.74), [-10.41, -3.54]	127	88.85 (16.41)	88.32 (16.71)	-0.26 (1.86), [-3.92, 3.41]	-4.34	-6.72 [-11.15, -2.29], 0.003	-0.36 [-0.60, -0.12]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 4.1.4: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	84.89 (18.66)	84.58 (19.02)	-0.09 (1.17), [-2.40, 2.21]	169	85.26 (16.44)	84.16 (15.14)	-0.60 (1.23), [-3.02, 1.82]	0.78	0.51 [-2.22, 3.24], 0.713	0.04 [-0.17, 0.25]
Cycle 2 - Day 1	158	85.23 (18.45)	84.23 (21.32)	-0.94 (1.33), [-3.54, 1.67]	159	85.27 (16.75)	84.96 (15.84)	0.18 (1.37), [-2.52, 2.87]	-0.69	-1.12 [-4.32, 2.09], 0.494	-0.08 [-0.30, 0.14]
Cycle 3 - Day 1	152	85.31 (18.24)	85.31 (19.53)	0.80 (1.38), [-1.91, 3.51]	138	86.65 (13.90)	85.02 (16.94)	-0.91 (1.45), [-3.77, 1.95]	1.63	1.71 [-1.73, 5.15], 0.328	0.11 [-0.12, 0.35]
Cycle 4 - Day 1	144	85.01 (17.45)	84.32 (21.08)	-0.14 (1.41), [-2.91, 2.62]	127	86.09 (15.47)	84.65 (17.27)	-1.07 (1.49), [-4.01, 1.86]	0.75	0.93 [-2.61, 4.48], 0.605	0.06 [-0.18, 0.30]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 4.1.5: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	87.72 (16.43)	86.52 (16.73)	-1.15 (1.09), [-3.30, 0.99]	169	89.74 (15.85)	88.48 (14.57)	-0.48 (1.14), [-2.72, 1.77]	0.06	-0.68 [-3.22, 1.87], 0.602	-0.06 [-0.27, 0.16]
Cycle 2 - Day 1	158	87.76 (16.34)	86.29 (19.32)	-1.26 (1.22), [-3.66, 1.14]	159	89.83 (15.68)	88.78 (16.18)	-0.29 (1.26), [-2.76, 2.19]	-0.43	-0.98 [-3.93, 1.97], 0.515	-0.07 [-0.29, 0.15]
Cycle 3 - Day 1	152	87.50 (16.86)	86.95 (19.08)	-0.25 (1.25), [-2.70, 2.20]	138	91.30 (13.69)	89.61 (13.98)	-0.14 (1.31), [-2.72, 2.45]	1.14	-0.11 [-3.22, 2.99], 0.943	-0.01 [-0.24, 0.22]
Cycle 4 - Day 1	144	86.92 (16.97)	85.65 (19.47)	-1.95 (1.38), [-4.66, 0.76]	127	90.81 (13.88)	88.45 (16.06)	-1.01 (1.46), [-3.88, 1.85]	1.09	-0.94 [-4.47, 2.60], 0.602	-0.06 [-0.30, 0.18]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.6: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	84.41 (20.78)	85.35 (18.09)	-0.16 (1.33), [-2.79, 2.46]	169	86.39 (19.22)	87.48 (18.13)	1.37 (1.40), [-1.38, 4.12]	-0.14	-1.53 [-4.64, 1.58], 0.335	-0.10 [-0.32, 0.11]
Cycle 2 - Day 1	158	85.44 (19.97)	86.29 (21.49)	0.29 (1.54), [-2.75, 3.32]	159	86.27 (19.35)	86.16 (20.73)	-0.02 (1.59), [-3.14, 3.11]	0.95	0.31 [-3.46, 4.07], 0.873	0.02 [-0.20, 0.24]
Cycle 3 - Day 1	152	84.54 (20.49)	86.62 (19.75)	0.94 (1.57), [-2.15, 4.04]	138	88.53 (17.30)	89.98 (17.15)	2.66 (1.66), [-0.61, 5.92]	0.63	-1.71 [-5.66, 2.23], 0.393	-0.10 [-0.33, 0.13]
Cycle 4 - Day 1	144	85.07 (19.48)	84.26 (22.37)	-1.72 (1.66), [-4.98, 1.54]	127	89.76 (15.86)	89.37 (17.27)	1.46 (1.76), [-2.00, 4.92]	-0.42	-3.18 [-7.42, 1.06], 0.141	-0.18 [-0.42, 0.06]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.7: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Fatigue scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	20.66 (19.96)	24.07 (18.86)	4.91 (1.30), [2.36, 7.46]	169	19.40 (18.98)	21.65 (16.90)	3.24 (1.37), [0.56, 5.93]	1.15	1.67 [-1.37, 4.70], 0.281	0.12 [-0.10, 0.33]
Cycle 2 - Day 1	158	20.25 (19.37)	23.07 (20.47)	4.32 (1.46), [1.45, 7.19]	159	19.64 (19.29)	21.94 (18.41)	3.62 (1.51), [0.65, 6.59]	0.51	0.70 [-2.84, 4.24], 0.698	0.04 [-0.18, 0.26]
Cycle 3 - Day 1	152	21.05 (20.27)	24.78 (22.31)	5.16 (1.56), [2.10, 8.22]	138	17.15 (17.51)	19.40 (18.75)	1.75 (1.64), [-1.48, 4.98]	1.47	3.41 [-0.52, 7.33], 0.088	0.20 [-0.03, 0.43]
Cycle 4 - Day 1	144	20.52 (19.72)	24.23 (20.93)	5.25 (1.64), [2.02, 8.47]	127	16.62 (17.42)	21.52 (20.03)	4.35 (1.75), [0.91, 7.80]	-1.20	0.89 [-3.33, 5.12], 0.678	0.05 [-0.19, 0.29]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.8: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Pain scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	14.13 (21.08)	15.63 (21.54)	3.02 (1.59), [-0.12, 6.15]	169	12.23 (18.50)	13.53 (18.84)	1.53 (1.67), [-1.76, 4.83]	0.20	1.48 [-2.25, 5.21], 0.436	0.08 [-0.13, 0.30]
Cycle 2 - Day 1	158	13.50 (20.36)	13.82 (22.82)	1.59 (1.74), [-1.83, 5.01]	159	12.68 (18.89)	13.94 (19.57)	2.05 (1.80), [-1.48, 5.58]	-0.94	-0.46 [-4.62, 3.70], 0.829	-0.02 [-0.24, 0.20]
Cycle 3 - Day 1	152	14.69 (21.44)	16.78 (26.47)	3.82 (1.99), [-0.09, 7.73]	138	11.35 (16.36)	11.47 (20.12)	0.74 (2.09), [-3.38, 4.86]	1.96	3.08 [-1.98, 8.15], 0.232	0.14 [-0.09, 0.37]
Cycle 4 - Day 1	144	13.54 (20.10)	15.86 (24.01)	3.64 (1.82), [0.05, 7.22]	127	12.07 (18.15)	12.34 (18.69)	1.82 (1.93), [-1.97, 5.61]	2.05	1.82 [-2.72, 6.35], 0.431	0.10 [-0.14, 0.33]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.9: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	11.31 (21.74)	10.43 (18.44)	-1.20 (1.26), [-3.68, 1.28]	168	10.91 (20.47)	9.03 (18.68)	-3.02 (1.33), [-5.64, -0.41]	1.01	1.82 [-1.12, 4.77], 0.225	0.13 [-0.08, 0.34]
Cycle 2 - Day 1	158	11.60 (22.23)	10.34 (21.25)	-1.80 (1.39), [-4.53, 0.94]	158	11.18 (20.82)	9.92 (20.78)	-1.92 (1.45), [-4.77, 0.92]	0.00	0.13 [-3.22, 3.47], 0.940	0.01 [-0.21, 0.23]
Cycle 3 - Day 1	152	10.96 (21.28)	10.96 (21.96)	-0.23 (1.49), [-3.17, 2.70]	137	9.49 (18.94)	7.30 (17.49)	-3.02 (1.58), [-6.12, 0.08]	2.19	2.78 [-0.95, 6.52], 0.144	0.17 [-0.06, 0.40]
Cycle 4 - Day 1	144	11.11 (20.48)	10.19 (20.59)	-1.57 (1.52), [-4.57, 1.42]	126	7.67 (16.42)	5.82 (14.65)	-4.13 (1.63), [-7.33, -0.93]	0.93	2.56 [-1.31, 6.43], 0.195	0.16 [-0.08, 0.40]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.10: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	2.24 (6.99)	3.12 (7.79)	1.35 (0.71), [-0.05, 2.75]	169	2.07 (6.08)	3.06 (8.20)	1.25 (0.75), [-0.23, 2.72]	-0.11	0.10 [-1.57, 1.77], 0.905	0.01 [-0.20, 0.23]
Cycle 2 - Day 1	158	1.90 (5.94)	2.74 (8.17)	1.08 (0.83), [-0.54, 2.71]	159	2.20 (6.25)	3.77 (10.59)	1.93 (0.85), [0.25, 3.60]	-0.73	-0.85 [-2.87, 1.18], 0.411	-0.09 [-0.31, 0.13]
Cycle 3 - Day 1	152	2.19 (7.10)	2.96 (8.81)	1.22 (0.79), [-0.34, 2.78]	138	1.93 (5.72)	2.78 (9.36)	0.90 (0.84), [-0.75, 2.54]	-0.08	0.32 [-1.63, 2.27], 0.746	0.04 [-0.19, 0.27]
Cycle 4 - Day 1	144	1.85 (6.86)	3.47 (12.60)	1.74 (0.96), [-0.15, 3.63]	127	1.84 (5.24)	2.49 (7.30)	0.91 (1.02), [-1.10, 2.92]	0.96	0.83 [-1.68, 3.34], 0.515	0.08 [-0.16, 0.32]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.11: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	8.97 (19.74)	9.94 (18.43)	2.12 (1.31), [-0.46, 4.70]	169	7.30 (15.19)	9.27 (16.64)	1.88 (1.38), [-0.84, 4.59]	-1.00	0.25 [-2.82, 3.31], 0.874	0.02 [-0.20, 0.23]
Cycle 2 - Day 1	158	8.44 (18.41)	9.49 (21.31)	1.54 (1.49), [-1.39, 4.47]	159	7.55 (15.43)	9.85 (18.96)	2.68 (1.54), [-0.35, 5.70]	-1.25	-1.14 [-4.76, 2.49], 0.538	-0.07 [-0.29, 0.15]
Cycle 3 - Day 1	152	9.65 (20.53)	10.53 (20.09)	1.91 (1.47), [-0.99, 4.80]	138	6.76 (14.61)	7.25 (16.96)	0.38 (1.55), [-2.67, 3.44]	0.39	1.52 [-2.11, 5.15], 0.410	0.10 [-0.13, 0.33]
Cycle 4 - Day 1	144	8.56 (19.61)	11.11 (21.23)	2.92 (1.60), [-0.22, 6.06]	127	7.09 (14.92)	9.19 (16.63)	2.56 (1.69), [-0.77, 5.90]	0.45	0.36 [-3.69, 4.40], 0.863	0.02 [-0.22, 0.26]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.12: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Insomnia scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	19.69 (25.22)	19.95 (23.27)	1.45 (1.75), [-2.00, 4.89]	169	17.55 (25.48)	18.21 (22.41)	0.74 (1.84), [-2.88, 4.36]	-0.40	0.70 [-3.39, 4.80], 0.735	0.04 [-0.18, 0.25]
Cycle 2 - Day 1	158	19.41 (24.73)	18.57 (25.93)	-0.03 (1.92), [-3.81, 3.75]	159	17.82 (25.92)	16.56 (23.38)	-1.15 (1.99), [-5.07, 2.76]	0.41	1.12 [-3.50, 5.75], 0.633	0.05 [-0.17, 0.27]
Cycle 3 - Day 1	152	20.61 (25.72)	22.59 (27.29)	2.77 (2.07), [-1.31, 6.85]	138	16.43 (24.91)	17.63 (25.21)	-0.32 (2.18), [-4.61, 3.97]	0.77	3.09 [-2.11, 8.29], 0.244	0.14 [-0.09, 0.37]
Cycle 4 - Day 1	144	19.21 (24.80)	20.14 (28.21)	1.60 (2.18), [-2.69, 5.89]	127	17.06 (25.15)	21.52 (25.73)	3.69 (2.32), [-0.87, 8.26]	-3.54	-2.09 [-7.67, 3.48], 0.460	-0.09 [-0.33, 0.15]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

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Table 4.1.13: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	15.98 (23.80)	12.64 (19.83)	-1.16 (1.50), [-4.12, 1.80]	169	14.60 (23.51)	10.75 (19.62)	-2.67 (1.59), [-5.80, 0.45]	0.50	1.51 [-1.99, 5.02], 0.396	0.09 [-0.12, 0.30]
Cycle 2 - Day 1	158	15.40 (23.08)	14.56 (24.22)	0.53 (1.79), [-2.99, 4.04]	159	14.88 (23.61)	12.37 (22.98)	-0.89 (1.85), [-4.52, 2.74]	1.67	1.42 [-2.97, 5.81], 0.525	0.07 [-0.15, 0.29]
Cycle 3 - Day 1	152	15.57 (23.62)	12.50 (22.96)	-1.83 (1.78), [-5.32, 1.67]	138	13.53 (21.55)	9.66 (20.62)	-3.31 (1.88), [-7.01, 0.39]	0.79	1.48 [-2.96, 5.92], 0.512	0.08 [-0.15, 0.31]
Cycle 4 - Day 1	144	15.97 (23.97)	11.57 (21.35)	-2.18 (1.76), [-5.64, 1.29]	127	13.12 (21.48)	8.66 (18.41)	-3.81 (1.88), [-7.51, -0.12]	0.06	1.64 [-2.77, 6.05], 0.465	0.09 [-0.15, 0.33]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 4.1.14: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Constipation scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	11.31 (20.18)	9.49 (16.48)	-1.67 (1.21), [-4.05, 0.71]	169	9.47 (19.65)	9.17 (15.42)	-0.81 (1.28), [-3.32, 1.70]	-1.52	-0.85 [-3.68, 1.97], 0.552	-0.06 [-0.28, 0.15]
Cycle 2 - Day 1	158	11.18 (20.12)	9.28 (19.50)	-1.71 (1.48), [-4.62, 1.19]	159	10.06 (20.11)	8.60 (17.68)	-2.01 (1.52), [-5.00, 0.99]	-0.43	0.29 [-3.37, 3.95], 0.875	0.02 [-0.20, 0.24]
Cycle 3 - Day 1	152	11.40 (19.97)	9.21 (18.07)	-1.50 (1.45), [-4.35, 1.36]	138	7.00 (15.83)	9.42 (17.08)	-0.52 (1.54), [-3.55, 2.51]	-4.61	-0.98 [-4.65, 2.69], 0.599	-0.06 [-0.29, 0.17]
Cycle 4 - Day 1	144	11.81 (20.66)	9.95 (19.74)	-1.79 (1.48), [-4.70, 1.12]	127	7.87 (17.55)	8.92 (18.52)	0.08 (1.58), [-3.02, 3.19]	-2.90	-1.88 [-5.65, 1.90], 0.328	-0.12 [-0.36, 0.12]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 4.1.15: Mixed model repeated measures analysis: change from Baseline in the EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	171	2.92 (11.34)	5.56 (11.19)	2.66 (1.01), [0.66, 4.65]	169	4.14 (11.61)	5.39 (11.33)	2.21 (1.07), [0.11, 4.31]	1.38	0.44 [-1.93, 2.82], 0.715	0.04 [-0.17, 0.25]
Cycle 2 - Day 1	158	2.74 (11.26)	4.64 (12.74)	1.56 (1.23), [-0.85, 3.98]	159	4.19 (11.71)	6.08 (14.93)	2.81 (1.26), [0.33, 5.29]	0.01	-1.25 [-4.29, 1.79], 0.419	-0.09 [-0.31, 0.13]
Cycle 3 - Day 1	152	3.07 (11.73)	4.61 (12.75)	1.55 (1.19), [-0.79, 3.90]	138	4.11 (11.00)	4.83 (14.27)	1.41 (1.26), [-1.07, 3.90]	0.81	0.14 [-2.85, 3.13], 0.926	0.01 [-0.22, 0.24]
Cycle 4 - Day 1	144	3.47 (12.29)	7.87 (19.70)	4.85 (1.46), [1.97, 7.73]	127	3.67 (11.29)	5.51 (12.43)	2.42 (1.56), [-0.65, 5.49]	2.56	2.44 [-1.44, 6.31], 0.217	0.15 [-0.09, 0.39]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table A4.1.1.1: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 GHS/QoL scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-4.04 (1.05), [-6.10, -1.97]	-2.45 (1.13), [-4.68, -0.22]	-1.58 [-4.12, 0.96], 0.221	-0.09 [-0.29, 0.11]
Month 3	-3.62 (1.12), [-5.81, -1.42]	-2.73 (1.18), [-5.05, -0.41]	-0.89 [-3.62, 1.84], 0.522	-0.05 [-0.25, 0.15]
Month 6	-3.72 (1.07), [-5.83, -1.61]	-2.65 (1.14), [-4.88, -0.42]	-1.07 [-3.66, 1.52], 0.416	-0.06 [-0.26, 0.14]
Month 9	-3.82 (1.05), [-5.89, -1.76]	-2.57 (1.11), [-4.76, -0.38]	-1.25 [-3.76, 1.25], 0.326	-0.07 [-0.27, 0.13]
Month 12	-3.93 (1.04), [-5.98, -1.88]	-2.49 (1.12), [-4.68, -0.30]	-1.44 [-3.94, 1.06], 0.258	-0.08 [-0.28, 0.12]
Month 15	-4.03 (1.05), [-6.10, -1.96]	-2.41 (1.14), [-4.66, -0.17]	-1.62 [-4.18, 0.94], 0.214	-0.09 [-0.29, 0.11]
Month 18	-4.14 (1.08), [-6.26, -2.01]	-2.34 (1.19), [-4.68, 0.00]	-1.80 [-4.49, 0.88], 0.187	-0.10 [-0.30, 0.10]
Month 21	-4.24 (1.12), [-6.46, -2.03]	-2.26 (1.26), [-4.73, 0.22]	-1.99 [-4.85, 0.88], 0.174	-0.11 [-0.31, 0.09]
Month 24	-4.35 (1.18), [-6.68, -2.02]	-2.18 (1.34), [-4.82, 0.46]	-2.17 [-5.27, 0.93], 0.170	-0.12 [-0.32, 0.08]
Month 27	-4.45 (1.25), [-6.92, -1.99]	-2.10 (1.44), [-4.94, 0.73]	-2.35 [-5.72, 1.02], 0.170	-0.13 [-0.34, 0.07]
Month 30	-4.56 (1.34), [-7.19, -1.93]	-2.02 (1.55), [-5.08, 1.03]	-2.53 [-6.20, 1.13], 0.175	-0.15 [-0.35, 0.06]
Month 33	-4.66 (1.43), [-7.47, -1.86]	-1.95 (1.67), [-5.24, 1.34]	-2.72 [-6.70, 1.27], 0.181	-0.16 [-0.36, 0.05]
Month 36	-4.77 (1.52), [-7.77, -1.77]	-1.87 (1.80), [-5.41, 1.67]	-2.90 [-7.23, 1.43], 0.188	-0.17 [-0.37, 0.03]
Month 39	-4.87 (1.63), [-8.07, -1.67]	-1.79 (1.93), [-5.59, 2.01]	-3.08 [-7.76, 1.60], 0.195	-0.18 [-0.38, 0.02]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.2: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Physical Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-3.27 (0.90), [-5.05, -1.50]	-3.65 (0.98), [-5.58, -1.73]	0.38 [-1.84, 2.60], 0.735	0.03 [-0.17, 0.23]
Month 3	-2.72 (0.95), [-4.59, -0.84]	-3.31 (1.00), [-5.28, -1.34]	0.59 [-1.74, 2.93], 0.616	0.04 [-0.16, 0.24]
Month 6	-2.86 (0.91), [-4.66, -1.06]	-3.40 (0.96), [-5.29, -1.51]	0.54 [-1.67, 2.75], 0.631	0.04 [-0.16, 0.24]
Month 9	-3.00 (0.89), [-4.76, -1.25]	-3.49 (0.95), [-5.35, -1.63]	0.48 [-1.66, 2.63], 0.658	0.03 [-0.17, 0.23]
Month 12	-3.15 (0.89), [-4.90, -1.40]	-3.58 (0.95), [-5.45, -1.70]	0.43 [-1.73, 2.59], 0.697	0.03 [-0.17, 0.23]
Month 15	-3.29 (0.91), [-5.08, -1.51]	-3.67 (0.99), [-5.61, -1.72]	0.37 [-1.87, 2.61], 0.744	0.02 [-0.18, 0.23]
Month 18	-3.44 (0.94), [-5.29, -1.59]	-3.75 (1.04), [-5.80, -1.71]	0.32 [-2.07, 2.70], 0.795	0.02 [-0.18, 0.22]
Month 21	-3.58 (0.99), [-5.53, -1.64]	-3.84 (1.11), [-6.03, -1.65]	0.26 [-2.33, 2.85], 0.843	0.02 [-0.18, 0.22]
Month 24	-3.73 (1.05), [-5.80, -1.66]	-3.93 (1.20), [-6.29, -1.57]	0.20 [-2.62, 3.03], 0.887	0.01 [-0.19, 0.21]
Month 27	-3.87 (1.12), [-6.09, -1.66]	-4.02 (1.30), [-6.58, -1.46]	0.15 [-2.95, 3.25], 0.925	0.01 [-0.19, 0.21]
Month 30	-4.02 (1.21), [-6.39, -1.64]	-4.11 (1.41), [-6.88, -1.34]	0.09 [-3.31, 3.49], 0.957	0.01 [-0.19, 0.21]
Month 33	-4.16 (1.30), [-6.72, -1.60]	-4.20 (1.52), [-7.20, -1.20]	0.04 [-3.68, 3.75], 0.985	0.00 [-0.20, 0.20]
Month 36	-4.30 (1.39), [-7.05, -1.56]	-4.29 (1.64), [-7.53, -1.04]	-0.02 [-4.06, 4.03], 0.992	0.00 [-0.20, 0.20]
Month 39	-4.45 (1.49), [-7.40, -1.50]	-4.37 (1.77), [-7.86, -0.88]	-0.08 [-4.46, 4.31], 0.973	-0.01 [-0.21, 0.20]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.3: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Role Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-5.77 (1.33), [-8.39, -3.15]	-2.67 (1.44), [-5.50, 0.17]	-3.10 [-6.33, 0.13], 0.060	-0.14 [-0.34, 0.07]
Month 3	-5.27 (1.44), [-8.10, -2.44]	-3.09 (1.52), [-6.09, -0.10]	-2.18 [-5.72, 1.37], 0.228	-0.09 [-0.30, 0.11]
Month 6	-5.40 (1.38), [-8.11, -2.69]	-2.98 (1.46), [-5.84, -0.12]	-2.42 [-5.75, 0.91], 0.153	-0.11 [-0.31, 0.09]
Month 9	-5.53 (1.34), [-8.16, -2.90]	-2.87 (1.42), [-5.66, -0.07]	-2.66 [-5.87, 0.54], 0.103	-0.12 [-0.32, 0.08]
Month 12	-5.66 (1.32), [-8.26, -3.06]	-2.75 (1.42), [-5.54, 0.04]	-2.91 [-6.08, 0.27], 0.073	-0.13 [-0.33, 0.07]
Month 15	-5.79 (1.34), [-8.42, -3.16]	-2.64 (1.45), [-5.50, 0.21]	-3.15 [-6.41, 0.11], 0.058	-0.14 [-0.34, 0.06]
Month 18	-5.92 (1.37), [-8.62, -3.22]	-2.53 (1.52), [-5.52, 0.46]	-3.39 [-6.83, 0.04], 0.053	-0.15 [-0.35, 0.05]
Month 21	-6.05 (1.43), [-8.88, -3.23]	-2.42 (1.61), [-5.59, 0.75]	-3.63 [-7.33, 0.06], 0.054	-0.16 [-0.36, 0.04]
Month 24	-6.18 (1.52), [-9.17, -3.20]	-2.31 (1.73), [-5.71, 1.10]	-3.88 [-7.90, 0.14], 0.059	-0.17 [-0.37, 0.03]
Month 27	-6.31 (1.62), [-9.50, -3.13]	-2.19 (1.87), [-5.87, 1.48]	-4.12 [-8.52, 0.28], 0.066	-0.18 [-0.38, 0.02]
Month 30	-6.44 (1.73), [-9.85, -3.04]	-2.08 (2.02), [-6.06, 1.90]	-4.36 [-9.18, 0.46], 0.076	-0.19 [-0.39, 0.01]
Month 33	-6.58 (1.86), [-10.23, -2.92]	-1.97 (2.19), [-6.28, 2.33]	-4.60 [-9.87, 0.66], 0.086	-0.20 [-0.40, 0.00]
Month 36	-6.71 (1.99), [-10.63, -2.78]	-1.86 (2.36), [-6.51, 2.79]	-4.85 [-10.59, 0.89], 0.097	-0.21 [-0.41, -0.01]
Month 39	-6.84 (2.14), [-11.05, -2.62]	-1.75 (2.54), [-6.76, 3.26]	-5.09 [-11.32, 1.14], 0.109	-0.22 [-0.42, -0.02]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.4: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Emotional Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-2.52 (1.12), [-4.73, -0.32]	-1.55 (1.21), [-3.93, 0.83]	-0.97 [-3.71, 1.77], 0.487	-0.05 [-0.25, 0.15]
Month 3	-1.77 (1.13), [-4.00, 0.46]	-2.02 (1.20), [-4.38, 0.34]	0.25 [-2.49, 2.99], 0.857	0.01 [-0.19, 0.21]
Month 6	-1.97 (1.10), [-4.14, 0.21]	-1.90 (1.17), [-4.19, 0.40]	-0.07 [-2.71, 2.57], 0.959	0.00 [-0.20, 0.20]
Month 9	-2.16 (1.09), [-4.31, -0.01]	-1.77 (1.16), [-4.05, 0.51]	-0.39 [-3.00, 2.22], 0.769	-0.02 [-0.22, 0.18]
Month 12	-2.36 (1.10), [-4.52, -0.19]	-1.65 (1.18), [-3.96, 0.67]	-0.71 [-3.36, 1.94], 0.598	-0.04 [-0.24, 0.16]
Month 15	-2.56 (1.13), [-4.77, -0.34]	-1.52 (1.22), [-3.92, 0.88]	-1.03 [-3.80, 1.73], 0.463	-0.06 [-0.26, 0.14]
Month 18	-2.75 (1.17), [-5.06, -0.45]	-1.40 (1.29), [-3.93, 1.13]	-1.35 [-4.30, 1.59], 0.366	-0.08 [-0.28, 0.12]
Month 21	-2.95 (1.23), [-5.37, -0.53]	-1.28 (1.37), [-3.97, 1.42]	-1.67 [-4.85, 1.50], 0.300	-0.09 [-0.29, 0.11]
Month 24	-3.15 (1.30), [-5.71, -0.58]	-1.15 (1.47), [-4.04, 1.74]	-2.00 [-5.44, 1.45], 0.256	-0.11 [-0.31, 0.09]
Month 27	-3.34 (1.39), [-6.08, -0.61]	-1.03 (1.58), [-4.14, 2.08]	-2.32 [-6.07, 1.44], 0.225	-0.13 [-0.33, 0.07]
Month 30	-3.54 (1.48), [-6.46, -0.62]	-0.90 (1.70), [-4.25, 2.45]	-2.64 [-6.72, 1.45], 0.205	-0.15 [-0.35, 0.05]
Month 33	-3.74 (1.58), [-6.86, -0.62]	-0.78 (1.83), [-4.39, 2.83]	-2.96 [-7.40, 1.48], 0.190	-0.17 [-0.37, 0.03]
Month 36	-3.94 (1.69), [-7.27, -0.61]	-0.66 (1.97), [-4.53, 3.22]	-3.28 [-8.08, 1.52], 0.180	-0.18 [-0.39, 0.02]
Month 39	-4.13 (1.80), [-7.69, -0.58]	-0.53 (2.11), [-4.69, 3.63]	-3.60 [-8.78, 1.58], 0.172	-0.20 [-0.40, 0.00]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.5: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Cognitive Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-3.41 (1.07), [-5.50, -1.31]	-2.04 (1.15), [-4.30, 0.23]	-1.37 [-3.99, 1.25], 0.306	-0.08 [-0.28, 0.12]
Month 3	-1.71 (1.04), [-3.77, 0.34]	-1.07 (1.11), [-3.24, 1.11]	-0.65 [-3.16, 1.87], 0.614	-0.04 [-0.24, 0.16]
Month 6	-2.16 (1.03), [-4.18, -0.14]	-1.32 (1.09), [-3.46, 0.82]	-0.84 [-3.29, 1.62], 0.504	-0.05 [-0.25, 0.15]
Month 9	-2.60 (1.03), [-4.63, -0.58]	-1.58 (1.09), [-3.73, 0.57]	-1.03 [-3.49, 1.43], 0.413	-0.06 [-0.26, 0.14]
Month 12	-3.05 (1.04), [-5.10, -1.00]	-1.84 (1.12), [-4.03, 0.36]	-1.22 [-3.74, 1.31], 0.344	-0.07 [-0.27, 0.13]
Month 15	-3.50 (1.07), [-5.61, -1.39]	-2.09 (1.16), [-4.38, 0.19]	-1.41 [-4.06, 1.25], 0.298	-0.09 [-0.29, 0.12]
Month 18	-3.94 (1.12), [-6.14, -1.74]	-2.35 (1.22), [-4.76, 0.06]	-1.60 [-4.42, 1.23], 0.268	-0.10 [-0.30, 0.10]
Month 21	-4.39 (1.18), [-6.70, -2.08]	-2.61 (1.30), [-5.17, -0.04]	-1.79 [-4.83, 1.26], 0.250	-0.11 [-0.31, 0.09]
Month 24	-4.84 (1.24), [-7.29, -2.39]	-2.86 (1.39), [-5.61, -0.12]	-1.98 [-5.27, 1.32], 0.239	-0.12 [-0.32, 0.08]
Month 27	-5.28 (1.32), [-7.88, -2.68]	-3.12 (1.50), [-6.06, -0.17]	-2.17 [-5.74, 1.41], 0.234	-0.13 [-0.33, 0.07]
Month 30	-5.73 (1.41), [-8.50, -2.96]	-3.38 (1.61), [-6.54, -0.21]	-2.36 [-6.23, 1.52], 0.233	-0.14 [-0.34, 0.06]
Month 33	-6.18 (1.50), [-9.13, -3.23]	-3.63 (1.72), [-7.03, -0.24]	-2.55 [-6.74, 1.65], 0.233	-0.15 [-0.35, 0.05]
Month 36	-6.62 (1.59), [-9.76, -3.49]	-3.89 (1.85), [-7.53, -0.25]	-2.74 [-7.26, 1.79], 0.235	-0.17 [-0.37, 0.04]
Month 39	-7.07 (1.69), [-10.41, -3.73]	-4.15 (1.98), [-8.04, -0.26]	-2.93 [-7.79, 1.94], 0.237	-0.18 [-0.38, 0.02]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.6: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Social Functioning scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-1.17 (1.19), [-3.51, 1.18]	0.65 (1.28), [-1.87, 3.16]	-1.81 [-4.68, 1.05], 0.214	-0.09 [-0.29, 0.11]
Month 3	-1.27 (1.37), [-3.97, 1.42]	-0.55 (1.44), [-3.38, 2.28]	-0.72 [-4.14, 2.70], 0.679	-0.03 [-0.23, 0.17]
Month 6	-1.24 (1.30), [-3.79, 1.31]	-0.23 (1.36), [-2.90, 2.44]	-1.01 [-4.17, 2.15], 0.531	-0.05 [-0.25, 0.15]
Month 9	-1.21 (1.24), [-3.64, 1.23]	0.09 (1.30), [-2.47, 2.65]	-1.30 [-4.27, 1.68], 0.393	-0.06 [-0.26, 0.14]
Month 12	-1.17 (1.20), [-3.54, 1.19]	0.41 (1.28), [-2.10, 2.92]	-1.58 [-4.46, 1.29], 0.280	-0.08 [-0.28, 0.12]
Month 15	-1.14 (1.19), [-3.48, 1.21]	0.73 (1.28), [-1.79, 3.26]	-1.87 [-4.74, 1.00], 0.201	-0.09 [-0.29, 0.11]
Month 18	-1.10 (1.20), [-3.47, 1.26]	1.05 (1.32), [-1.54, 3.65]	-2.16 [-5.12, 0.80], 0.152	-0.10 [-0.30, 0.10]
Month 21	-1.07 (1.24), [-3.51, 1.37]	1.38 (1.39), [-1.35, 4.10]	-2.45 [-5.58, 0.69], 0.126	-0.12 [-0.32, 0.08]
Month 24	-1.04 (1.30), [-3.59, 1.52]	1.70 (1.48), [-1.21, 4.61]	-2.73 [-6.12, 0.65], 0.113	-0.13 [-0.33, 0.07]
Month 27	-1.00 (1.38), [-3.71, 1.71]	2.02 (1.59), [-1.11, 5.15]	-3.02 [-6.71, 0.67], 0.108	-0.14 [-0.35, 0.06]
Month 30	-0.97 (1.47), [-3.86, 1.92]	2.34 (1.72), [-1.04, 5.72]	-3.31 [-7.35, 0.73], 0.108	-0.16 [-0.36, 0.04]
Month 33	-0.93 (1.58), [-4.04, 2.17]	2.66 (1.86), [-1.00, 6.32]	-3.60 [-8.02, 0.83], 0.111	-0.17 [-0.37, 0.03]
Month 36	-0.90 (1.69), [-4.24, 2.43]	2.98 (2.01), [-0.97, 6.94]	-3.88 [-8.72, 0.95], 0.115	-0.19 [-0.39, 0.01]
Month 39	-0.87 (1.82), [-4.45, 2.72]	3.31 (2.17), [-0.97, 7.58]	-4.17 [-9.44, 1.10], 0.120	-0.20 [-0.40, 0.00]

Note(s): A positive change from baseline value indicates improvement in functioning and Global health status/QoL. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
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Table A4.1.1.7: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Fatigue scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	5.36 (1.23), [2.95, 7.77]	2.96 (1.33), [0.35, 5.57]	2.40 [-0.60, 5.40], 0.116	0.12 [-0.08, 0.32]
Month 3	5.60 (1.25), [3.13, 8.06]	3.64 (1.33), [1.03, 6.24]	1.96 [-1.09, 5.00], 0.207	0.10 [-0.10, 0.30]
Month 6	5.53 (1.21), [3.15, 7.92]	3.46 (1.28), [0.93, 5.98]	2.08 [-0.83, 4.98], 0.161	0.10 [-0.10, 0.30]
Month 9	5.47 (1.20), [3.11, 7.82]	3.27 (1.27), [0.77, 5.77]	2.19 [-0.67, 5.05], 0.132	0.11 [-0.09, 0.31]
Month 12	5.40 (1.20), [3.03, 7.77]	3.09 (1.29), [0.55, 5.63]	2.31 [-0.59, 5.21], 0.118	0.12 [-0.09, 0.32]
Month 15	5.34 (1.23), [2.91, 7.76]	2.91 (1.34), [0.27, 5.54]	2.43 [-0.61, 5.46], 0.117	0.12 [-0.08, 0.32]
Month 18	5.27 (1.28), [2.75, 7.80]	2.73 (1.42), [-0.06, 5.51]	2.54 [-0.70, 5.79], 0.124	0.13 [-0.07, 0.33]
Month 21	5.20 (1.35), [2.54, 7.87]	2.54 (1.52), [-0.44, 5.53]	2.66 [-0.86, 6.18], 0.138	0.13 [-0.07, 0.33]
Month 24	5.14 (1.44), [2.31, 7.97]	2.36 (1.63), [-0.85, 5.58]	2.78 [-1.07, 6.62], 0.156	0.14 [-0.06, 0.34]
Month 27	5.07 (1.54), [2.04, 8.10]	2.18 (1.77), [-1.30, 5.66]	2.89 [-1.31, 7.10], 0.176	0.14 [-0.06, 0.35]
Month 30	5.01 (1.65), [1.76, 8.26]	2.00 (1.91), [-1.77, 5.76]	3.01 [-1.59, 7.61], 0.198	0.15 [-0.05, 0.35]
Month 33	4.94 (1.77), [1.46, 8.43]	1.81 (2.07), [-2.25, 5.88]	3.13 [-1.89, 8.14], 0.220	0.16 [-0.04, 0.36]
Month 36	4.88 (1.90), [1.14, 8.61]	1.63 (2.23), [-2.75, 6.02]	3.25 [-2.20, 8.69], 0.242	0.16 [-0.04, 0.36]
Month 39	4.81 (2.03), [0.81, 8.81]	1.45 (2.39), [-3.27, 6.17]	3.36 [-2.53, 9.26], 0.262	0.17 [-0.03, 0.37]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
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Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.8: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Pain scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	4.90 (1.48), [1.98, 7.82]	4.57 (1.59), [1.45, 7.69]	0.33 [-3.26, 3.91], 0.857	0.02 [-0.18, 0.22]
Month 3	3.92 (1.50), [0.97, 6.86]	4.33 (1.58), [1.22, 7.43]	-0.41 [-4.01, 3.19], 0.823	-0.02 [-0.22, 0.18]
Month 6	4.18 (1.47), [1.28, 7.08]	4.39 (1.55), [1.33, 7.45]	-0.21 [-3.73, 3.30], 0.904	-0.01 [-0.21, 0.19]
Month 9	4.43 (1.46), [1.55, 7.31]	4.45 (1.55), [1.41, 7.50]	-0.02 [-3.51, 3.47], 0.991	0.00 [-0.20, 0.20]
Month 12	4.69 (1.47), [1.80, 7.58]	4.52 (1.56), [1.45, 7.59]	0.17 [-3.35, 3.69], 0.923	0.01 [-0.19, 0.21]
Month 15	4.95 (1.49), [2.02, 7.88]	4.58 (1.59), [1.45, 7.72]	0.37 [-3.24, 3.97], 0.841	0.02 [-0.18, 0.22]
Month 18	5.21 (1.52), [2.22, 8.20]	4.65 (1.65), [1.41, 7.88]	0.56 [-3.18, 4.30], 0.768	0.03 [-0.17, 0.23]
Month 21	5.47 (1.56), [2.39, 8.54]	4.71 (1.71), [1.34, 8.08]	0.75 [-3.17, 4.68], 0.705	0.04 [-0.16, 0.24]
Month 24	5.72 (1.62), [2.54, 8.91]	4.77 (1.79), [1.25, 8.30]	0.95 [-3.20, 5.10], 0.653	0.05 [-0.15, 0.25]
Month 27	5.98 (1.69), [2.66, 9.30]	4.84 (1.89), [1.12, 8.55]	1.14 [-3.27, 5.55], 0.610	0.05 [-0.15, 0.26]
Month 30	6.24 (1.76), [2.77, 9.71]	4.90 (1.99), [0.98, 8.83]	1.34 [-3.36, 6.03], 0.575	0.06 [-0.14, 0.26]
Month 33	6.50 (1.84), [2.87, 10.13]	4.97 (2.11), [0.82, 9.12]	1.53 [-3.48, 6.54], 0.547	0.07 [-0.13, 0.27]
Month 36	6.76 (1.93), [2.95, 10.57]	5.03 (2.23), [0.64, 9.42]	1.72 [-3.61, 7.06], 0.525	0.08 [-0.12, 0.28]
Month 39	7.01 (2.03), [3.01, 11.01]	5.09 (2.36), [0.45, 9.74]	1.92 [-3.76, 7.60], 0.506	0.09 [-0.11, 0.29]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.9: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Financial Difficulties scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-0.67 (1.10), [-2.84, 1.50]	-2.50 (1.19), [-4.84, -0.15]	1.83 [-0.84, 4.50], 0.179	0.08 [-0.12, 0.28]
Month 3	-1.26 (1.20), [-3.62, 1.11]	-0.87 (1.27), [-3.37, 1.64]	-0.39 [-3.36, 2.58], 0.797	-0.02 [-0.22, 0.18]
Month 6	-1.10 (1.14), [-3.35, 1.15]	-1.30 (1.21), [-3.67, 1.08]	0.19 [-2.57, 2.95], 0.890	0.01 [-0.19, 0.21]
Month 9	-0.95 (1.11), [-3.12, 1.23]	-1.72 (1.17), [-4.03, 0.58]	0.78 [-1.86, 3.42], 0.563	0.04 [-0.17, 0.24]
Month 12	-0.79 (1.09), [-2.94, 1.36]	-2.15 (1.17), [-4.45, 0.15]	1.36 [-1.26, 3.97], 0.308	0.06 [-0.14, 0.26]
Month 15	-0.64 (1.11), [-2.81, 1.54]	-2.58 (1.20), [-4.94, -0.21]	1.94 [-0.75, 4.63], 0.157	0.09 [-0.11, 0.29]
Month 18	-0.48 (1.14), [-2.73, 1.77]	-3.00 (1.27), [-5.49, -0.52]	2.52 [-0.34, 5.39], 0.084	0.11 [-0.09, 0.32]
Month 21	-0.33 (1.21), [-2.70, 2.05]	-3.43 (1.35), [-6.10, -0.77]	3.11 [-0.01, 6.22], 0.050	0.14 [-0.06, 0.34]
Month 24	-0.17 (1.29), [-2.70, 2.36]	-3.86 (1.47), [-6.74, -0.98]	3.69 [0.27, 7.11], 0.035	0.17 [-0.03, 0.37]
Month 27	-0.01 (1.38), [-2.73, 2.71]	-4.29 (1.59), [-7.42, -1.15]	4.27 [0.50, 8.05], 0.027	0.19 [-0.01, 0.39]
Month 30	0.14 (1.49), [-2.80, 3.08]	-4.71 (1.74), [-8.13, -1.30]	4.85 [0.69, 9.02], 0.023	0.22 [0.02, 0.42]
Month 33	0.30 (1.61), [-2.88, 3.47]	-5.14 (1.89), [-8.86, -1.43]	5.44 [0.86, 10.02], 0.020	0.25 [0.05, 0.45]
Month 36	0.45 (1.74), [-2.97, 3.87]	-5.57 (2.05), [-9.60, -1.54]	6.02 [1.01, 11.03], 0.019	0.27 [0.07, 0.47]
Month 39	0.61 (1.87), [-3.08, 4.30]	-6.00 (2.21), [-10.36, -1.64]	6.60 [1.14, 12.06], 0.018	0.30 [0.10, 0.50]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.10: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Nausea/Vomiting scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	1.34 (0.58), [0.20, 2.48]	0.98 (0.62), [-0.25, 2.21]	0.36 [-1.03, 1.75], 0.612	0.06 [-0.14, 0.26]
Month 3	1.37 (0.65), [0.09, 2.65]	1.13 (0.69), [-0.22, 2.48]	0.24 [-1.37, 1.85], 0.771	0.04 [-0.16, 0.24]
Month 6	1.36 (0.62), [0.14, 2.58]	1.09 (0.66), [-0.20, 2.38]	0.27 [-1.24, 1.78], 0.725	0.04 [-0.16, 0.24]
Month 9	1.35 (0.60), [0.18, 2.53]	1.05 (0.63), [-0.19, 2.30]	0.30 [-1.13, 1.74], 0.679	0.05 [-0.15, 0.25]
Month 12	1.35 (0.58), [0.20, 2.49]	1.01 (0.62), [-0.21, 2.24]	0.33 [-1.06, 1.73], 0.639	0.05 [-0.15, 0.25]
Month 15	1.34 (0.58), [0.20, 2.48]	0.98 (0.63), [-0.26, 2.21]	0.36 [-1.03, 1.76], 0.606	0.06 [-0.14, 0.26]
Month 18	1.33 (0.58), [0.19, 2.48]	0.94 (0.64), [-0.33, 2.20]	0.40 [-1.03, 1.82], 0.585	0.06 [-0.14, 0.26]
Month 21	1.33 (0.60), [0.15, 2.50]	0.90 (0.67), [-0.42, 2.22]	0.43 [-1.07, 1.93], 0.574	0.07 [-0.13, 0.27]
Month 24	1.32 (0.62), [0.10, 2.54]	0.86 (0.70), [-0.53, 2.25]	0.46 [-1.14, 2.06], 0.571	0.07 [-0.13, 0.27]
Month 27	1.31 (0.65), [0.03, 2.60]	0.82 (0.75), [-0.66, 2.31]	0.49 [-1.24, 2.22], 0.575	0.08 [-0.12, 0.28]
Month 30	1.31 (0.69), [-0.05, 2.67]	0.78 (0.80), [-0.81, 2.37]	0.52 [-1.35, 2.40], 0.582	0.08 [-0.12, 0.28]
Month 33	1.30 (0.73), [-0.15, 2.74]	0.75 (0.86), [-0.96, 2.45]	0.55 [-1.48, 2.59], 0.591	0.09 [-0.11, 0.29]
Month 36	1.29 (0.78), [-0.25, 2.83]	0.71 (0.93), [-1.13, 2.54]	0.58 [-1.62, 2.79], 0.600	0.09 [-0.11, 0.29]
Month 39	1.28 (0.83), [-0.36, 2.93]	0.67 (0.99), [-1.30, 2.64]	0.62 [-1.77, 3.00], 0.610	0.10 [-0.10, 0.30]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.11: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Dyspnoea scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	4.33 (1.27), [1.83, 6.83]	3.53 (1.38), [0.82, 6.25]	0.80 [-2.33, 3.92], 0.616	0.04 [-0.16, 0.24]
Month 3	2.46 (1.29), [-0.07, 4.99]	2.55 (1.36), [-0.13, 5.23]	-0.09 [-3.22, 3.03], 0.953	-0.01 [-0.21, 0.20]
Month 6	2.95 (1.25), [0.50, 5.41]	2.81 (1.32), [0.22, 5.41]	0.14 [-2.84, 3.12], 0.926	0.01 [-0.19, 0.21]
Month 9	3.45 (1.23), [1.03, 5.87]	3.07 (1.31), [0.50, 5.65]	0.38 [-2.56, 3.32], 0.802	0.02 [-0.18, 0.22]
Month 12	3.95 (1.24), [1.50, 6.39]	3.33 (1.33), [0.71, 5.96]	0.61 [-2.39, 3.61], 0.690	0.03 [-0.17, 0.23]
Month 15	4.44 (1.28), [1.92, 6.96]	3.60 (1.39), [0.85, 6.34]	0.84 [-2.32, 4.01], 0.600	0.05 [-0.15, 0.25]
Month 18	4.94 (1.34), [2.29, 7.58]	3.86 (1.48), [0.94, 6.78]	1.08 [-2.34, 4.49], 0.534	0.06 [-0.14, 0.26]
Month 21	5.43 (1.43), [2.62, 8.24]	4.12 (1.60), [0.97, 7.26]	1.31 [-2.42, 5.05], 0.489	0.07 [-0.13, 0.27]
Month 24	5.93 (1.53), [2.92, 8.93]	4.38 (1.73), [0.96, 7.79]	1.55 [-2.55, 5.65], 0.458	0.08 [-0.12, 0.28]
Month 27	6.42 (1.64), [3.19, 9.66]	4.64 (1.89), [0.93, 8.35]	1.78 [-2.73, 6.30], 0.437	0.10 [-0.10, 0.30]
Month 30	6.92 (1.77), [3.43, 10.40]	4.90 (2.05), [0.86, 8.93]	2.02 [-2.94, 6.97], 0.423	0.11 [-0.09, 0.31]
Month 33	7.41 (1.91), [3.66, 11.16]	5.16 (2.22), [0.79, 9.53]	2.25 [-3.16, 7.67], 0.413	0.12 [-0.08, 0.32]
Month 36	7.91 (2.05), [3.87, 11.94]	5.42 (2.40), [0.69, 10.15]	2.49 [-3.41, 8.38], 0.407	0.13 [-0.07, 0.34]
Month 39	8.40 (2.20), [4.07, 12.73]	5.68 (2.59), [0.58, 10.78]	2.72 [-3.67, 9.11], 0.402	0.15 [-0.05, 0.35]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table A4.1.1.12: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Insomnia scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	1.69 (1.51), [-1.29, 4.66]	2.38 (1.63), [-0.82, 5.59]	-0.69 [-4.35, 2.96], 0.709	-0.03 [-0.23, 0.17]
Month 3	2.46 (1.62), [-0.74, 5.65]	1.18 (1.72), [-2.20, 4.55]	1.28 [-2.70, 5.27], 0.527	0.05 [-0.15, 0.25]
Month 6	2.26 (1.56), [-0.82, 5.33]	1.49 (1.65), [-1.75, 4.74]	0.76 [-3.01, 4.54], 0.691	0.03 [-0.17, 0.23]
Month 9	2.05 (1.52), [-0.94, 5.05]	1.81 (1.62), [-1.37, 4.99]	0.24 [-3.41, 3.89], 0.896	0.01 [-0.19, 0.21]
Month 12	1.85 (1.51), [-1.12, 4.82]	2.13 (1.61), [-1.04, 5.30]	-0.28 [-3.89, 3.34], 0.880	-0.01 [-0.21, 0.19]
Month 15	1.65 (1.52), [-1.33, 4.63]	2.45 (1.64), [-0.78, 5.67]	-0.80 [-4.47, 2.88], 0.670	-0.03 [-0.23, 0.17]
Month 18	1.45 (1.55), [-1.60, 4.49]	2.76 (1.70), [-0.58, 6.10]	-1.32 [-5.14, 2.51], 0.498	-0.05 [-0.25, 0.15]
Month 21	1.24 (1.60), [-1.91, 4.39]	3.08 (1.78), [-0.43, 6.59]	-1.84 [-5.89, 2.22], 0.373	-0.07 [-0.27, 0.13]
Month 24	1.04 (1.68), [-2.26, 4.34]	3.40 (1.89), [-0.33, 7.12]	-2.36 [-6.71, 2.00], 0.287	-0.09 [-0.29, 0.11]
Month 27	0.84 (1.77), [-2.64, 4.32]	3.72 (2.02), [-0.26, 7.70]	-2.88 [-7.58, 1.83], 0.229	-0.11 [-0.31, 0.09]
Month 30	0.64 (1.87), [-3.05, 4.33]	4.03 (2.17), [-0.23, 8.30]	-3.40 [-8.50, 1.70], 0.191	-0.13 [-0.34, 0.07]
Month 33	0.43 (1.99), [-3.49, 4.36]	4.35 (2.33), [-0.23, 8.93]	-3.92 [-9.45, 1.61], 0.164	-0.16 [-0.36, 0.05]
Month 36	0.23 (2.12), [-3.95, 4.41]	4.67 (2.50), [-0.25, 9.59]	-4.44 [-10.43, 1.55], 0.145	-0.18 [-0.38, 0.02]
Month 39	0.03 (2.26), [-4.43, 4.48]	4.99 (2.67), [-0.28, 10.26]	-4.96 [-11.43, 1.51], 0.132	-0.20 [-0.40, 0.00]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
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Table A4.1.1.13: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Appetite Loss scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-1.44 (1.22), [-3.85, 0.97]	-2.63 (1.32), [-5.23, -0.03]	1.20 [-1.76, 4.15], 0.426	0.05 [-0.15, 0.25]
Month 3	0.75 (1.46), [-2.12, 3.62]	-1.06 (1.54), [-4.07, 1.96]	1.81 [-1.87, 5.48], 0.335	0.07 [-0.13, 0.27]
Month 6	0.16 (1.37), [-2.53, 2.86]	-1.48 (1.44), [-4.32, 1.36]	1.64 [-1.75, 5.04], 0.341	0.07 [-0.13, 0.27]
Month 9	-0.43 (1.30), [-2.98, 2.13]	-1.91 (1.38), [-4.62, 0.79]	1.48 [-1.68, 4.65], 0.358	0.06 [-0.14, 0.26]
Month 12	-1.02 (1.25), [-3.47, 1.44]	-2.34 (1.33), [-4.97, 0.29]	1.32 [-1.69, 4.34], 0.388	0.05 [-0.15, 0.25]
Month 15	-1.60 (1.22), [-4.01, 0.80]	-2.77 (1.32), [-5.37, -0.17]	1.16 [-1.78, 4.11], 0.437	0.05 [-0.15, 0.25]
Month 18	-2.19 (1.21), [-4.58, 0.20]	-3.20 (1.34), [-5.83, -0.56]	1.00 [-1.96, 3.97], 0.506	0.04 [-0.16, 0.24]
Month 21	-2.78 (1.23), [-5.21, -0.36]	-3.63 (1.38), [-6.35, -0.90]	0.84 [-2.23, 3.92], 0.589	0.03 [-0.17, 0.23]
Month 24	-3.37 (1.27), [-5.88, -0.87]	-4.05 (1.46), [-6.92, -1.19]	0.68 [-2.58, 3.94], 0.680	0.03 [-0.17, 0.23]
Month 27	-3.96 (1.33), [-6.59, -1.33]	-4.48 (1.55), [-7.53, -1.43]	0.52 [-2.99, 4.04], 0.770	0.02 [-0.18, 0.22]
Month 30	-4.55 (1.41), [-7.33, -1.77]	-4.91 (1.66), [-8.19, -1.63]	0.36 [-3.46, 4.18], 0.852	0.01 [-0.19, 0.21]
Month 33	-5.14 (1.50), [-8.11, -2.17]	-5.34 (1.79), [-8.87, -1.81]	0.20 [-3.97, 4.37], 0.924	0.01 [-0.19, 0.21]
Month 36	-5.73 (1.61), [-8.91, -2.55]	-5.77 (1.93), [-9.57, -1.96]	0.04 [-4.51, 4.59], 0.986	0.00 [-0.20, 0.20]
Month 39	-6.31 (1.73), [-9.73, -2.90]	-6.20 (2.08), [-10.29, -2.10]	-0.12 [-5.08, 4.84], 0.962	0.00 [-0.21, 0.20]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
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Table A4.1.1.14: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Constipation scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	0.08 (1.09), [-2.06, 2.22]	-0.34 (1.18), [-2.66, 1.99]	0.42 [-2.23, 3.06], 0.756	0.02 [-0.18, 0.22]
Month 3	-0.65 (1.19), [-2.98, 1.68]	-0.57 (1.26), [-3.03, 1.90]	-0.08 [-3.01, 2.84], 0.955	0.00 [-0.20, 0.20]
Month 6	-0.46 (1.13), [-2.68, 1.75]	-0.51 (1.19), [-2.85, 1.83]	0.05 [-2.68, 2.77], 0.972	0.00 [-0.20, 0.20]
Month 9	-0.27 (1.09), [-2.42, 1.87]	-0.45 (1.16), [-2.73, 1.83]	0.18 [-2.43, 2.79], 0.892	0.01 [-0.19, 0.21]
Month 12	-0.08 (1.08), [-2.20, 2.04]	-0.39 (1.16), [-2.67, 1.88]	0.31 [-2.28, 2.90], 0.813	0.02 [-0.19, 0.22]
Month 15	0.11 (1.09), [-2.04, 2.26]	-0.34 (1.19), [-2.68, 2.01]	0.44 [-2.22, 3.11], 0.744	0.02 [-0.18, 0.22]
Month 18	0.30 (1.13), [-1.92, 2.52]	-0.28 (1.25), [-2.75, 2.19]	0.58 [-2.26, 3.41], 0.690	0.03 [-0.17, 0.23]
Month 21	0.49 (1.19), [-1.85, 2.83]	-0.22 (1.34), [-2.87, 2.43]	0.71 [-2.38, 3.79], 0.652	0.03 [-0.17, 0.23]
Month 24	0.68 (1.27), [-1.82, 3.18]	-0.16 (1.46), [-3.03, 2.70]	0.84 [-2.55, 4.23], 0.626	0.04 [-0.16, 0.24]
Month 27	0.87 (1.36), [-1.82, 3.55]	-0.10 (1.58), [-3.22, 3.02]	0.97 [-2.77, 4.71], 0.609	0.05 [-0.15, 0.25]
Month 30	1.06 (1.47), [-1.84, 3.96]	-0.05 (1.73), [-3.45, 3.35]	1.10 [-3.02, 5.23], 0.598	0.05 [-0.15, 0.25]
Month 33	1.25 (1.59), [-1.88, 4.38]	0.01 (1.88), [-3.69, 3.71]	1.24 [-3.30, 5.77], 0.592	0.06 [-0.14, 0.26]
Month 36	1.44 (1.71), [-1.94, 4.82]	0.07 (2.04), [-3.95, 4.09]	1.37 [-3.59, 6.33], 0.587	0.07 [-0.13, 0.27]
Month 39	1.63 (1.85), [-2.01, 5.27]	0.13 (2.20), [-4.22, 4.47]	1.50 [-3.91, 6.90], 0.585	0.07 [-0.13, 0.27]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
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Table A4.1.1.15: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Diarrhoea scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	2.27 (0.84), [0.62, 3.92]	1.70 (0.92), [-0.11, 3.52]	0.56 [-1.51, 2.63], 0.592	0.05 [-0.15, 0.25]
Month 3	1.83 (0.91), [0.05, 3.62]	1.80 (0.97), [-0.10, 3.70]	0.04 [-2.22, 2.29], 0.974	0.00 [-0.20, 0.20]
Month 6	1.95 (0.85), [0.27, 3.62]	1.77 (0.90), [0.00, 3.55]	0.18 [-1.88, 2.23], 0.866	0.02 [-0.18, 0.22]
Month 9	2.06 (0.82), [0.45, 3.68]	1.75 (0.88), [0.03, 3.47]	0.31 [-1.64, 2.27], 0.752	0.03 [-0.17, 0.23]
Month 12	2.18 (0.82), [0.57, 3.79]	1.72 (0.89), [-0.02, 3.47]	0.45 [-1.52, 2.43], 0.652	0.04 [-0.16, 0.24]
Month 15	2.29 (0.85), [0.62, 3.96]	1.70 (0.94), [-0.14, 3.54]	0.59 [-1.51, 2.70], 0.580	0.05 [-0.15, 0.25]
Month 18	2.40 (0.90), [0.63, 4.18]	1.67 (1.02), [-0.33, 3.67]	0.73 [-1.60, 3.06], 0.537	0.07 [-0.13, 0.27]
Month 21	2.52 (0.98), [0.59, 4.44]	1.65 (1.12), [-0.56, 3.86]	0.87 [-1.75, 3.49], 0.514	0.08 [-0.12, 0.28]
Month 24	2.63 (1.07), [0.52, 4.74]	1.62 (1.25), [-0.83, 4.08]	1.01 [-1.95, 3.97], 0.503	0.09 [-0.11, 0.29]
Month 27	2.75 (1.18), [0.42, 5.07]	1.60 (1.39), [-1.13, 4.33]	1.15 [-2.19, 4.48], 0.499	0.11 [-0.10, 0.31]
Month 30	2.86 (1.30), [0.30, 5.42]	1.57 (1.53), [-1.45, 4.60]	1.29 [-2.45, 5.02], 0.498	0.12 [-0.08, 0.32]
Month 33	2.97 (1.42), [0.17, 5.78]	1.55 (1.69), [-1.78, 4.88]	1.42 [-2.73, 5.58], 0.500	0.13 [-0.07, 0.33]
Month 36	3.09 (1.55), [0.03, 6.15]	1.52 (1.85), [-2.12, 5.17]	1.56 [-3.02, 6.15], 0.502	0.14 [-0.06, 0.34]
Month 39	3.20 (1.69), [-0.13, 6.53]	1.50 (2.02), [-2.47, 5.47]	1.70 [-3.32, 6.72], 0.505	0.16 [-0.04, 0.36]

Note(s): A negative change from baseline value indicates improvement of symptoms. A negative difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	29 (18.4%)	33 (20.8%)
Odds ratio (95% CI)	0.899 (0.513, 1.575)	
P-value for Odds Ratio	0.7094	
Relative Risk (95% CI)	0.91 (0.58, 1.42)	
P-value for Relative Risk	0.6860	
Risk difference (95% CI)	-0.65 (-9.37, 8.07)	
P-value for Risk Difference	0.8837	
Improvement	30 (19.0%)	34 (21.4%)
Odds ratio (95% CI)	0.833 (0.476, 1.456)	
P-value for Odds Ratio	0.5208	
Relative Risk (95% CI)	0.87 (0.56, 1.35)	
P-value for Relative Risk	0.5413	
Risk difference (95% CI)	-3.56 (-12.09, 4.96)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4124	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	34 (22.4%)	26 (18.8%)
Odds ratio (95% CI)	1.277 (0.716, 2.280)	
P-value for Odds Ratio	0.4077	
Relative Risk (95% CI)	1.22 (0.78, 1.91)	
P-value for Relative Risk	0.3913	
Risk difference (95% CI)	3.26 (-5.74, 12.26)	
P-value for Risk Difference	0.4779	
Improvement	25 (16.4%)	27 (19.6%)
Odds ratio (95% CI)	0.795 (0.434, 1.456)	
P-value for Odds Ratio	0.4577	
Relative Risk (95% CI)	0.82 (0.50, 1.35)	
P-value for Relative Risk	0.4405	
Risk difference (95% CI)	-2.94 (-11.78, 5.90)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5149	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	32 (22.2%)	30 (23.6%)
Odds ratio (95% CI)	0.981 (0.545, 1.766)	
P-value for Odds Ratio	0.9489	
Relative Risk (95% CI)	0.97 (0.64, 1.48)	
P-value for Relative Risk	0.9057	
Risk difference (95% CI)	-3.08 (-13.74, 7.58)	
P-value for Risk Difference	0.5716	
Improvement	28 (19.4%)	28 (22.0%)
Odds ratio (95% CI)	0.785 (0.430, 1.435)	
P-value for Odds Ratio	0.4322	
Relative Risk (95% CI)	0.86 (0.54, 1.36)	
P-value for Relative Risk	0.5182	
Risk difference (95% CI)	-4.77 (-14.18, 4.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3202	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	150
Deterioration	44 (27.8%)	38 (25.3%)
Odds ratio (95% CI)	1.149 (0.689, 1.915)	
P-value for Odds Ratio	0.5944	
Relative Risk (95% CI)	1.10 (0.75, 1.59)	
P-value for Relative Risk	0.6337	
Risk difference (95% CI)	3.33 (-6.43, 13.10)	
P-value for Risk Difference	0.5035	
Improvement	22 (13.9%)	30 (20.0%)
Odds ratio (95% CI)	0.646 (0.350, 1.190)	
P-value for Odds Ratio	0.1609	
Relative Risk (95% CI)	0.71 (0.43, 1.17)	
P-value for Relative Risk	0.1817	
Risk difference (95% CI)	-6.69 (-14.62, 1.25)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0986	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	25 (18.7%)	16 (16.3%)
Odds ratio (95% CI)	1.252 (0.614, 2.552)	
P-value for Odds Ratio	0.5366	
Relative Risk (95% CI)	1.19 (0.68, 2.08)	
P-value for Relative Risk	0.5353	
Risk difference (95% CI)	2.76 (-6.61, 12.13)	
P-value for Risk Difference	0.5637	
Improvement	22 (16.4%)	19 (19.4%)
Odds ratio (95% CI)	0.781 (0.390, 1.562)	
P-value for Odds Ratio	0.4841	
Relative Risk (95% CI)	0.85 (0.49, 1.48)	
P-value for Relative Risk	0.5736	
Risk difference (95% CI)	-4.57 (-14.53, 5.38)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3676	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	32 (27.4%)	13 (15.7%)
Odds ratio (95% CI)	2.235 (1.075, 4.649)	
P-value for Odds Ratio	0.0313	
Relative Risk (95% CI)	1.85 (1.04, 3.29)	
P-value for Relative Risk	0.0353	
Risk difference (95% CI)	12.00 (1.04, 22.96)	
P-value for Risk Difference	0.0319	
Improvement	17 (14.5%)	20 (24.1%)
Odds ratio (95% CI)	0.500 (0.240, 1.041)	
P-value for Odds Ratio	0.0638	
Relative Risk (95% CI)	0.59 (0.33, 1.04)	
P-value for Relative Risk	0.0700	
Risk difference (95% CI)	-10.76 (-21.82, 0.31)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0567	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	19 (19.2%)	16 (25.0%)
Odds ratio (95% CI)	0.781 (0.361, 1.692)	
P-value for Odds Ratio	0.5314	
Relative Risk (95% CI)	0.84 (0.47, 1.49)	
P-value for Relative Risk	0.5422	
Risk difference (95% CI)	-4.77 (-17.30, 7.77)	
P-value for Risk Difference	0.4559	
Improvement	19 (19.2%)	11 (17.2%)
Odds ratio (95% CI)	1.114 (0.487, 2.549)	
P-value for Odds Ratio	0.7983	
Relative Risk (95% CI)	1.10 (0.56, 2.17)	
P-value for Relative Risk	0.7742	
Risk difference (95% CI)	0.89 (-11.34, 13.12)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8865	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	25 (28.7%)	11 (20.0%)
Odds ratio (95% CI)	1.767 (0.775, 4.032)	
P-value for Odds Ratio	0.1761	
Relative Risk (95% CI)	1.49 (0.81, 2.76)	
P-value for Relative Risk	0.2038	
Risk difference (95% CI)	9.46 (-4.70, 23.61)	
P-value for Risk Difference	0.1904	
Improvement	11 (12.6%)	10 (18.2%)
Odds ratio (95% CI)	0.627 (0.244, 1.611)	
P-value for Odds Ratio	0.3325	
Relative Risk (95% CI)	0.68 (0.31, 1.50)	
P-value for Relative Risk	0.3434	
Risk difference (95% CI)	-6.39 (-18.63, 5.85)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3065	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	16 (20.8%)	9 (20.9%)
Odds ratio (95% CI)	1.091 (0.430, 2.771)	
P-value for Odds Ratio	0.8540	
Relative Risk (95% CI)	1.05 (0.51, 2.16)	
P-value for Relative Risk	0.8863	
Risk difference (95% CI)	3.53 (-12.88, 19.93)	
P-value for Risk Difference	0.6735	
Improvement	12 (15.6%)	8 (18.6%)
Odds ratio (95% CI)	0.755 (0.277, 2.059)	
P-value for Odds Ratio	0.5829	
Relative Risk (95% CI)	0.79 (0.35, 1.79)	
P-value for Relative Risk	0.5710	
Risk difference (95% CI)	-3.46 (-17.52, 10.61)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6299	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	20 (32.8%)	7 (18.9%)
Odds ratio (95% CI)	2.200 (0.778, 6.221)	
P-value for Odds Ratio	0.1369	
Relative Risk (95% CI)	1.63 (0.80, 3.36)	
P-value for Relative Risk	0.1811	
Risk difference (95% CI)	12.69 (-3.79, 29.17)	
P-value for Risk Difference	0.1312	
Improvement	6 (9.8%)	4 (10.8%)
Odds ratio (95% CI)	0.810 (0.206, 3.185)	
P-value for Odds Ratio	0.7634	
Relative Risk (95% CI)	0.86 (0.26, 2.83)	
P-value for Relative Risk	0.8032	
Risk difference (95% CI)	-1.98 (-15.35, 11.38)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7713	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	15 (42.9%)	6 (20.0%)
Odds ratio (95% CI)	2.784 (0.858, 9.028)	
P-value for Odds Ratio	0.0881	
Relative Risk (95% CI)	1.77 (0.79, 3.98)	
P-value for Relative Risk	0.1648	
Risk difference (95% CI)	22.48 (22.48, 22.48)*	
P-value for Risk Difference	NE	
Improvement	3 (8.6%)	5 (16.7%)
Odds ratio (95% CI)	0.540 (0.105, 2.776)	
P-value for Odds Ratio	0.4603	
Relative Risk (95% CI)	0.58 (0.14, 2.40)	
P-value for Relative Risk	0.4540	
Risk difference (95% CI)	-6.13 (-21.66, 9.39)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4386	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	9 (31.0%)	6 (28.6%)
Odds ratio (95% CI)	1.008 (0.278, 3.658)	
P-value for Odds Ratio	0.9900	
Relative Risk (95% CI)	1.06 (0.42, 2.68)	
P-value for Relative Risk	0.9021	
Risk difference (95% CI)	-0.88 (-25.73, 23.96)	
P-value for Risk Difference	0.9444	
Improvement	1 (3.4%)	2 (9.5%)
Odds ratio (95% CI)	0.378 (0.031, 4.631)	
P-value for Odds Ratio	0.4467	
Relative Risk (95% CI)	0.34 (0.34, 0.34)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-6.12 (-40.57, 28.33)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7277	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	5 (25.0%)	3 (18.8%)
Odds ratio (95% CI)	2.547 (0.374, 17.361)	
P-value for Odds Ratio	0.3398	
Relative Risk (95% CI)	1.56 (0.49, 4.95)	
P-value for Relative Risk	0.4472	
Risk difference (95% CI)	13.42 (-16.99, 43.84)	
P-value for Risk Difference	0.3870	
Improvement	2 (10.0%)	1 (6.3%)
Odds ratio (95% CI)	2.250 (0.170, 29.767)	
P-value for Odds Ratio	0.5383	
Relative Risk (95% CI)	2.00 (0.21, 18.69)	
P-value for Relative Risk	0.5432	
Risk difference (95% CI)	4.26 (-30.41, 38.93)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8097	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	3 (60.0%)	3 (42.9%)
Odds ratio (95% CI)	2.023 (0.076, 53.630)	
P-value for Odds Ratio	0.6736	
Relative Risk (95% CI)	1.10 (0.45, 2.68)	
P-value for Relative Risk	0.8386	
Risk difference (95% CI)	7.58 (-70.07, 85.23)	
P-value for Risk Difference	0.8483	
Improvement	0	2 (28.6%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.33 (0.02, 4.85)	
P-value for Relative Risk	0.3778	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (50.0%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.04, 7.10)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Global health status / QoL :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	27 (17.1%)	28 (17.6%)
Odds ratio (95% CI)	0.960 (0.531, 1.737)	
P-value for Odds Ratio	0.8939	
Relative Risk (95% CI)	0.95 (0.59, 1.53)	
P-value for Relative Risk	0.8430	
Risk difference (95% CI)	-0.96 (-8.72, 6.79)	
P-value for Risk Difference	0.8076	
Improvement	26 (16.5%)	16 (10.1%)
Odds ratio (95% CI)	1.802 (0.918, 3.537)	
P-value for Odds Ratio	0.0872	
Relative Risk (95% CI)	1.65 (0.92, 2.94)	
P-value for Relative Risk	0.0923	
Risk difference (95% CI)	5.35 (-1.99, 12.69)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1533	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	22 (14.5%)	23 (16.7%)
Odds ratio (95% CI)	0.860 (0.454, 1.633)	
P-value for Odds Ratio	0.6456	
Relative Risk (95% CI)	0.88 (0.52, 1.51)	
P-value for Relative Risk	0.6466	
Risk difference (95% CI)	-2.46 (-10.58, 5.65)	
P-value for Risk Difference	0.5523	
Improvement	21 (13.8%)	8 (5.8%)
Odds ratio (95% CI)	2.633 (1.123, 6.171)	
P-value for Odds Ratio	0.0259	
Relative Risk (95% CI)	2.40 (1.10, 5.24)	
P-value for Relative Risk	0.0284	
Risk difference (95% CI)	9.44 (2.03, 16.85)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0125	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	23 (16.0%)	22 (17.3%)
Odds ratio (95% CI)	0.928 (0.485, 1.776)	
P-value for Odds Ratio	0.8208	
Relative Risk (95% CI)	0.95 (0.56, 1.62)	
P-value for Relative Risk	0.8589	
Risk difference (95% CI)	-2.05 (-10.55, 6.46)	
P-value for Risk Difference	0.6372	
Improvement	21 (14.6%)	12 (9.4%)
Odds ratio (95% CI)	1.727 (0.808, 3.694)	
P-value for Odds Ratio	0.1587	
Relative Risk (95% CI)	1.58 (0.82, 3.08)	
P-value for Relative Risk	0.1738	
Risk difference (95% CI)	7.89 (-1.08, 16.87)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0848	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	31 (19.5%)	28 (18.7%)
Odds ratio (95% CI)	1.050 (0.593, 1.860)	
P-value for Odds Ratio	0.8676	
Relative Risk (95% CI)	1.03 (0.65, 1.64)	
P-value for Relative Risk	0.8843	
Risk difference (95% CI)	0.90 (-7.80, 9.59)	
P-value for Risk Difference	0.8394	
Improvement	27 (17.0%)	15 (10.0%)
Odds ratio (95% CI)	1.927 (0.974, 3.811)	
P-value for Odds Ratio	0.0594	
Relative Risk (95% CI)	1.72 (0.96, 3.09)	
P-value for Relative Risk	0.0699	
Risk difference (95% CI)	9.50 (1.23, 17.76)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0244	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

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Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	133	98
Deterioration	23 (17.3%)	17 (17.3%)
Odds ratio (95% CI)	1.100 (0.542, 2.229)	
P-value for Odds Ratio	0.7924	
Relative Risk (95% CI)	1.06 (0.61, 1.86)	
P-value for Relative Risk	0.8337	
Risk difference (95% CI)	1.68 (-7.63, 10.98)	
P-value for Risk Difference	0.7240	
Improvement	22 (16.5%)	5 (5.1%)
Odds ratio (95% CI)	3.687 (1.323, 10.280)	
P-value for Odds Ratio	0.0126	
Relative Risk (95% CI)	3.16 (1.25, 8.02)	
P-value for Relative Risk	0.0154	
Risk difference (95% CI)	9.08 (-3.01, 21.17)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1409	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	23 (19.7%)	21 (25.3%)
Odds ratio (95% CI)	0.769 (0.388, 1.522)	
P-value for Odds Ratio	0.4508	
Relative Risk (95% CI)	0.82 (0.49, 1.37)	
P-value for Relative Risk	0.4427	
Risk difference (95% CI)	-3.76 (-16.04, 8.52)	
P-value for Risk Difference	0.5481	
Improvement	13 (11.1%)	3 (3.6%)
Odds ratio (95% CI)	3.200 (0.873, 11.730)	
P-value for Odds Ratio	0.0792	
Relative Risk (95% CI)	1.46 (1.46, 1.46)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	6.06 (-4.70, 16.81)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2699	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	13 (13.1%)	10 (15.6%)
Odds ratio (95% CI)	0.919 (0.370, 2.285)	
P-value for Odds Ratio	0.8559	
Relative Risk (95% CI)	0.93 (0.44, 1.98)	
P-value for Relative Risk	0.8478	
Risk difference (95% CI)	-0.06 (-11.64, 11.52)	
P-value for Risk Difference	0.9917	
Improvement	19 (19.2%)	4 (6.3%)
Odds ratio (95% CI)	3.391 (1.089, 10.566)	
P-value for Odds Ratio	0.0352	
Relative Risk (95% CI)	2.90 (1.03, 8.10)	
P-value for Relative Risk	0.0429	
Risk difference (95% CI)	11.14 (-2.02, 24.31)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0971	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	15 (17.2%)	9 (16.4%)
Odds ratio (95% CI)	1.142 (0.451, 2.893)	
P-value for Odds Ratio	0.7791	
Relative Risk (95% CI)	1.06 (0.51, 2.21)	
P-value for Relative Risk	0.8796	
Risk difference (95% CI)	5.77 (-6.22, 17.76)	
P-value for Risk Difference	0.3456	
Improvement	14 (16.1%)	5 (9.1%)
Odds ratio (95% CI)	2.019 (0.671, 6.073)	
P-value for Odds Ratio	0.2111	
Relative Risk (95% CI)	1.79 (0.69, 4.63)	
P-value for Relative Risk	0.2270	
Risk difference (95% CI)	5.75 (-10.13, 21.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4778	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	10 (13.0%)	5 (11.6%)
Odds ratio (95% CI)	1.229 (0.383, 3.950)	
P-value for Odds Ratio	0.7288	
Relative Risk (95% CI)	1.23 (0.45, 3.34)	
P-value for Relative Risk	0.6811	
Risk difference (95% CI)	-1.26 (-15.94, 13.42)	
P-value for Risk Difference	0.8663	
Improvement	15 (19.5%)	3 (7.0%)
Odds ratio (95% CI)	3.414 (0.913, 12.763)	
P-value for Odds Ratio	0.0680	
Relative Risk (95% CI)	2.78 (0.86, 9.00)	
P-value for Relative Risk	0.0888	
Risk difference (95% CI)	11.75 (-7.17, 30.67)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2235	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	14 (23.0%)	9 (24.3%)
Odds ratio (95% CI)	0.924 (0.334, 2.552)	
P-value for Odds Ratio	0.8786	
Relative Risk (95% CI)	0.90 (0.45, 1.80)	
P-value for Relative Risk	0.7717	
Risk difference (95% CI)	-0.72 (-19.14, 17.70)	
P-value for Risk Difference	0.9391	
Improvement	8 (13.1%)	2 (5.4%)
Odds ratio (95% CI)	2.626 (0.509, 13.556)	
P-value for Odds Ratio	0.2489	
Relative Risk (95% CI)	2.35 (0.53, 10.40)	
P-value for Relative Risk	0.2592	
Risk difference (95% CI)	6.05 (-14.03, 26.12)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5549	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	13 (37.1%)	5 (16.7%)
Odds ratio (95% CI)	2.507 (0.755, 8.326)	
P-value for Odds Ratio	0.1333	
Relative Risk (95% CI)	1.96 (0.79, 4.86)	
P-value for Relative Risk	0.1439	
Risk difference (95% CI)	17.65 (17.65, 17.65)*	
P-value for Risk Difference	NE	
Improvement	3 (8.6%)	1 (3.3%)
Odds ratio (95% CI)	2.952 (0.275, 31.648)	
P-value for Odds Ratio	0.3710	
Relative Risk (95% CI)	2.82 (0.32, 24.78)	
P-value for Relative Risk	0.3507	
Risk difference (95% CI)	4.54 (-20.29, 29.36)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7203	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	8 (27.6%)	5 (23.8%)
Odds ratio (95% CI)	1.252 (0.338, 4.640)	
P-value for Odds Ratio	0.7364	
Relative Risk (95% CI)	1.16 (0.44, 3.09)	
P-value for Relative Risk	0.7669	
Risk difference (95% CI)	5.30 (-20.12, 30.71)	
P-value for Risk Difference	0.6830	
Improvement	3 (10.3%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.41 (0.42, 27.47)	
P-value for Relative Risk	0.2221	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	4 (20.0%)	2 (12.5%)
Odds ratio (95% CI)	2.307 (0.336, 15.825)	
P-value for Odds Ratio	0.3947	
Relative Risk (95% CI)	1.97 (0.41, 9.32)	
P-value for Relative Risk	0.3948	
Risk difference (95% CI)	9.30 (-14.97, 33.56)	
P-value for Risk Difference	0.4527	
Improvement	2 (10.0%)	1 (6.3%)
Odds ratio (95% CI)	0.726 (0.037, 14.140)	
P-value for Odds Ratio	0.8329	
Relative Risk (95% CI)	0.97 (0.97, 0.97)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-0.71 (-27.84, 26.42)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9593	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	1 (20.0%)	2 (28.6%)
Odds ratio (95% CI)	1.689 (0.054, 53.146)	
P-value for Odds Ratio	0.7659	
Relative Risk (95% CI)	0.58 (0.58, 0.58)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	7.47 (7.47, 7.47)*	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Physical Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	35 (22.2%)	37 (23.3%)
Odds ratio (95% CI)	0.941 (0.555, 1.597)	
P-value for Odds Ratio	0.8229	
Relative Risk (95% CI)	0.95 (0.63, 1.43)	
P-value for Relative Risk	0.8183	
Risk difference (95% CI)	-1.19 (-10.39, 8.01)	
P-value for Risk Difference	0.7996	
Improvement	29 (18.4%)	34 (21.4%)
Odds ratio (95% CI)	0.807 (0.462, 1.409)	
P-value for Odds Ratio	0.4514	
Relative Risk (95% CI)	0.84 (0.54, 1.31)	
P-value for Relative Risk	0.4453	
Risk difference (95% CI)	-3.25 (-12.01, 5.50)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4666	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	39 (25.7%)	34 (24.6%)
Odds ratio (95% CI)	1.030 (0.597, 1.778)	
P-value for Odds Ratio	0.9143	
Relative Risk (95% CI)	1.01 (0.68, 1.49)	
P-value for Relative Risk	0.9644	
Risk difference (95% CI)	0.02 (-9.70, 9.75)	
P-value for Risk Difference	0.9960	
Improvement	31 (20.4%)	26 (18.8%)
Odds ratio (95% CI)	1.088 (0.606, 1.953)	
P-value for Odds Ratio	0.7776	
Relative Risk (95% CI)	1.07 (0.67, 1.71)	
P-value for Relative Risk	0.7789	
Risk difference (95% CI)	1.22 (-7.88, 10.33)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7925	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	51 (35.4%)	30 (23.6%)
Odds ratio (95% CI)	1.800 (1.050, 3.086)	
P-value for Odds Ratio	0.0326	
Relative Risk (95% CI)	1.51 (1.03, 2.22)	
P-value for Relative Risk	0.0335	
Risk difference (95% CI)	11.67 (1.02, 22.32)	
P-value for Risk Difference	0.0317	
Improvement	24 (16.7%)	24 (18.9%)
Odds ratio (95% CI)	0.882 (0.471, 1.651)	
P-value for Odds Ratio	0.6947	
Relative Risk (95% CI)	0.89 (0.53, 1.49)	
P-value for Relative Risk	0.6636	
Risk difference (95% CI)	-1.07 (-10.62, 8.48)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8262	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	43 (27.0%)	38 (25.3%)
Odds ratio (95% CI)	1.102 (0.662, 1.836)	
P-value for Odds Ratio	0.7090	
Relative Risk (95% CI)	1.08 (0.74, 1.57)	
P-value for Relative Risk	0.7061	
Risk difference (95% CI)	1.77 (-8.00, 11.54)	
P-value for Risk Difference	0.7227	
Improvement	38 (23.9%)	30 (20.0%)
Odds ratio (95% CI)	1.288 (0.746, 2.223)	
P-value for Odds Ratio	0.3639	
Relative Risk (95% CI)	1.21 (0.79, 1.84)	
P-value for Relative Risk	0.3807	
Risk difference (95% CI)	4.75 (-4.55, 14.05)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3168	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	40 (29.9%)	20 (20.4%)
Odds ratio (95% CI)	1.851 (0.985, 3.476)	
P-value for Odds Ratio	0.0556	
Relative Risk (95% CI)	1.56 (0.98, 2.48)	
P-value for Relative Risk	0.0612	
Risk difference (95% CI)	9.78 (-0.88, 20.45)	
P-value for Risk Difference	0.0721	
Improvement	30 (22.4%)	21 (21.4%)
Odds ratio (95% CI)	1.033 (0.544, 1.961)	
P-value for Odds Ratio	0.9214	
Relative Risk (95% CI)	1.02 (0.63, 1.67)	
P-value for Relative Risk	0.9283	
Risk difference (95% CI)	1.46 (-9.40, 12.33)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7918	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	36 (30.8%)	16 (19.3%)
Odds ratio (95% CI)	2.068 (1.043, 4.098)	
P-value for Odds Ratio	0.0374	
Relative Risk (95% CI)	1.68 (1.01, 2.80)	
P-value for Relative Risk	0.0465	
Risk difference (95% CI)	13.15 (-0.03, 26.33)	
P-value for Risk Difference	0.0505	
Improvement	23 (19.7%)	19 (22.9%)
Odds ratio (95% CI)	0.847 (0.425, 1.688)	
P-value for Odds Ratio	0.6361	
Relative Risk (95% CI)	0.87 (0.51, 1.50)	
P-value for Relative Risk	0.6202	
Risk difference (95% CI)	-2.49 (-14.30, 9.31)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6788	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	31 (31.3%)	17 (26.6%)
Odds ratio (95% CI)	1.285 (0.635, 2.599)	
P-value for Odds Ratio	0.4858	
Relative Risk (95% CI)	1.19 (0.72, 1.96)	
P-value for Relative Risk	0.5038	
Risk difference (95% CI)	5.81 (-8.96, 20.59)	
P-value for Risk Difference	0.4407	
Improvement	30 (30.3%)	12 (18.8%)
Odds ratio (95% CI)	1.877 (0.874, 4.034)	
P-value for Odds Ratio	0.1066	
Relative Risk (95% CI)	1.61 (0.88, 2.94)	
P-value for Relative Risk	0.1188	
Risk difference (95% CI)	12.05 (-1.20, 25.30)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0746	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	26 (29.9%)	12 (21.8%)
Odds ratio (95% CI)	1.606 (0.723, 3.565)	
P-value for Odds Ratio	0.2447	
Relative Risk (95% CI)	1.39 (0.77, 2.50)	
P-value for Relative Risk	0.2788	
Risk difference (95% CI)	11.10 (-4.07, 26.28)	
P-value for Risk Difference	0.1515	
Improvement	17 (19.5%)	8 (14.5%)
Odds ratio (95% CI)	1.425 (0.565, 3.592)	
P-value for Odds Ratio	0.4530	
Relative Risk (95% CI)	1.33 (0.62, 2.89)	
P-value for Relative Risk	0.4648	
Risk difference (95% CI)	5.09 (-7.15, 17.32)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4152	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	22 (28.6%)	8 (18.6%)
Odds ratio (95% CI)	1.806 (0.710, 4.592)	
P-value for Odds Ratio	0.2148	
Relative Risk (95% CI)	1.49 (0.73, 3.05)	
P-value for Relative Risk	0.2685	
Risk difference (95% CI)	13.00 (-2.59, 28.59)	
P-value for Risk Difference	0.1023	
Improvement	20 (26.0%)	5 (11.6%)
Odds ratio (95% CI)	2.769 (0.949, 8.085)	
P-value for Odds Ratio	0.0624	
Relative Risk (95% CI)	2.32 (0.94, 5.75)	
P-value for Relative Risk	0.0680	
Risk difference (95% CI)	13.79 (-0.06, 27.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0510	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	24 (39.3%)	12 (32.4%)
Odds ratio (95% CI)	1.458 (0.608, 3.496)	
P-value for Odds Ratio	0.3986	
Relative Risk (95% CI)	1.30 (0.74, 2.27)	
P-value for Relative Risk	0.3660	
Risk difference (95% CI)	3.89 (-16.16, 23.94)	
P-value for Risk Difference	0.7038	
Improvement	15 (24.6%)	9 (24.3%)
Odds ratio (95% CI)	1.040 (0.397, 2.722)	
P-value for Odds Ratio	0.9370	
Relative Risk (95% CI)	1.02 (0.50, 2.08)	
P-value for Relative Risk	0.9586	
Risk difference (95% CI)	1.56 (-16.59, 19.70)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8665	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	12 (34.3%)	4 (13.3%)
Odds ratio (95% CI)	3.004 (0.821, 11.000)	
P-value for Odds Ratio	0.0967	
Relative Risk (95% CI)	2.28 (0.82, 6.30)	
P-value for Relative Risk	0.1124	
Risk difference (95% CI)	17.88 (17.88, 17.88)*	
P-value for Risk Difference	NE	
Improvement	6 (17.1%)	7 (23.3%)
Odds ratio (95% CI)	0.806 (0.222, 2.924)	
P-value for Odds Ratio	0.7423	
Relative Risk (95% CI)	0.88 (0.32, 2.41)	
P-value for Relative Risk	0.8035	
Risk difference (95% CI)	-2.97 (-23.60, 17.66)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7780	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	11 (37.9%)	5 (23.8%)
Odds ratio (95% CI)	1.923 (0.539, 6.865)	
P-value for Odds Ratio	0.3137	
Relative Risk (95% CI)	1.61 (0.66, 3.92)	
P-value for Relative Risk	0.2952	
Risk difference (95% CI)	12.86 (-12.79, 38.52)	
P-value for Risk Difference	0.3258	
Improvement	7 (24.1%)	6 (28.6%)
Odds ratio (95% CI)	0.887 (0.240, 3.286)	
P-value for Odds Ratio	0.8581	
Relative Risk (95% CI)	0.93 (0.37, 2.34)	
P-value for Relative Risk	0.8785	
Risk difference (95% CI)	-2.50 (-29.27, 24.26)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8546	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	7 (35.0%)	3 (18.8%)
Odds ratio (95% CI)	4.089 (0.630, 26.546)	
P-value for Odds Ratio	0.1401	
Relative Risk (95% CI)	2.10 (0.55, 8.10)	
P-value for Relative Risk	0.2798	
Risk difference (95% CI)	26.21 (-7.21, 59.63)	
P-value for Risk Difference	0.1242	
Improvement	3 (15.0%)	6 (37.5%)
Odds ratio (95% CI)	0.320 (0.057, 1.813)	
P-value for Odds Ratio	0.1979	
Relative Risk (95% CI)	0.44 (0.11, 1.78)	
P-value for Relative Risk	0.2520	
Risk difference (95% CI)	-19.51 (-55.26, 16.23)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2847	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	3 (60.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	19.38 (0.09, 4360.22)	
P-value for Relative Risk	0.2834	
Risk difference (95% CI)	69.55 (-22.79, 161.90)	
P-value for Risk Difference	0.1399	
Improvement	1 (20.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-16.00 (-16.00, -16.00)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Role Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	25 (15.8%)	20 (12.6%)
Odds ratio (95% CI)	1.363 (0.719, 2.585)	
P-value for Odds Ratio	0.3428	
Relative Risk (95% CI)	1.30 (0.75, 2.23)	
P-value for Relative Risk	0.3495	
Risk difference (95% CI)	3.61 (-3.70, 10.92)	
P-value for Risk Difference	0.3328	
Improvement	22 (13.9%)	17 (10.7%)
Odds ratio (95% CI)	1.342 (0.676, 2.664)	
P-value for Odds Ratio	0.4006	
Relative Risk (95% CI)	1.28 (0.71, 2.31)	
P-value for Relative Risk	0.4062	
Risk difference (95% CI)	2.41 (-4.58, 9.40)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4994	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	25 (16.4%)	28 (20.3%)
Odds ratio (95% CI)	0.785 (0.432, 1.429)	
P-value for Odds Ratio	0.4290	
Relative Risk (95% CI)	0.82 (0.50, 1.34)	
P-value for Relative Risk	0.4279	
Risk difference (95% CI)	-3.65 (-12.77, 5.47)	
P-value for Risk Difference	0.4329	
Improvement	27 (17.8%)	20 (14.5%)
Odds ratio (95% CI)	1.198 (0.629, 2.283)	
P-value for Odds Ratio	0.5833	
Relative Risk (95% CI)	1.17 (0.69, 1.98)	
P-value for Relative Risk	0.5583	
Risk difference (95% CI)	0.98 (-7.22, 9.18)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8147	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	29 (20.1%)	19 (15.0%)
Odds ratio (95% CI)	1.411 (0.741, 2.686)	
P-value for Odds Ratio	0.2951	
Relative Risk (95% CI)	1.31 (0.77, 2.21)	
P-value for Relative Risk	0.3141	
Risk difference (95% CI)	4.91 (-3.91, 13.72)	
P-value for Risk Difference	0.2750	
Improvement	28 (19.4%)	16 (12.6%)
Odds ratio (95% CI)	1.664 (0.846, 3.273)	
P-value for Odds Ratio	0.1404	
Relative Risk (95% CI)	1.58 (0.90, 2.77)	
P-value for Relative Risk	0.1104	
Risk difference (95% CI)	3.98 (-4.90, 12.86)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3800	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	37 (23.3%)	30 (20.0%)
Odds ratio (95% CI)	1.226 (0.709, 2.118)	
P-value for Odds Ratio	0.4658	
Relative Risk (95% CI)	1.18 (0.77, 1.80)	
P-value for Relative Risk	0.4500	
Risk difference (95% CI)	3.02 (-6.19, 12.22)	
P-value for Risk Difference	0.5210	
Improvement	23 (14.5%)	24 (16.0%)
Odds ratio (95% CI)	0.908 (0.483, 1.707)	
P-value for Odds Ratio	0.7642	
Relative Risk (95% CI)	0.94 (0.56, 1.58)	
P-value for Relative Risk	0.8052	
Risk difference (95% CI)	-2.17 (-9.91, 5.56)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5818	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	27 (20.1%)	15 (15.3%)
Odds ratio (95% CI)	1.399 (0.695, 2.819)	
P-value for Odds Ratio	0.3471	
Relative Risk (95% CI)	1.31 (0.74, 2.34)	
P-value for Relative Risk	0.3543	
Risk difference (95% CI)	5.03 (-5.22, 15.28)	
P-value for Risk Difference	0.3364	
Improvement	18 (13.4%)	18 (18.4%)
Odds ratio (95% CI)	0.700 (0.338, 1.450)	
P-value for Odds Ratio	0.3369	
Relative Risk (95% CI)	0.77 (0.42, 1.40)	
P-value for Relative Risk	0.3867	
Risk difference (95% CI)	-6.52 (-15.56, 2.52)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1576	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	22 (18.8%)	10 (12.0%)
Odds ratio (95% CI)	1.675 (0.737, 3.808)	
P-value for Odds Ratio	0.2181	
Relative Risk (95% CI)	1.57 (0.79, 3.12)	
P-value for Relative Risk	0.2005	
Risk difference (95% CI)	5.46 (-4.73, 15.65)	
P-value for Risk Difference	0.2938	
Improvement	13 (11.1%)	16 (19.3%)
Odds ratio (95% CI)	0.540 (0.239, 1.216)	
P-value for Odds Ratio	0.1368	
Relative Risk (95% CI)	0.60 (0.31, 1.18)	
P-value for Relative Risk	0.1421	
Risk difference (95% CI)	-6.65 (-16.45, 3.14)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1828	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	23 (23.2%)	11 (17.2%)
Odds ratio (95% CI)	1.596 (0.701, 3.630)	
P-value for Odds Ratio	0.2651	
Relative Risk (95% CI)	1.45 (0.76, 2.74)	
P-value for Relative Risk	0.2586	
Risk difference (95% CI)	9.36 (-5.03, 23.75)	
P-value for Risk Difference	0.2023	
Improvement	18 (18.2%)	12 (18.8%)
Odds ratio (95% CI)	0.994 (0.435, 2.269)	
P-value for Odds Ratio	0.9880	
Relative Risk (95% CI)	0.98 (0.51, 1.89)	
P-value for Relative Risk	0.9506	
Risk difference (95% CI)	1.10 (-10.86, 13.05)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8572	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	18 (20.7%)	9 (16.4%)
Odds ratio (95% CI)	1.335 (0.536, 3.324)	
P-value for Odds Ratio	0.5352	
Relative Risk (95% CI)	1.20 (0.59, 2.42)	
P-value for Relative Risk	0.6157	
Risk difference (95% CI)	9.00 (-6.63, 24.64)	
P-value for Risk Difference	0.2590	
Improvement	19 (21.8%)	9 (16.4%)
Odds ratio (95% CI)	1.380 (0.565, 3.373)	
P-value for Odds Ratio	0.4794	
Relative Risk (95% CI)	1.30 (0.64, 2.65)	
P-value for Relative Risk	0.4640	
Risk difference (95% CI)	4.34 (-8.44, 17.12)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5053	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	19 (24.7%)	5 (11.6%)
Odds ratio (95% CI)	2.603 (0.884, 7.668)	
P-value for Odds Ratio	0.0826	
Relative Risk (95% CI)	2.22 (0.90, 5.52)	
P-value for Relative Risk	0.0853	
Risk difference (95% CI)	12.55 (-1.58, 26.69)	
P-value for Risk Difference	0.0818	
Improvement	14 (18.2%)	10 (23.3%)
Odds ratio (95% CI)	0.685 (0.269, 1.744)	
P-value for Odds Ratio	0.4274	
Relative Risk (95% CI)	0.75 (0.37, 1.53)	
P-value for Relative Risk	0.4274	
Risk difference (95% CI)	-6.40 (-21.42, 8.61)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4032	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	18 (29.5%)	5 (13.5%)
Odds ratio (95% CI)	2.635 (0.857, 8.100)	
P-value for Odds Ratio	0.0908	
Relative Risk (95% CI)	2.19 (0.90, 5.31)	
P-value for Relative Risk	0.0826	
Risk difference (95% CI)	16.33 (-2.27, 34.93)	
P-value for Risk Difference	0.0853	
Improvement	10 (16.4%)	8 (21.6%)
Odds ratio (95% CI)	0.643 (0.221, 1.870)	
P-value for Odds Ratio	0.4171	
Relative Risk (95% CI)	0.70 (0.31, 1.60)	
P-value for Relative Risk	0.4001	
Risk difference (95% CI)	-6.34 (-22.06, 9.37)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4289	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	14 (40.0%)	5 (16.7%)
Odds ratio (95% CI)	2.642 (0.790, 8.836)	
P-value for Odds Ratio	0.1146	
Relative Risk (95% CI)	1.96 (0.79, 4.83)	
P-value for Relative Risk	0.1460	
Risk difference (95% CI)	16.97 (16.97, 16.97)*	
P-value for Risk Difference	NE	
Improvement	6 (17.1%)	5 (16.7%)
Odds ratio (95% CI)	1.354 (0.328, 5.594)	
P-value for Odds Ratio	0.6755	
Relative Risk (95% CI)	1.23 (0.39, 3.85)	
P-value for Relative Risk	0.7258	
Risk difference (95% CI)	5.36 (-13.42, 24.14)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5758	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	7 (24.1%)	3 (14.3%)
Odds ratio (95% CI)	1.571 (0.331, 7.471)	
P-value for Odds Ratio	0.5699	
Relative Risk (95% CI)	1.02 (1.02, 1.02)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	5.76 (-20.17, 31.68)	
P-value for Risk Difference	0.6633	
Improvement	7 (24.1%)	5 (23.8%)
Odds ratio (95% CI)	1.085 (0.280, 4.210)	
P-value for Odds Ratio	0.9060	
Relative Risk (95% CI)	1.00 (0.37, 2.73)	
P-value for Relative Risk	0.9954	
Risk difference (95% CI)	4.50 (-19.93, 28.94)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7179	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	5 (25.0%)	4 (25.0%)
Odds ratio (95% CI)	1.005 (0.195, 5.192)	
P-value for Odds Ratio	0.9952	
Relative Risk (95% CI)	1.01 (0.32, 3.19)	
P-value for Relative Risk	0.9884	
Risk difference (95% CI)	0.93 (-32.03, 33.89)	
P-value for Risk Difference	0.9558	
Improvement	3 (15.0%)	2 (12.5%)
Odds ratio (95% CI)	1.627 (0.208, 12.707)	
P-value for Odds Ratio	0.6428	
Relative Risk (95% CI)	1.55 (0.25, 9.74)	
P-value for Relative Risk	0.6396	
Risk difference (95% CI)	4.53 (-24.68, 33.74)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7612	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	3 (60.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.55 (0.78, 16.11)	
P-value for Relative Risk	0.0905	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (20.0%)	2 (28.6%)
Odds ratio (95% CI)	0.555 (0.021, 14.878)	
P-value for Odds Ratio	0.7258	
Relative Risk (95% CI)	0.33 (0.00, 69.99)	
P-value for Relative Risk	0.6836	
Risk difference (95% CI)	-5.11 (-66.11, 55.90)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8696	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Emotional Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	34 (21.5%)	35 (22.0%)
Odds ratio (95% CI)	0.949 (0.554, 1.626)	
P-value for Odds Ratio	0.8500	
Relative Risk (95% CI)	0.97 (0.64, 1.47)	
P-value for Relative Risk	0.8852	
Risk difference (95% CI)	-1.58 (-10.71, 7.55)	
P-value for Risk Difference	0.7345	
Improvement	28 (17.7%)	22 (13.8%)
Odds ratio (95% CI)	1.329 (0.720, 2.452)	
P-value for Odds Ratio	0.3636	
Relative Risk (95% CI)	1.29 (0.77, 2.14)	
P-value for Relative Risk	0.3370	
Risk difference (95% CI)	3.27 (-4.66, 11.21)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4185	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	33 (21.7%)	29 (21.0%)
Odds ratio (95% CI)	1.050 (0.594, 1.855)	
P-value for Odds Ratio	0.8669	
Relative Risk (95% CI)	1.07 (0.69, 1.67)	
P-value for Relative Risk	0.7539	
Risk difference (95% CI)	-2.03 (-11.81, 7.75)	
P-value for Risk Difference	0.6839	
Improvement	30 (19.7%)	16 (11.6%)
Odds ratio (95% CI)	1.823 (0.942, 3.530)	
P-value for Odds Ratio	0.0748	
Relative Risk (95% CI)	1.65 (0.94, 2.90)	
P-value for Relative Risk	0.0791	
Risk difference (95% CI)	7.97 (-0.24, 16.17)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0571	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	39 (27.1%)	29 (22.8%)
Odds ratio (95% CI)	1.282 (0.732, 2.243)	
P-value for Odds Ratio	0.3844	
Relative Risk (95% CI)	1.18 (0.78, 1.80)	
P-value for Relative Risk	0.4246	
Risk difference (95% CI)	5.08 (-5.10, 15.26)	
P-value for Risk Difference	0.3280	
Improvement	28 (19.4%)	15 (11.8%)
Odds ratio (95% CI)	1.806 (0.912, 3.579)	
P-value for Odds Ratio	0.0901	
Relative Risk (95% CI)	1.66 (0.93, 2.96)	
P-value for Relative Risk	0.0876	
Risk difference (95% CI)	7.44 (-1.37, 16.24)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0978	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	48 (30.2%)	38 (25.3%)
Odds ratio (95% CI)	1.278 (0.773, 2.113)	
P-value for Odds Ratio	0.3385	
Relative Risk (95% CI)	1.19 (0.83, 1.71)	
P-value for Relative Risk	0.3522	
Risk difference (95% CI)	5.06 (-4.90, 15.01)	
P-value for Risk Difference	0.3196	
Improvement	26 (16.4%)	26 (17.3%)
Odds ratio (95% CI)	0.928 (0.508, 1.694)	
P-value for Odds Ratio	0.8074	
Relative Risk (95% CI)	0.94 (0.58, 1.55)	
P-value for Relative Risk	0.8214	
Risk difference (95% CI)	-1.67 (-9.97, 6.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6944	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	40 (29.9%)	29 (29.6%)
Odds ratio (95% CI)	1.052 (0.591, 1.873)	
P-value for Odds Ratio	0.8621	
Relative Risk (95% CI)	1.03 (0.69, 1.54)	
P-value for Relative Risk	0.8682	
Risk difference (95% CI)	1.30 (-10.76, 13.37)	
P-value for Risk Difference	0.8322	
Improvement	28 (20.9%)	16 (16.3%)
Odds ratio (95% CI)	1.449 (0.727, 2.891)	
P-value for Odds Ratio	0.2922	
Relative Risk (95% CI)	1.34 (0.77, 2.32)	
P-value for Relative Risk	0.3007	
Risk difference (95% CI)	5.99 (-4.51, 16.49)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2636	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	35 (29.9%)	20 (24.1%)
Odds ratio (95% CI)	1.404 (0.734, 2.683)	
P-value for Odds Ratio	0.3052	
Relative Risk (95% CI)	1.27 (0.79, 2.02)	
P-value for Relative Risk	0.3240	
Risk difference (95% CI)	7.97 (-5.16, 21.11)	
P-value for Risk Difference	0.2340	
Improvement	21 (17.9%)	13 (15.7%)
Odds ratio (95% CI)	1.240 (0.577, 2.667)	
P-value for Odds Ratio	0.5819	
Relative Risk (95% CI)	1.19 (0.63, 2.23)	
P-value for Relative Risk	0.5939	
Risk difference (95% CI)	2.84 (-7.73, 13.41)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5983	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	32 (32.3%)	23 (35.9%)
Odds ratio (95% CI)	0.874 (0.448, 1.705)	
P-value for Odds Ratio	0.6937	
Relative Risk (95% CI)	0.91 (0.59, 1.41)	
P-value for Relative Risk	0.6789	
Risk difference (95% CI)	-2.83 (-18.01, 12.35)	
P-value for Risk Difference	0.7151	
Improvement	17 (17.2%)	9 (14.1%)
Odds ratio (95% CI)	1.268 (0.519, 3.095)	
P-value for Odds Ratio	0.6025	
Relative Risk (95% CI)	1.17 (0.56, 2.47)	
P-value for Relative Risk	0.6775	
Risk difference (95% CI)	5.56 (-5.46, 16.58)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3229	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	30 (34.5%)	13 (23.6%)
Odds ratio (95% CI)	1.658 (0.770, 3.572)	
P-value for Odds Ratio	0.1966	
Relative Risk (95% CI)	1.45 (0.83, 2.53)	
P-value for Relative Risk	0.1881	
Risk difference (95% CI)	9.83 (-5.48, 25.14)	
P-value for Risk Difference	0.2082	
Improvement	16 (18.4%)	7 (12.7%)
Odds ratio (95% CI)	1.608 (0.611, 4.231)	
P-value for Odds Ratio	0.3361	
Relative Risk (95% CI)	1.46 (0.64, 3.32)	
P-value for Relative Risk	0.3645	
Risk difference (95% CI)	8.73 (-4.06, 21.52)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1809	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	25 (32.5%)	10 (23.3%)
Odds ratio (95% CI)	1.614 (0.678, 3.842)	
P-value for Odds Ratio	0.2797	
Relative Risk (95% CI)	1.35 (0.72, 2.53)	
P-value for Relative Risk	0.3525	
Risk difference (95% CI)	11.28 (-5.61, 28.16)	
P-value for Risk Difference	0.1905	
Improvement	16 (20.8%)	4 (9.3%)
Odds ratio (95% CI)	2.332 (0.712, 7.635)	
P-value for Odds Ratio	0.1618	
Relative Risk (95% CI)	2.08 (0.74, 5.88)	
P-value for Relative Risk	0.1653	
Risk difference (95% CI)	8.59 (-4.00, 21.19)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1812	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	25 (41.0%)	9 (24.3%)
Odds ratio (95% CI)	2.348 (0.929, 5.933)	
P-value for Odds Ratio	0.0711	
Relative Risk (95% CI)	1.74 (0.91, 3.31)	
P-value for Relative Risk	0.0931	
Risk difference (95% CI)	16.71 (-3.11, 36.53)	
P-value for Risk Difference	0.0984	
Improvement	11 (18.0%)	5 (13.5%)
Odds ratio (95% CI)	1.464 (0.460, 4.663)	
P-value for Odds Ratio	0.5189	
Relative Risk (95% CI)	1.32 (0.50, 3.51)	
P-value for Relative Risk	0.5714	
Risk difference (95% CI)	8.47 (-8.39, 25.33)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3247	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	19 (54.3%)	10 (33.3%)
Odds ratio (95% CI)	1.943 (0.687, 5.497)	
P-value for Odds Ratio	0.2106	
Relative Risk (95% CI)	1.42 (0.78, 2.57)	
P-value for Relative Risk	0.2508	
Risk difference (95% CI)	15.38 (-9.55, 40.30)	
P-value for Risk Difference	0.2265	
Improvement	6 (17.1%)	4 (13.3%)
Odds ratio (95% CI)	1.172 (0.290, 4.741)	
P-value for Odds Ratio	0.8241	
Relative Risk (95% CI)	1.12 (0.35, 3.60)	
P-value for Relative Risk	0.8497	
Risk difference (95% CI)	2.82 (2.82, 2.82)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	14 (48.3%)	5 (23.8%)
Odds ratio (95% CI)	2.695 (0.741, 9.807)	
P-value for Odds Ratio	0.1324	
Relative Risk (95% CI)	1.83 (0.76, 4.39)	
P-value for Relative Risk	0.1776	
Risk difference (95% CI)	19.97 (-6.38, 46.32)	
P-value for Risk Difference	0.1375	
Improvement	5 (17.2%)	1 (4.8%)
Odds ratio (95% CI)	4.253 (0.447, 40.490)	
P-value for Odds Ratio	0.2079	
Relative Risk (95% CI)	3.65 (0.45, 29.35)	
P-value for Relative Risk	0.2240	
Risk difference (95% CI)	10.31 (-17.30, 37.93)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4642	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	12 (60.0%)	6 (37.5%)
Odds ratio (95% CI)	2.651 (0.611, 11.494)	
P-value for Odds Ratio	0.1928	
Relative Risk (95% CI)	1.74 (0.62, 4.87)	
P-value for Relative Risk	0.2904	
Risk difference (95% CI)	25.91 (-8.43, 60.26)	
P-value for Risk Difference	0.1392	
Improvement	3 (15.0%)	3 (18.8%)
Odds ratio (95% CI)	0.643 (0.095, 4.373)	
P-value for Odds Ratio	0.6516	
Relative Risk (95% CI)	0.92 (0.92, 0.92)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-9.99 (-41.94, 21.97)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5402	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	3 (60.0%)	3 (42.9%)
Odds ratio (95% CI)	6.440 (0.348, 119.170)	
P-value for Odds Ratio	0.2109	
Relative Risk (95% CI)	1.56 (0.47, 5.19)	
P-value for Relative Risk	0.4653	
Risk difference (95% CI)	39.75 (-17.84, 97.34)	
P-value for Risk Difference	0.1761	
Improvement	1 (20.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.21 (0.00, 11.31)	
P-value for Relative Risk	0.4402	
Risk difference (95% CI)	-9.60 (-9.60, -9.60)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Cognitive Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	29 (18.4%)	35 (22.0%)
Odds ratio (95% CI)	0.767 (0.439, 1.341)	
P-value for Odds Ratio	0.3528	
Relative Risk (95% CI)	0.80 (0.51, 1.24)	
P-value for Relative Risk	0.3108	
Risk difference (95% CI)	-2.61 (-11.29, 6.06)	
P-value for Risk Difference	0.5546	
Improvement	37 (23.4%)	33 (20.8%)
Odds ratio (95% CI)	1.127 (0.658, 1.931)	
P-value for Odds Ratio	0.6641	
Relative Risk (95% CI)	1.10 (0.73, 1.66)	
P-value for Relative Risk	0.6390	
Risk difference (95% CI)	1.68 (-7.37, 10.72)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7167	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	35 (23.0%)	27 (19.6%)
Odds ratio (95% CI)	1.245 (0.702, 2.206)	
P-value for Odds Ratio	0.4533	
Relative Risk (95% CI)	1.20 (0.77, 1.87)	
P-value for Relative Risk	0.4228	
Risk difference (95% CI)	2.72 (-6.48, 11.93)	
P-value for Risk Difference	0.5618	
Improvement	44 (28.9%)	36 (26.1%)
Odds ratio (95% CI)	1.113 (0.660, 1.877)	
P-value for Odds Ratio	0.6883	
Relative Risk (95% CI)	1.09 (0.75, 1.58)	
P-value for Relative Risk	0.6552	
Risk difference (95% CI)	1.67 (-8.58, 11.91)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7496	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	40 (27.8%)	28 (22.0%)
Odds ratio (95% CI)	1.367 (0.780, 2.393)	
P-value for Odds Ratio	0.2748	
Relative Risk (95% CI)	1.25 (0.82, 1.90)	
P-value for Relative Risk	0.3076	
Risk difference (95% CI)	6.49 (-3.71, 16.68)	
P-value for Risk Difference	0.2126	
Improvement	39 (27.1%)	29 (22.8%)
Odds ratio (95% CI)	1.256 (0.718, 2.198)	
P-value for Odds Ratio	0.4247	
Relative Risk (95% CI)	1.20 (0.79, 1.82)	
P-value for Relative Risk	0.3950	
Risk difference (95% CI)	3.38 (-6.93, 13.69)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5205	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	157	150
Deterioration	38 (24.2%)	33 (22.0%)
Odds ratio (95% CI)	1.113 (0.650, 1.904)	
P-value for Odds Ratio	0.6972	
Relative Risk (95% CI)	1.10 (0.73, 1.65)	
P-value for Relative Risk	0.6525	
Risk difference (95% CI)	1.07 (-8.26, 10.41)	
P-value for Risk Difference	0.8216	
Improvement	43 (27.4%)	34 (22.7%)
Odds ratio (95% CI)	1.301 (0.770, 2.198)	
P-value for Odds Ratio	0.3256	
Relative Risk (95% CI)	1.24 (0.84, 1.83)	
P-value for Relative Risk	0.2757	
Risk difference (95% CI)	3.95 (-5.70, 13.60)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4225	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	34 (25.4%)	16 (16.3%)
Odds ratio (95% CI)	1.847 (0.939, 3.631)	
P-value for Odds Ratio	0.0754	
Relative Risk (95% CI)	1.57 (0.92, 2.66)	
P-value for Relative Risk	0.0985	
Risk difference (95% CI)	10.04 (0.14, 19.93)	
P-value for Risk Difference	0.0468	
Improvement	36 (26.9%)	24 (24.5%)
Odds ratio (95% CI)	1.168 (0.637, 2.142)	
P-value for Odds Ratio	0.6157	
Relative Risk (95% CI)	1.13 (0.73, 1.77)	
P-value for Relative Risk	0.5808	
Risk difference (95% CI)	2.23 (-9.29, 13.74)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7049	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	28 (23.9%)	15 (18.1%)
Odds ratio (95% CI)	1.444 (0.708, 2.946)	
P-value for Odds Ratio	0.3124	
Relative Risk (95% CI)	1.35 (0.78, 2.35)	
P-value for Relative Risk	0.2874	
Risk difference (95% CI)	4.11 (-7.26, 15.48)	
P-value for Risk Difference	0.4791	
Improvement	27 (23.1%)	19 (22.9%)
Odds ratio (95% CI)	1.051 (0.535, 2.066)	
P-value for Odds Ratio	0.8856	
Relative Risk (95% CI)	1.03 (0.62, 1.72)	
P-value for Relative Risk	0.9105	
Risk difference (95% CI)	1.82 (-10.57, 14.21)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7736	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	23 (23.2%)	14 (21.9%)
Odds ratio (95% CI)	1.155 (0.537, 2.480)	
P-value for Odds Ratio	0.7127	
Relative Risk (95% CI)	1.10 (0.62, 1.97)	
P-value for Relative Risk	0.7386	
Risk difference (95% CI)	4.58 (-9.69, 18.85)	
P-value for Risk Difference	0.5291	
Improvement	24 (24.2%)	14 (21.9%)
Odds ratio (95% CI)	1.182 (0.553, 2.528)	
P-value for Odds Ratio	0.6668	
Relative Risk (95% CI)	1.15 (0.64, 2.05)	
P-value for Relative Risk	0.6463	
Risk difference (95% CI)	2.57 (-10.54, 15.69)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7005	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	18 (20.7%)	9 (16.4%)
Odds ratio (95% CI)	1.388 (0.567, 3.397)	
P-value for Odds Ratio	0.4727	
Relative Risk (95% CI)	1.27 (0.62, 2.59)	
P-value for Relative Risk	0.5191	
Risk difference (95% CI)	7.71 (-7.60, 23.02)	
P-value for Risk Difference	0.3236	
Improvement	21 (24.1%)	15 (27.3%)
Odds ratio (95% CI)	0.808 (0.370, 1.766)	
P-value for Odds Ratio	0.5936	
Relative Risk (95% CI)	0.86 (0.49, 1.52)	
P-value for Relative Risk	0.6057	
Risk difference (95% CI)	-4.06 (-18.74, 10.61)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5873	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	18 (23.4%)	6 (14.0%)
Odds ratio (95% CI)	2.114 (0.758, 5.895)	
P-value for Odds Ratio	0.1525	
Relative Risk (95% CI)	1.81 (0.78, 4.17)	
P-value for Relative Risk	0.1658	
Risk difference (95% CI)	10.30 (-6.09, 26.69)	
P-value for Risk Difference	0.2180	
Improvement	23 (29.9%)	8 (18.6%)
Odds ratio (95% CI)	1.759 (0.698, 4.436)	
P-value for Odds Ratio	0.2314	
Relative Risk (95% CI)	1.53 (0.75, 3.12)	
P-value for Relative Risk	0.2390	
Risk difference (95% CI)	9.48 (-5.88, 24.83)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2265	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	14 (23.0%)	6 (16.2%)
Odds ratio (95% CI)	1.483 (0.508, 4.325)	
P-value for Odds Ratio	0.4710	
Relative Risk (95% CI)	1.36 (0.57, 3.24)	
P-value for Relative Risk	0.4829	
Risk difference (95% CI)	6.27 (-10.29, 22.82)	
P-value for Risk Difference	0.4580	
Improvement	13 (21.3%)	8 (21.6%)
Odds ratio (95% CI)	1.002 (0.366, 2.741)	
P-value for Odds Ratio	0.9974	
Relative Risk (95% CI)	0.99 (0.46, 2.16)	
P-value for Relative Risk	0.9816	
Risk difference (95% CI)	0.81 (-16.39, 18.01)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9261	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	12 (34.3%)	3 (10.0%)
Odds ratio (95% CI)	4.664 (1.129, 19.274)	
P-value for Odds Ratio	0.0334	
Relative Risk (95% CI)	3.28 (1.03, 10.48)	
P-value for Relative Risk	0.0447	
Risk difference (95% CI)	22.52 (-2.74, 47.79)	
P-value for Risk Difference	0.0806	
Improvement	7 (20.0%)	7 (23.3%)
Odds ratio (95% CI)	0.846 (0.239, 2.989)	
P-value for Odds Ratio	0.7947	
Relative Risk (95% CI)	0.87 (0.34, 2.27)	
P-value for Relative Risk	0.7819	
Risk difference (95% CI)	-2.31 (-23.11, 18.49)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8277	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	7 (24.1%)	5 (23.8%)
Odds ratio (95% CI)	0.858 (0.213, 3.456)	
P-value for Odds Ratio	0.8295	
Relative Risk (95% CI)	0.98 (0.98, 0.98)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-3.04 (-27.82, 21.74)	
P-value for Risk Difference	0.8099	
Improvement	7 (24.1%)	4 (19.0%)
Odds ratio (95% CI)	1.348 (0.323, 5.617)	
P-value for Odds Ratio	0.6818	
Relative Risk (95% CI)	1.27 (0.43, 3.82)	
P-value for Relative Risk	0.6642	
Risk difference (95% CI)	3.52 (-22.09, 29.12)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7878	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	4 (20.0%)	5 (31.3%)
Odds ratio (95% CI)	0.731 (0.138, 3.870)	
P-value for Odds Ratio	0.7129	
Relative Risk (95% CI)	0.85 (0.27, 2.66)	
P-value for Relative Risk	0.7840	
Risk difference (95% CI)	-6.51 (-39.29, 26.27)	
P-value for Risk Difference	0.6972	
Improvement	5 (25.0%)	4 (25.0%)
Odds ratio (95% CI)	1.338 (0.261, 6.853)	
P-value for Odds Ratio	0.7270	
Relative Risk (95% CI)	1.36 (0.44, 4.27)	
P-value for Relative Risk	0.5937	
Risk difference (95% CI)	2.16 (-33.78, 38.10)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9061	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	2 (40.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	35.20 (35.20, 35.20)*	
P-value for Risk Difference	NE	
Improvement	2 (40.0%)	2 (28.6%)
Odds ratio (95% CI)	0.668 (0.030, 14.673)	
P-value for Odds Ratio	0.7978	
Relative Risk (95% CI)	0.77 (0.06, 9.37)	
P-value for Relative Risk	0.8348	
Risk difference (95% CI)	-3.50 (-70.08, 63.08)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9179	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (50.0%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.04, 7.10)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Social Functioning :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	62 (39.2%)	58 (36.5%)
Odds ratio (95% CI)	1.116 (0.705, 1.768)	
P-value for Odds Ratio	0.6396	
Relative Risk (95% CI)	1.07 (0.81, 1.42)	
P-value for Relative Risk	0.6358	
Risk difference (95% CI)	2.71 (-7.87, 13.28)	
P-value for Risk Difference	0.6160	
Improvement	38 (24.1%)	38 (23.9%)
Odds ratio (95% CI)	1.010 (0.599, 1.704)	
P-value for Odds Ratio	0.9689	
Relative Risk (95% CI)	1.01 (0.69, 1.49)	
P-value for Relative Risk	0.9497	
Risk difference (95% CI)	-0.04 (-9.48, 9.40)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9931	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	56 (36.8%)	48 (34.8%)
Odds ratio (95% CI)	1.123 (0.691, 1.826)	
P-value for Odds Ratio	0.6399	
Relative Risk (95% CI)	1.08 (0.79, 1.47)	
P-value for Relative Risk	0.6180	
Risk difference (95% CI)	2.44 (-8.49, 13.37)	
P-value for Risk Difference	0.6620	
Improvement	38 (25.0%)	38 (27.5%)
Odds ratio (95% CI)	0.860 (0.507, 1.457)	
P-value for Odds Ratio	0.5743	
Relative Risk (95% CI)	0.90 (0.61, 1.32)	
P-value for Relative Risk	0.5787	
Risk difference (95% CI)	-2.88 (-13.05, 7.29)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5792	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	65 (45.1%)	53 (41.7%)
Odds ratio (95% CI)	1.147 (0.700, 1.879)	
P-value for Odds Ratio	0.5873	
Relative Risk (95% CI)	1.09 (0.84, 1.42)	
P-value for Relative Risk	0.5231	
Risk difference (95% CI)	3.04 (-8.54, 14.62)	
P-value for Risk Difference	0.6071	
Improvement	35 (24.3%)	27 (21.3%)
Odds ratio (95% CI)	1.227 (0.690, 2.185)	
P-value for Odds Ratio	0.4861	
Relative Risk (95% CI)	1.18 (0.76, 1.83)	
P-value for Relative Risk	0.4580	
Risk difference (95% CI)	3.50 (-6.50, 13.51)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4926	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	68 (42.8%)	61 (40.7%)
Odds ratio (95% CI)	1.081 (0.683, 1.710)	
P-value for Odds Ratio	0.7394	
Relative Risk (95% CI)	1.04 (0.81, 1.36)	
P-value for Relative Risk	0.7423	
Risk difference (95% CI)	1.82 (-9.08, 12.72)	
P-value for Risk Difference	0.7434	
Improvement	34 (21.4%)	37 (24.7%)
Odds ratio (95% CI)	0.827 (0.485, 1.409)	
P-value for Odds Ratio	0.4841	
Relative Risk (95% CI)	0.86 (0.57, 1.29)	
P-value for Relative Risk	0.4570	
Risk difference (95% CI)	-2.90 (-12.35, 6.55)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5478	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	49 (36.6%)	34 (34.7%)
Odds ratio (95% CI)	1.176 (0.675, 2.048)	
P-value for Odds Ratio	0.5680	
Relative Risk (95% CI)	1.11 (0.79, 1.58)	
P-value for Relative Risk	0.5434	
Risk difference (95% CI)	2.63 (-9.41, 14.66)	
P-value for Risk Difference	0.6687	
Improvement	37 (27.6%)	28 (28.6%)
Odds ratio (95% CI)	0.958 (0.530, 1.732)	
P-value for Odds Ratio	0.8877	
Relative Risk (95% CI)	0.97 (0.65, 1.47)	
P-value for Relative Risk	0.8996	
Risk difference (95% CI)	-1.08 (-12.72, 10.55)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8551	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	48 (41.0%)	27 (32.5%)
Odds ratio (95% CI)	1.547 (0.851, 2.815)	
P-value for Odds Ratio	0.1527	
Relative Risk (95% CI)	1.33 (0.91, 1.93)	
P-value for Relative Risk	0.1414	
Risk difference (95% CI)	8.51 (-4.65, 21.67)	
P-value for Risk Difference	0.2051	
Improvement	26 (22.2%)	20 (24.1%)
Odds ratio (95% CI)	0.909 (0.465, 1.780)	
P-value for Odds Ratio	0.7817	
Relative Risk (95% CI)	0.93 (0.56, 1.55)	
P-value for Relative Risk	0.7919	
Risk difference (95% CI)	-1.94 (-14.07, 10.19)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7540	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	41 (41.4%)	22 (34.4%)
Odds ratio (95% CI)	1.479 (0.757, 2.889)	
P-value for Odds Ratio	0.2523	
Relative Risk (95% CI)	1.28 (0.85, 1.92)	
P-value for Relative Risk	0.2343	
Risk difference (95% CI)	8.38 (-6.46, 23.23)	
P-value for Risk Difference	0.2684	
Improvement	28 (28.3%)	13 (20.3%)
Odds ratio (95% CI)	1.469 (0.689, 3.133)	
P-value for Odds Ratio	0.3190	
Relative Risk (95% CI)	1.36 (0.76, 2.42)	
P-value for Relative Risk	0.2976	
Risk difference (95% CI)	6.08 (-7.62, 19.78)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3841	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	37 (42.5%)	20 (36.4%)
Odds ratio (95% CI)	1.305 (0.649, 2.625)	
P-value for Odds Ratio	0.4555	
Relative Risk (95% CI)	1.18 (0.77, 1.81)	
P-value for Relative Risk	0.4528	
Risk difference (95% CI)	6.25 (-10.17, 22.68)	
P-value for Risk Difference	0.4555	
Improvement	23 (26.4%)	11 (20.0%)
Odds ratio (95% CI)	1.420 (0.625, 3.228)	
P-value for Odds Ratio	0.4026	
Relative Risk (95% CI)	1.33 (0.71, 2.50)	
P-value for Relative Risk	0.3771	
Risk difference (95% CI)	4.59 (-10.03, 19.22)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5383	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	24 (31.2%)	11 (25.6%)
Odds ratio (95% CI)	1.327 (0.568, 3.100)	
P-value for Odds Ratio	0.5141	
Relative Risk (95% CI)	1.25 (0.68, 2.30)	
P-value for Relative Risk	0.4803	
Risk difference (95% CI)	4.95 (-11.55, 21.45)	
P-value for Risk Difference	0.5564	
Improvement	24 (31.2%)	7 (16.3%)
Odds ratio (95% CI)	2.491 (0.949, 6.541)	
P-value for Odds Ratio	0.0639	
Relative Risk (95% CI)	1.94 (0.92, 4.08)	
P-value for Relative Risk	0.0810	
Risk difference (95% CI)	13.58 (-4.57, 31.74)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1425	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	28 (45.9%)	12 (32.4%)
Odds ratio (95% CI)	1.723 (0.724, 4.098)	
P-value for Odds Ratio	0.2184	
Relative Risk (95% CI)	1.40 (0.81, 2.41)	
P-value for Relative Risk	0.2271	
Risk difference (95% CI)	12.46 (-7.14, 32.06)	
P-value for Risk Difference	0.2127	
Improvement	12 (19.7%)	9 (24.3%)
Odds ratio (95% CI)	0.819 (0.296, 2.261)	
P-value for Odds Ratio	0.6996	
Relative Risk (95% CI)	0.91 (0.43, 1.92)	
P-value for Relative Risk	0.8002	
Risk difference (95% CI)	-8.27 (-28.18, 11.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4156	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	18 (51.4%)	9 (30.0%)
Odds ratio (95% CI)	1.927 (0.667, 5.569)	
P-value for Odds Ratio	0.2258	
Relative Risk (95% CI)	1.40 (0.73, 2.67)	
P-value for Relative Risk	0.3087	
Risk difference (95% CI)	14.90 (-9.61, 39.42)	
P-value for Risk Difference	0.2334	
Improvement	4 (11.4%)	6 (20.0%)
Odds ratio (95% CI)	0.630 (0.143, 2.776)	
P-value for Odds Ratio	0.5412	
Relative Risk (95% CI)	0.71 (0.22, 2.30)	
P-value for Relative Risk	0.5708	
Risk difference (95% CI)	-3.56 (-27.79, 20.68)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7737	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	11 (37.9%)	8 (38.1%)
Odds ratio (95% CI)	1.037 (0.310, 3.473)	
P-value for Odds Ratio	0.9524	
Relative Risk (95% CI)	1.09 (0.55, 2.17)	
P-value for Relative Risk	0.8065	
Risk difference (95% CI)	-0.09 (-26.98, 26.81)	
P-value for Risk Difference	0.9950	
Improvement	6 (20.7%)	4 (19.0%)
Odds ratio (95% CI)	1.195 (0.282, 5.057)	
P-value for Odds Ratio	0.8088	
Relative Risk (95% CI)	1.18 (0.38, 3.64)	
P-value for Relative Risk	0.7783	
Risk difference (95% CI)	1.67 (-24.29, 27.63)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8997	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	7 (35.0%)	6 (37.5%)
Odds ratio (95% CI)	0.957 (0.184, 4.972)	
P-value for Odds Ratio	0.9587	
Relative Risk (95% CI)	0.79 (0.24, 2.66)	
P-value for Relative Risk	0.7074	
Risk difference (95% CI)	-1.20 (-38.01, 35.62)	
P-value for Risk Difference	0.9493	
Improvement	7 (35.0%)	4 (25.0%)
Odds ratio (95% CI)	2.078 (0.435, 9.939)	
P-value for Odds Ratio	0.3596	
Relative Risk (95% CI)	1.03 (1.03, 1.03)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	14.47 (-22.44, 51.38)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4422	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	3 (60.0%)	2 (28.6%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.28 (1.28, 1.28)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	39.47 (39.47, 39.47)*	
P-value for Risk Difference	NE	
Improvement	2 (40.0%)	2 (28.6%)
Odds ratio (95% CI)	1.000 (0.034, 29.807)	
P-value for Odds Ratio	1.0000	
Relative Risk (95% CI)	1.00 (0.31, 3.27)	
P-value for Relative Risk	0.9992	
Risk difference (95% CI)	1.07 (1.07, 1.07)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (50.0%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.04, 7.10)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Fatigue :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	14 (8.9%)	24 (15.1%)
Odds ratio (95% CI)	0.574 (0.284, 1.162)	
P-value for Odds Ratio	0.1228	
Relative Risk (95% CI)	0.62 (0.33, 1.15)	
P-value for Relative Risk	0.1302	
Risk difference (95% CI)	-5.63 (-14.31, 3.05)	
P-value for Risk Difference	0.2035	
Improvement	12 (7.6%)	14 (8.8%)
Odds ratio (95% CI)	0.859 (0.383, 1.927)	
P-value for Odds Ratio	0.7127	
Relative Risk (95% CI)	0.87 (0.41, 1.82)	
P-value for Relative Risk	0.7099	
Risk difference (95% CI)	-1.01 (-7.15, 5.14)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7480	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	16 (10.5%)	15 (10.9%)
Odds ratio (95% CI)	0.944 (0.446, 2.000)	
P-value for Odds Ratio	0.8803	
Relative Risk (95% CI)	0.96 (0.49, 1.86)	
P-value for Relative Risk	0.8923	
Risk difference (95% CI)	-0.85 (-7.99, 6.30)	
P-value for Risk Difference	0.8161	
Improvement	13 (8.6%)	11 (8.0%)
Odds ratio (95% CI)	1.113 (0.480, 2.580)	
P-value for Odds Ratio	0.8035	
Relative Risk (95% CI)	1.11 (0.52, 2.40)	
P-value for Relative Risk	0.7843	
Risk difference (95% CI)	-0.34 (-6.79, 6.10)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9170	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	14 (9.7%)	11 (8.7%)
Odds ratio (95% CI)	1.140 (0.493, 2.635)	
P-value for Odds Ratio	0.7592	
Relative Risk (95% CI)	1.12 (0.53, 2.38)	
P-value for Relative Risk	0.7654	
Risk difference (95% CI)	0.11 (-6.83, 7.05)	
P-value for Risk Difference	0.9751	
Improvement	9 (6.3%)	10 (7.9%)
Odds ratio (95% CI)	0.810 (0.317, 2.072)	
P-value for Odds Ratio	0.6604	
Relative Risk (95% CI)	0.82 (0.35, 1.96)	
P-value for Relative Risk	0.6586	
Risk difference (95% CI)	-0.99 (-9.12, 7.15)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8122	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	17 (10.7%)	14 (9.3%)
Odds ratio (95% CI)	1.215 (0.574, 2.576)	
P-value for Odds Ratio	0.6106	
Relative Risk (95% CI)	1.18 (0.61, 2.31)	
P-value for Relative Risk	0.6221	
Risk difference (95% CI)	3.48 (-4.35, 11.31)	
P-value for Risk Difference	0.3833	
Improvement	13 (8.2%)	11 (7.3%)
Odds ratio (95% CI)	1.206 (0.518, 2.807)	
P-value for Odds Ratio	0.6635	
Relative Risk (95% CI)	1.19 (0.55, 2.56)	
P-value for Relative Risk	0.6572	
Risk difference (95% CI)	1.25 (-7.05, 9.54)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7685	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	15 (11.2%)	9 (9.2%)
Odds ratio (95% CI)	1.310 (0.544, 3.152)	
P-value for Odds Ratio	0.5473	
Relative Risk (95% CI)	1.26 (0.58, 2.76)	
P-value for Relative Risk	0.5633	
Risk difference (95% CI)	3.64 (-5.16, 12.43)	
P-value for Risk Difference	0.4176	
Improvement	10 (7.5%)	7 (7.1%)
Odds ratio (95% CI)	1.047 (0.380, 2.882)	
P-value for Odds Ratio	0.9299	
Relative Risk (95% CI)	1.03 (0.41, 2.63)	
P-value for Relative Risk	0.9451	
Risk difference (95% CI)	1.93 (-5.78, 9.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6242	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	13 (11.1%)	7 (8.4%)
Odds ratio (95% CI)	1.481 (0.560, 3.919)	
P-value for Odds Ratio	0.4288	
Relative Risk (95% CI)	1.42 (0.59, 3.39)	
P-value for Relative Risk	0.4291	
Risk difference (95% CI)	2.88 (-8.32, 14.08)	
P-value for Risk Difference	0.6140	
Improvement	9 (7.7%)	4 (4.8%)
Odds ratio (95% CI)	1.594 (0.469, 5.411)	
P-value for Odds Ratio	0.4550	
Relative Risk (95% CI)	1.52 (0.48, 4.79)	
P-value for Relative Risk	0.4730	
Risk difference (95% CI)	4.21 (-4.68, 13.10)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3537	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	7 (7.1%)	8 (12.5%)
Odds ratio (95% CI)	0.585 (0.198, 1.725)	
P-value for Odds Ratio	0.3314	
Relative Risk (95% CI)	0.62 (0.24, 1.62)	
P-value for Relative Risk	0.3310	
Risk difference (95% CI)	-4.17 (-16.64, 8.30)	
P-value for Risk Difference	0.5119	
Improvement	7 (7.1%)	5 (7.8%)
Odds ratio (95% CI)	0.887 (0.265, 2.966)	
P-value for Odds Ratio	0.8459	
Relative Risk (95% CI)	0.89 (0.29, 2.72)	
P-value for Relative Risk	0.8441	
Risk difference (95% CI)	-0.72 (-8.85, 7.42)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8630	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	6 (6.9%)	8 (14.5%)
Odds ratio (95% CI)	0.436 (0.140, 1.356)	
P-value for Odds Ratio	0.1514	
Relative Risk (95% CI)	0.48 (0.18, 1.28)	
P-value for Relative Risk	0.1423	
Risk difference (95% CI)	-5.96 (-20.59, 8.66)	
P-value for Risk Difference	0.4243	
Improvement	8 (9.2%)	4 (7.3%)
Odds ratio (95% CI)	1.326 (0.377, 4.661)	
P-value for Odds Ratio	0.6598	
Relative Risk (95% CI)	1.31 (0.42, 4.12)	
P-value for Relative Risk	0.6469	
Risk difference (95% CI)	0.39 (-11.65, 12.44)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9488	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	5 (6.5%)	4 (9.3%)
Odds ratio (95% CI)	0.688 (0.173, 2.746)	
P-value for Odds Ratio	0.5968	
Relative Risk (95% CI)	0.72 (0.20, 2.53)	
P-value for Relative Risk	0.6039	
Risk difference (95% CI)	-3.01 (-15.23, 9.21)	
P-value for Risk Difference	0.6294	
Improvement	6 (7.8%)	3 (7.0%)
Odds ratio (95% CI)	1.092 (0.254, 4.695)	
P-value for Odds Ratio	0.9063	
Relative Risk (95% CI)	1.06 (0.28, 4.08)	
P-value for Relative Risk	0.9318	
Risk difference (95% CI)	3.89 (-8.27, 16.04)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5309	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	7 (11.5%)	1 (2.7%)
Odds ratio (95% CI)	4.703 (0.540, 40.923)	
P-value for Odds Ratio	0.1608	
Relative Risk (95% CI)	4.30 (0.56, 32.91)	
P-value for Relative Risk	0.1597	
Risk difference (95% CI)	7.20 (-16.30, 30.70)	
P-value for Risk Difference	0.5480	
Improvement	6 (9.8%)	4 (10.8%)
Odds ratio (95% CI)	0.923 (0.238, 3.574)	
P-value for Odds Ratio	0.9078	
Relative Risk (95% CI)	0.95 (0.29, 3.15)	
P-value for Relative Risk	0.9320	
Risk difference (95% CI)	-3.13 (-18.76, 12.50)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6948	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	4 (11.4%)	1 (3.3%)
Odds ratio (95% CI)	3.232 (0.331, 31.611)	
P-value for Odds Ratio	0.3133	
Relative Risk (95% CI)	1.57 (1.57, 1.57)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	7.23 (-17.02, 31.47)	
P-value for Risk Difference	0.5591	
Improvement	4 (11.4%)	1 (3.3%)
Odds ratio (95% CI)	4.032 (0.407, 39.990)	
P-value for Odds Ratio	0.2336	
Relative Risk (95% CI)	3.69 (0.45, 30.63)	
P-value for Relative Risk	0.2262	
Risk difference (95% CI)	6.72 (-15.05, 28.49)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5450	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	3 (10.3%)	2 (9.5%)
Odds ratio (95% CI)	1.056 (0.150, 7.422)	
P-value for Odds Ratio	0.9563	
Relative Risk (95% CI)	1.11 (0.20, 6.14)	
P-value for Relative Risk	0.9068	
Risk difference (95% CI)	-1.00 (-25.91, 23.91)	
P-value for Risk Difference	0.9371	
Improvement	4 (13.8%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.28 (0.60, 18.07)	
P-value for Relative Risk	0.1519	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	0	1 (6.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.56 (0.03, 9.73)	
P-value for Relative Risk	0.6933	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	2 (10.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	5.00 (0.27, 92.62)	
P-value for Relative Risk	0.2248	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	1 (20.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Nausea / Vomiting :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	34 (21.5%)	40 (25.2%)
Odds ratio (95% CI)	0.819 (0.483, 1.388)	
P-value for Odds Ratio	0.4587	
Relative Risk (95% CI)	0.85 (0.57, 1.26)	
P-value for Relative Risk	0.4173	
Risk difference (95% CI)	-3.30 (-12.39, 5.78)	
P-value for Risk Difference	0.4759	
Improvement	43 (27.2%)	31 (19.5%)
Odds ratio (95% CI)	1.588 (0.935, 2.699)	
P-value for Odds Ratio	0.0872	
Relative Risk (95% CI)	1.41 (0.94, 2.12)	
P-value for Relative Risk	0.0956	
Risk difference (95% CI)	8.49 (-0.69, 17.66)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0699	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	37 (24.3%)	28 (20.3%)
Odds ratio (95% CI)	1.263 (0.720, 2.217)	
P-value for Odds Ratio	0.4157	
Relative Risk (95% CI)	1.17 (0.76, 1.80)	
P-value for Relative Risk	0.4844	
Risk difference (95% CI)	4.46 (-4.88, 13.80)	
P-value for Risk Difference	0.3495	
Improvement	38 (25.0%)	34 (24.6%)
Odds ratio (95% CI)	1.007 (0.587, 1.726)	
P-value for Odds Ratio	0.9796	
Relative Risk (95% CI)	0.99 (0.67, 1.48)	
P-value for Relative Risk	0.9770	
Risk difference (95% CI)	0.01 (-9.88, 9.90)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9985	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	41 (28.5%)	28 (22.0%)
Odds ratio (95% CI)	1.488 (0.845, 2.621)	
P-value for Odds Ratio	0.1686	
Relative Risk (95% CI)	1.32 (0.88, 2.00)	
P-value for Relative Risk	0.1828	
Risk difference (95% CI)	5.88 (-4.05, 15.80)	
P-value for Risk Difference	0.2458	
Improvement	32 (22.2%)	28 (22.0%)
Odds ratio (95% CI)	1.048 (0.586, 1.875)	
P-value for Odds Ratio	0.8731	
Relative Risk (95% CI)	1.07 (0.69, 1.67)	
P-value for Relative Risk	0.7657	
Risk difference (95% CI)	-1.79 (-11.92, 8.33)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7286	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	50 (31.4%)	37 (24.7%)
Odds ratio (95% CI)	1.393 (0.841, 2.305)	
P-value for Odds Ratio	0.1976	
Relative Risk (95% CI)	1.26 (0.88, 1.81)	
P-value for Relative Risk	0.2137	
Risk difference (95% CI)	6.62 (-3.28, 16.53)	
P-value for Risk Difference	0.1899	
Improvement	35 (22.0%)	30 (20.0%)
Odds ratio (95% CI)	1.199 (0.686, 2.097)	
P-value for Odds Ratio	0.5242	
Relative Risk (95% CI)	1.16 (0.76, 1.78)	
P-value for Relative Risk	0.4846	
Risk difference (95% CI)	1.76 (-7.10, 10.63)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6970	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	39 (29.1%)	25 (25.5%)
Odds ratio (95% CI)	1.306 (0.715, 2.388)	
P-value for Odds Ratio	0.3852	
Relative Risk (95% CI)	1.12 (0.73, 1.72)	
P-value for Relative Risk	0.5964	
Risk difference (95% CI)	8.77 (-3.36, 20.89)	
P-value for Risk Difference	0.1565	
Improvement	30 (22.4%)	23 (23.5%)
Odds ratio (95% CI)	1.017 (0.541, 1.913)	
P-value for Odds Ratio	0.9577	
Relative Risk (95% CI)	0.99 (0.62, 1.59)	
P-value for Relative Risk	0.9796	
Risk difference (95% CI)	1.64 (-9.27, 12.55)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7681	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	30 (25.6%)	17 (20.5%)
Odds ratio (95% CI)	1.391 (0.704, 2.749)	
P-value for Odds Ratio	0.3428	
Relative Risk (95% CI)	1.26 (0.75, 2.13)	
P-value for Relative Risk	0.3877	
Risk difference (95% CI)	7.82 (-4.72, 20.36)	
P-value for Risk Difference	0.2217	
Improvement	27 (23.1%)	20 (24.1%)
Odds ratio (95% CI)	1.029 (0.525, 2.015)	
P-value for Odds Ratio	0.9342	
Relative Risk (95% CI)	1.02 (0.62, 1.68)	
P-value for Relative Risk	0.9381	
Risk difference (95% CI)	-0.45 (-11.66, 10.77)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9379	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	31 (31.3%)	13 (20.3%)
Odds ratio (95% CI)	1.882 (0.888, 3.989)	
P-value for Odds Ratio	0.0991	
Relative Risk (95% CI)	1.59 (0.90, 2.80)	
P-value for Relative Risk	0.1094	
Risk difference (95% CI)	11.86 (-1.60, 25.33)	
P-value for Risk Difference	0.0842	
Improvement	23 (23.2%)	13 (20.3%)
Odds ratio (95% CI)	1.231 (0.564, 2.687)	
P-value for Odds Ratio	0.6011	
Relative Risk (95% CI)	1.18 (0.65, 2.15)	
P-value for Relative Risk	0.5878	
Risk difference (95% CI)	2.27 (-10.61, 15.15)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7301	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	23 (26.4%)	9 (16.4%)
Odds ratio (95% CI)	1.903 (0.802, 4.514)	
P-value for Odds Ratio	0.1445	
Relative Risk (95% CI)	1.64 (0.82, 3.27)	
P-value for Relative Risk	0.1629	
Risk difference (95% CI)	12.37 (-1.86, 26.59)	
P-value for Risk Difference	0.0884	
Improvement	24 (27.6%)	11 (20.0%)
Odds ratio (95% CI)	1.535 (0.676, 3.484)	
P-value for Odds Ratio	0.3056	
Relative Risk (95% CI)	1.38 (0.74, 2.59)	
P-value for Relative Risk	0.3153	
Risk difference (95% CI)	7.88 (-6.14, 21.90)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2705	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	21 (27.3%)	6 (14.0%)
Odds ratio (95% CI)	2.643 (0.955, 7.311)	
P-value for Odds Ratio	0.0612	
Relative Risk (95% CI)	2.09 (0.92, 4.73)	
P-value for Relative Risk	0.0768	
Risk difference (95% CI)	13.32 (-3.56, 30.20)	
P-value for Risk Difference	0.1219	
Improvement	19 (24.7%)	11 (25.6%)
Odds ratio (95% CI)	0.970 (0.407, 2.310)	
P-value for Odds Ratio	0.9451	
Relative Risk (95% CI)	0.98 (0.51, 1.87)	
P-value for Relative Risk	0.9461	
Risk difference (95% CI)	-1.26 (-17.85, 15.34)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8821	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	24 (39.3%)	7 (18.9%)
Odds ratio (95% CI)	2.780 (1.036, 7.463)	
P-value for Odds Ratio	0.0424	
Relative Risk (95% CI)	1.94 (0.92, 4.08)	
P-value for Relative Risk	0.0795	
Risk difference (95% CI)	23.40 (6.22, 40.58)	
P-value for Risk Difference	0.0076	
Improvement	15 (24.6%)	4 (10.8%)
Odds ratio (95% CI)	2.699 (0.814, 8.954)	
P-value for Odds Ratio	0.1045	
Relative Risk (95% CI)	2.28 (0.82, 6.35)	
P-value for Relative Risk	0.1145	
Risk difference (95% CI)	14.24 (-1.32, 29.80)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0729	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	11 (31.4%)	4 (13.3%)
Odds ratio (95% CI)	2.600 (0.711, 9.509)	
P-value for Odds Ratio	0.1485	
Relative Risk (95% CI)	2.08 (0.74, 5.81)	
P-value for Relative Risk	0.1638	
Risk difference (95% CI)	16.46 (16.46, 16.46)*	
P-value for Risk Difference	NE	
Improvement	7 (20.0%)	6 (20.0%)
Odds ratio (95% CI)	0.978 (0.278, 3.439)	
P-value for Odds Ratio	0.9729	
Relative Risk (95% CI)	1.04 (0.39, 2.75)	
P-value for Relative Risk	0.9391	
Risk difference (95% CI)	-1.22 (-1.22, -1.22)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	10 (34.5%)	5 (23.8%)
Odds ratio (95% CI)	1.660 (0.453, 6.080)	
P-value for Odds Ratio	0.4445	
Relative Risk (95% CI)	1.45 (0.59, 3.57)	
P-value for Relative Risk	0.4143	
Risk difference (95% CI)	10.14 (-16.13, 36.41)	
P-value for Risk Difference	0.4493	
Improvement	8 (27.6%)	5 (23.8%)
Odds ratio (95% CI)	1.424 (0.376, 5.392)	
P-value for Odds Ratio	0.6027	
Relative Risk (95% CI)	1.42 (0.54, 3.71)	
P-value for Relative Risk	0.4769	
Risk difference (95% CI)	3.91 (-22.70, 30.52)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7734	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	5 (25.0%)	5 (31.3%)
Odds ratio (95% CI)	0.819 (0.166, 4.046)	
P-value for Odds Ratio	0.8065	
Relative Risk (95% CI)	0.81 (0.24, 2.73)	
P-value for Relative Risk	0.7308	
Risk difference (95% CI)	-2.44 (-36.16, 31.29)	
P-value for Risk Difference	0.8874	
Improvement	4 (20.0%)	4 (25.0%)
Odds ratio (95% CI)	0.808 (0.151, 4.315)	
P-value for Odds Ratio	0.8029	
Relative Risk (95% CI)	0.98 (0.98, 0.98)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-4.16 (-33.75, 25.44)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7832	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	3 (60.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.24 (1.24, 1.24)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	42.36 (-51.54, 136.25)	
P-value for Risk Difference	0.3766	
Improvement	0	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.56 (0.03, 9.73)	
P-value for Relative Risk	0.6933	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Pain :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	17 (10.8%)	22 (13.8%)
Odds ratio (95% CI)	0.747 (0.379, 1.472)	
P-value for Odds Ratio	0.3987	
Relative Risk (95% CI)	0.77 (0.43, 1.41)	
P-value for Relative Risk	0.4006	
Risk difference (95% CI)	-3.26 (-10.58, 4.05)	
P-value for Risk Difference	0.3820	
Improvement	15 (9.5%)	12 (7.5%)
Odds ratio (95% CI)	1.318 (0.593, 2.931)	
P-value for Odds Ratio	0.4980	
Relative Risk (95% CI)	1.28 (0.62, 2.64)	
P-value for Relative Risk	0.5072	
Risk difference (95% CI)	2.03 (-3.91, 7.97)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5036	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	17 (11.2%)	15 (10.9%)
Odds ratio (95% CI)	1.013 (0.480, 2.140)	
P-value for Odds Ratio	0.9727	
Relative Risk (95% CI)	1.00 (0.52, 1.93)	
P-value for Relative Risk	0.9886	
Risk difference (95% CI)	0.47 (-6.43, 7.37)	
P-value for Risk Difference	0.8935	
Improvement	13 (8.6%)	15 (10.9%)
Odds ratio (95% CI)	0.749 (0.339, 1.655)	
P-value for Odds Ratio	0.4756	
Relative Risk (95% CI)	0.76 (0.38, 1.54)	
P-value for Relative Risk	0.4469	
Risk difference (95% CI)	-1.52 (-7.96, 4.92)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6445	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	19 (13.2%)	20 (15.7%)
Odds ratio (95% CI)	0.813 (0.410, 1.612)	
P-value for Odds Ratio	0.5533	
Relative Risk (95% CI)	0.84 (0.47, 1.50)	
P-value for Relative Risk	0.5530	
Risk difference (95% CI)	-2.78 (-11.12, 5.56)	
P-value for Risk Difference	0.5133	
Improvement	9 (6.3%)	12 (9.4%)
Odds ratio (95% CI)	0.612 (0.245, 1.527)	
P-value for Odds Ratio	0.2923	
Relative Risk (95% CI)	0.63 (0.28, 1.45)	
P-value for Relative Risk	0.2805	
Risk difference (95% CI)	-2.35 (-8.52, 3.82)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4550	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	26 (16.4%)	26 (17.3%)
Odds ratio (95% CI)	0.909 (0.499, 1.656)	
P-value for Odds Ratio	0.7545	
Relative Risk (95% CI)	0.92 (0.56, 1.51)	
P-value for Relative Risk	0.7279	
Risk difference (95% CI)	-1.04 (-9.34, 7.25)	
P-value for Risk Difference	0.8053	
Improvement	16 (10.1%)	13 (8.7%)
Odds ratio (95% CI)	1.240 (0.572, 2.689)	
P-value for Odds Ratio	0.5862	
Relative Risk (95% CI)	1.20 (0.60, 2.41)	
P-value for Relative Risk	0.6015	
Risk difference (95% CI)	2.71 (-3.75, 9.18)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4104	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	30 (22.4%)	17 (17.3%)
Odds ratio (95% CI)	1.381 (0.706, 2.700)	
P-value for Odds Ratio	0.3460	
Relative Risk (95% CI)	1.27 (0.74, 2.18)	
P-value for Relative Risk	0.3869	
Risk difference (95% CI)	5.44 (-4.75, 15.64)	
P-value for Risk Difference	0.2951	
Improvement	12 (9.0%)	11 (11.2%)
Odds ratio (95% CI)	0.845 (0.351, 2.034)	
P-value for Odds Ratio	0.7067	
Relative Risk (95% CI)	0.85 (0.39, 1.84)	
P-value for Relative Risk	0.6824	
Risk difference (95% CI)	-1.02 (-10.51, 8.47)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8337	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	20 (17.1%)	18 (21.7%)
Odds ratio (95% CI)	0.805 (0.392, 1.652)	
P-value for Odds Ratio	0.5537	
Relative Risk (95% CI)	0.84 (0.48, 1.49)	
P-value for Relative Risk	0.5555	
Risk difference (95% CI)	-1.90 (-13.94, 10.13)	
P-value for Risk Difference	0.7565	
Improvement	9 (7.7%)	11 (13.3%)
Odds ratio (95% CI)	0.534 (0.207, 1.373)	
P-value for Odds Ratio	0.1928	
Relative Risk (95% CI)	0.56 (0.24, 1.30)	
P-value for Relative Risk	0.1759	
Risk difference (95% CI)	-4.90 (-14.04, 4.23)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2930	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	17 (17.2%)	13 (20.3%)
Odds ratio (95% CI)	0.891 (0.393, 2.024)	
P-value for Odds Ratio	0.7835	
Relative Risk (95% CI)	0.92 (0.48, 1.76)	
P-value for Relative Risk	0.8104	
Risk difference (95% CI)	-1.85 (-14.59, 10.88)	
P-value for Risk Difference	0.7753	
Improvement	6 (6.1%)	4 (6.3%)
Odds ratio (95% CI)	1.017 (0.270, 3.821)	
P-value for Odds Ratio	0.9805	
Relative Risk (95% CI)	1.00 (0.29, 3.43)	
P-value for Relative Risk	0.9993	
Risk difference (95% CI)	1.69 (-5.97, 9.35)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6658	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	21 (24.1%)	8 (14.5%)
Odds ratio (95% CI)	1.925 (0.779, 4.755)	
P-value for Odds Ratio	0.1556	
Relative Risk (95% CI)	1.70 (0.81, 3.56)	
P-value for Relative Risk	0.1599	
Risk difference (95% CI)	10.62 (-3.06, 24.29)	
P-value for Risk Difference	0.1282	
Improvement	8 (9.2%)	5 (9.1%)
Odds ratio (95% CI)	0.958 (0.289, 3.176)	
P-value for Odds Ratio	0.9438	
Relative Risk (95% CI)	0.92 (0.32, 2.68)	
P-value for Relative Risk	0.8791	
Risk difference (95% CI)	5.91 (-9.64, 21.46)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4565	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	16 (20.8%)	4 (9.3%)
Odds ratio (95% CI)	2.487 (0.768, 8.056)	
P-value for Odds Ratio	0.1288	
Relative Risk (95% CI)	2.16 (0.77, 6.09)	
P-value for Relative Risk	0.1456	
Risk difference (95% CI)	11.82 (-0.24, 23.88)	
P-value for Risk Difference	0.0548	
Improvement	7 (9.1%)	4 (9.3%)
Odds ratio (95% CI)	0.988 (0.266, 3.675)	
P-value for Odds Ratio	0.9860	
Relative Risk (95% CI)	0.97 (0.31, 3.09)	
P-value for Relative Risk	0.9617	
Risk difference (95% CI)	0.66 (-13.52, 14.84)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9272	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	16 (26.2%)	7 (18.9%)
Odds ratio (95% CI)	1.582 (0.573, 4.370)	
P-value for Odds Ratio	0.3763	
Relative Risk (95% CI)	1.40 (0.63, 3.12)	
P-value for Relative Risk	0.4069	
Risk difference (95% CI)	8.40 (-10.52, 27.32)	
P-value for Risk Difference	0.3839	
Improvement	5 (8.2%)	2 (5.4%)
Odds ratio (95% CI)	1.469 (0.256, 8.426)	
P-value for Odds Ratio	0.6662	
Relative Risk (95% CI)	1.45 (0.31, 6.87)	
P-value for Relative Risk	0.6410	
Risk difference (95% CI)	0.82 (-22.39, 24.02)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9451	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	16 (45.7%)	6 (20.0%)
Odds ratio (95% CI)	3.470 (1.055, 11.419)	
P-value for Odds Ratio	0.0406	
Relative Risk (95% CI)	2.30 (0.94, 5.62)	
P-value for Relative Risk	0.0675	
Risk difference (95% CI)	27.44 (5.12, 49.77)	
P-value for Risk Difference	0.0160	
Improvement	3 (8.6%)	3 (10.0%)
Odds ratio (95% CI)	0.938 (0.154, 5.726)	
P-value for Odds Ratio	0.9445	
Relative Risk (95% CI)	0.94 (0.23, 3.85)	
P-value for Relative Risk	0.9328	
Risk difference (95% CI)	0.83 (-29.62, 31.28)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9575	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	11 (37.9%)	4 (19.0%)
Odds ratio (95% CI)	2.434 (0.635, 9.333)	
P-value for Odds Ratio	0.1947	
Relative Risk (95% CI)	1.83 (0.65, 5.15)	
P-value for Relative Risk	0.2486	
Risk difference (95% CI)	19.51 (-5.16, 44.17)	
P-value for Risk Difference	0.1212	
Improvement	2 (6.9%)	1 (4.8%)
Odds ratio (95% CI)	1.792 (0.133, 24.129)	
P-value for Odds Ratio	0.6600	
Relative Risk (95% CI)	1.49 (0.16, 13.77)	
P-value for Relative Risk	0.7236	
Risk difference (95% CI)	4.52 (-31.37, 40.40)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8052	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	6 (30.0%)	2 (12.5%)
Odds ratio (95% CI)	4.134 (0.624, 27.394)	
P-value for Odds Ratio	0.1413	
Relative Risk (95% CI)	2.65 (0.62, 11.33)	
P-value for Relative Risk	0.1890	
Risk difference (95% CI)	17.71 (17.71, 17.71)*	
P-value for Risk Difference	NE	
Improvement	1 (5.0%)	1 (6.3%)
Odds ratio (95% CI)	0.263 (0.006, 11.228)	
P-value for Odds Ratio	0.4859	
Relative Risk (95% CI)	0.45 (0.45, 0.45)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-3.54 (-65.53, 58.46)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9110	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	2 (40.0%)	1 (14.3%)
Odds ratio (95% CI)	1.689 (0.054, 53.146)	
P-value for Odds Ratio	0.7659	
Relative Risk (95% CI)	0.58 (0.58, 0.58)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	7.47 (7.47, 7.47)*	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	2 (100.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.63 (0.51, 13.57)	
P-value for Relative Risk	0.2560	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Dyspnoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	27 (17.1%)	30 (18.9%)
Odds ratio (95% CI)	0.898 (0.504, 1.599)	
P-value for Odds Ratio	0.7141	
Relative Risk (95% CI)	0.91 (0.57, 1.46)	
P-value for Relative Risk	0.6938	
Risk difference (95% CI)	-1.33 (-9.82, 7.16)	
P-value for Risk Difference	0.7588	
Improvement	29 (18.4%)	32 (20.1%)
Odds ratio (95% CI)	0.892 (0.508, 1.568)	
P-value for Odds Ratio	0.6922	
Relative Risk (95% CI)	0.92 (0.58, 1.44)	
P-value for Relative Risk	0.7039	
Risk difference (95% CI)	-1.84 (-10.55, 6.88)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6795	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	38 (25.0%)	25 (18.1%)
Odds ratio (95% CI)	1.583 (0.892, 2.811)	
P-value for Odds Ratio	0.1167	
Relative Risk (95% CI)	1.46 (0.93, 2.27)	
P-value for Relative Risk	0.0979	
Risk difference (95% CI)	6.07 (-3.17, 15.30)	
P-value for Risk Difference	0.1978	
Improvement	32 (21.1%)	21 (15.2%)
Odds ratio (95% CI)	1.437 (0.780, 2.649)	
P-value for Odds Ratio	0.2450	
Relative Risk (95% CI)	1.35 (0.82, 2.23)	
P-value for Relative Risk	0.2372	
Risk difference (95% CI)	4.99 (-3.96, 13.95)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2745	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	30 (20.8%)	37 (29.1%)
Odds ratio (95% CI)	0.613 (0.348, 1.079)	
P-value for Odds Ratio	0.0900	
Relative Risk (95% CI)	0.72 (0.47, 1.09)	
P-value for Relative Risk	0.1158	
Risk difference (95% CI)	-9.33 (-19.50, 0.84)	
P-value for Risk Difference	0.0721	
Improvement	30 (20.8%)	20 (15.7%)
Odds ratio (95% CI)	1.404 (0.747, 2.640)	
P-value for Odds Ratio	0.2916	
Relative Risk (95% CI)	1.29 (0.78, 2.16)	
P-value for Relative Risk	0.3242	
Risk difference (95% CI)	8.12 (-1.96, 18.20)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1143	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	39 (24.5%)	39 (26.0%)
Odds ratio (95% CI)	0.877 (0.520, 1.480)	
P-value for Odds Ratio	0.6228	
Relative Risk (95% CI)	0.92 (0.63, 1.33)	
P-value for Relative Risk	0.6480	
Risk difference (95% CI)	-2.32 (-11.79, 7.16)	
P-value for Risk Difference	0.6317	
Improvement	27 (17.0%)	24 (16.0%)
Odds ratio (95% CI)	1.088 (0.590, 2.004)	
P-value for Odds Ratio	0.7875	
Relative Risk (95% CI)	1.05 (0.64, 1.73)	
P-value for Relative Risk	0.8351	
Risk difference (95% CI)	2.66 (-5.47, 10.79)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5219	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	27 (20.1%)	23 (23.5%)
Odds ratio (95% CI)	0.845 (0.447, 1.595)	
P-value for Odds Ratio	0.6028	
Relative Risk (95% CI)	0.87 (0.53, 1.42)	
P-value for Relative Risk	0.5798	
Risk difference (95% CI)	-2.48 (-13.49, 8.52)	
P-value for Risk Difference	0.6582	
Improvement	27 (20.1%)	14 (14.3%)
Odds ratio (95% CI)	1.519 (0.746, 3.094)	
P-value for Odds Ratio	0.2494	
Relative Risk (95% CI)	1.41 (0.78, 2.55)	
P-value for Relative Risk	0.2606	
Risk difference (95% CI)	6.21 (-3.57, 16.00)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2132	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	27 (23.1%)	15 (18.1%)
Odds ratio (95% CI)	1.469 (0.716, 3.012)	
P-value for Odds Ratio	0.2945	
Relative Risk (95% CI)	1.34 (0.76, 2.34)	
P-value for Relative Risk	0.3086	
Risk difference (95% CI)	5.10 (-5.74, 15.94)	
P-value for Risk Difference	0.3565	
Improvement	19 (16.2%)	16 (19.3%)
Odds ratio (95% CI)	0.795 (0.379, 1.667)	
P-value for Odds Ratio	0.5441	
Relative Risk (95% CI)	0.83 (0.45, 1.51)	
P-value for Relative Risk	0.5344	
Risk difference (95% CI)	-3.28 (-14.56, 7.99)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5683	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	19 (19.2%)	15 (23.4%)
Odds ratio (95% CI)	0.795 (0.366, 1.727)	
P-value for Odds Ratio	0.5619	
Relative Risk (95% CI)	0.85 (0.47, 1.55)	
P-value for Relative Risk	0.6059	
Risk difference (95% CI)	-4.15 (-16.91, 8.61)	
P-value for Risk Difference	0.5236	
Improvement	21 (21.2%)	11 (17.2%)
Odds ratio (95% CI)	1.225 (0.540, 2.776)	
P-value for Odds Ratio	0.6273	
Relative Risk (95% CI)	1.17 (0.61, 2.25)	
P-value for Relative Risk	0.6413	
Risk difference (95% CI)	2.89 (-9.30, 15.07)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6423	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	10 (11.5%)	9 (16.4%)
Odds ratio (95% CI)	0.673 (0.247, 1.833)	
P-value for Odds Ratio	0.4388	
Relative Risk (95% CI)	0.73 (0.32, 1.66)	
P-value for Relative Risk	0.4566	
Risk difference (95% CI)	-6.07 (-17.09, 4.95)	
P-value for Risk Difference	0.2804	
Improvement	18 (20.7%)	5 (9.1%)
Odds ratio (95% CI)	2.561 (0.888, 7.383)	
P-value for Odds Ratio	0.0817	
Relative Risk (95% CI)	2.26 (0.89, 5.73)	
P-value for Relative Risk	0.0863	
Risk difference (95% CI)	11.61 (-0.41, 23.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0584	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	14 (18.2%)	6 (14.0%)
Odds ratio (95% CI)	1.393 (0.474, 4.094)	
P-value for Odds Ratio	0.5472	
Relative Risk (95% CI)	1.27 (0.54, 3.00)	
P-value for Relative Risk	0.5851	
Risk difference (95% CI)	4.86 (-6.95, 16.67)	
P-value for Risk Difference	0.4196	
Improvement	16 (20.8%)	4 (9.3%)
Odds ratio (95% CI)	2.739 (0.844, 8.895)	
P-value for Odds Ratio	0.0936	
Relative Risk (95% CI)	2.32 (0.83, 6.47)	
P-value for Relative Risk	0.1094	
Risk difference (95% CI)	13.10 (-2.44, 28.64)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0984	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	9 (14.8%)	8 (21.6%)
Odds ratio (95% CI)	0.627 (0.213, 1.845)	
P-value for Odds Ratio	0.3967	
Relative Risk (95% CI)	0.72 (0.30, 1.68)	
P-value for Relative Risk	0.4427	
Risk difference (95% CI)	-7.67 (-23.89, 8.55)	
P-value for Risk Difference	0.3541	
Improvement	10 (16.4%)	3 (8.1%)
Odds ratio (95% CI)	2.324 (0.576, 9.376)	
P-value for Odds Ratio	0.2362	
Relative Risk (95% CI)	2.02 (0.60, 6.84)	
P-value for Relative Risk	0.2568	
Risk difference (95% CI)	6.85 (-14.13, 27.83)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5223	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	7 (20.0%)	9 (30.0%)
Odds ratio (95% CI)	0.428 (0.128, 1.431)	
P-value for Odds Ratio	0.1680	
Relative Risk (95% CI)	0.47 (0.19, 1.16)	
P-value for Relative Risk	0.1011	
Risk difference (95% CI)	-13.65 (-13.65, -13.65)*	
P-value for Risk Difference	NE	
Improvement	4 (11.4%)	2 (6.7%)
Odds ratio (95% CI)	3.730 (0.382, 36.468)	
P-value for Odds Ratio	0.2578	
Relative Risk (95% CI)	1.88 (1.88, 1.88)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	5.76 (-30.46, 41.99)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7552	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	5 (17.2%)	7 (33.3%)
Odds ratio (95% CI)	0.345 (0.080, 1.482)	
P-value for Odds Ratio	0.1525	
Relative Risk (95% CI)	0.94 (0.94, 0.94)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-14.69 (-42.24, 12.85)	
P-value for Risk Difference	0.2958	
Improvement	5 (17.2%)	3 (14.3%)
Odds ratio (95% CI)	0.981 (0.186, 5.167)	
P-value for Odds Ratio	0.9822	
Relative Risk (95% CI)	0.73 (0.15, 3.43)	
P-value for Relative Risk	0.6869	
Risk difference (95% CI)	5.08 (-14.74, 24.89)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6156	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	6 (30.0%)	2 (12.5%)
Odds ratio (95% CI)	2.269 (0.339, 15.175)	
P-value for Odds Ratio	0.3980	
Relative Risk (95% CI)	1.87 (0.39, 8.92)	
P-value for Relative Risk	0.4323	
Risk difference (95% CI)	11.62 (-19.16, 42.41)	
P-value for Risk Difference	0.4593	
Improvement	3 (15.0%)	1 (6.3%)
Odds ratio (95% CI)	2.824 (0.241, 33.111)	
P-value for Odds Ratio	0.4085	
Relative Risk (95% CI)	2.42 (0.29, 20.55)	
P-value for Relative Risk	0.4167	
Risk difference (95% CI)	7.65 (7.65, 7.65)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	2 (40.0%)	1 (14.3%)
Odds ratio (95% CI)	5.025 (0.188, 134.596)	
P-value for Odds Ratio	0.3358	
Relative Risk (95% CI)	5.19 (5.19, 5.19)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	30.23 (-37.18, 97.63)	
P-value for Risk Difference	0.3795	
Improvement	1 (20.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Insomnia :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	19 (12.0%)	24 (15.1%)
Odds ratio (95% CI)	0.787 (0.409, 1.513)	
P-value for Odds Ratio	0.4722	
Relative Risk (95% CI)	0.83 (0.48, 1.45)	
P-value for Relative Risk	0.5117	
Risk difference (95% CI)	-4.95 (-13.24, 3.35)	
P-value for Risk Difference	0.2422	
Improvement	24 (15.2%)	32 (20.1%)
Odds ratio (95% CI)	0.735 (0.408, 1.324)	
P-value for Odds Ratio	0.3052	
Relative Risk (95% CI)	0.78 (0.48, 1.26)	
P-value for Relative Risk	0.3082	
Risk difference (95% CI)	-4.57 (-13.10, 3.96)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2940	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	20 (13.2%)	9 (6.5%)
Odds ratio (95% CI)	2.192 (0.944, 5.089)	
P-value for Odds Ratio	0.0677	
Relative Risk (95% CI)	1.98 (0.95, 4.15)	
P-value for Relative Risk	0.0701	
Risk difference (95% CI)	6.16 (-2.06, 14.37)	
P-value for Risk Difference	0.1417	
Improvement	31 (20.4%)	26 (18.8%)
Odds ratio (95% CI)	1.141 (0.633, 2.058)	
P-value for Odds Ratio	0.6598	
Relative Risk (95% CI)	1.09 (0.69, 1.73)	
P-value for Relative Risk	0.7185	
Risk difference (95% CI)	5.13 (-5.00, 15.26)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3207	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	20 (13.9%)	14 (11.0%)
Odds ratio (95% CI)	1.343 (0.641, 2.812)	
P-value for Odds Ratio	0.4347	
Relative Risk (95% CI)	1.30 (0.69, 2.45)	
P-value for Relative Risk	0.4199	
Risk difference (95% CI)	1.14 (-7.45, 9.74)	
P-value for Risk Difference	0.7945	
Improvement	33 (22.9%)	28 (22.0%)
Odds ratio (95% CI)	1.074 (0.599, 1.927)	
P-value for Odds Ratio	0.8108	
Relative Risk (95% CI)	1.06 (0.68, 1.63)	
P-value for Relative Risk	0.8018	
Risk difference (95% CI)	2.07 (-9.23, 13.37)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7194	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	26 (16.4%)	13 (8.7%)
Odds ratio (95% CI)	2.090 (1.018, 4.291)	
P-value for Odds Ratio	0.0445	
Relative Risk (95% CI)	1.87 (1.00, 3.48)	
P-value for Relative Risk	0.0492	
Risk difference (95% CI)	6.54 (-0.54, 13.61)	
P-value for Risk Difference	0.0702	
Improvement	38 (23.9%)	30 (20.0%)
Odds ratio (95% CI)	1.329 (0.762, 2.319)	
P-value for Odds Ratio	0.3167	
Relative Risk (95% CI)	1.23 (0.81, 1.85)	
P-value for Relative Risk	0.3344	
Risk difference (95% CI)	4.30 (-6.33, 14.92)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4280	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	15 (11.2%)	7 (7.1%)
Odds ratio (95% CI)	1.652 (0.637, 4.283)	
P-value for Odds Ratio	0.3018	
Relative Risk (95% CI)	1.51 (0.64, 3.55)	
P-value for Relative Risk	0.3471	
Risk difference (95% CI)	5.19 (-2.48, 12.85)	
P-value for Risk Difference	0.1846	
Improvement	34 (25.4%)	19 (19.4%)
Odds ratio (95% CI)	1.408 (0.734, 2.701)	
P-value for Odds Ratio	0.3037	
Relative Risk (95% CI)	1.31 (0.80, 2.14)	
P-value for Relative Risk	0.2814	
Risk difference (95% CI)	5.09 (-7.25, 17.44)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4186	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	15 (12.8%)	7 (8.4%)
Odds ratio (95% CI)	1.595 (0.613, 4.154)	
P-value for Odds Ratio	0.3387	
Relative Risk (95% CI)	1.45 (0.61, 3.43)	
P-value for Relative Risk	0.3966	
Risk difference (95% CI)	8.43 (-0.97, 17.83)	
P-value for Risk Difference	0.0789	
Improvement	24 (20.5%)	17 (20.5%)
Odds ratio (95% CI)	0.988 (0.486, 2.010)	
P-value for Odds Ratio	0.9738	
Relative Risk (95% CI)	0.98 (0.57, 1.69)	
P-value for Relative Risk	0.9350	
Risk difference (95% CI)	1.29 (-11.11, 13.70)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8383	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	10 (10.1%)	6 (9.4%)
Odds ratio (95% CI)	1.163 (0.396, 3.415)	
P-value for Odds Ratio	0.7841	
Relative Risk (95% CI)	1.17 (0.45, 3.08)	
P-value for Relative Risk	0.7461	
Risk difference (95% CI)	-2.32 (-13.35, 8.71)	
P-value for Risk Difference	0.6800	
Improvement	24 (24.2%)	12 (18.8%)
Odds ratio (95% CI)	1.336 (0.603, 2.961)	
P-value for Odds Ratio	0.4756	
Relative Risk (95% CI)	1.24 (0.68, 2.27)	
P-value for Relative Risk	0.4903	
Risk difference (95% CI)	6.57 (-7.45, 20.59)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3583	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	7 (8.0%)	6 (10.9%)
Odds ratio (95% CI)	0.655 (0.194, 2.212)	
P-value for Odds Ratio	0.4955	
Relative Risk (95% CI)	0.71 (0.26, 1.92)	
P-value for Relative Risk	0.5027	
Risk difference (95% CI)	-2.85 (-12.12, 6.41)	
P-value for Risk Difference	0.5458	
Improvement	26 (29.9%)	13 (23.6%)
Odds ratio (95% CI)	1.422 (0.641, 3.153)	
P-value for Odds Ratio	0.3868	
Relative Risk (95% CI)	1.28 (0.74, 2.24)	
P-value for Relative Risk	0.3785	
Risk difference (95% CI)	5.77 (-11.09, 22.62)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5025	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	1 (1.3%)	4 (9.3%)
Odds ratio (95% CI)	0.108 (0.011, 1.095)	
P-value for Odds Ratio	0.0597	
Relative Risk (95% CI)	0.12 (0.01, 1.05)	
P-value for Relative Risk	0.0554	
Risk difference (95% CI)	-7.56 (-31.85, 16.73)	
P-value for Risk Difference	0.5417	
Improvement	22 (28.6%)	10 (23.3%)
Odds ratio (95% CI)	1.400 (0.573, 3.419)	
P-value for Odds Ratio	0.4606	
Relative Risk (95% CI)	1.25 (0.67, 2.35)	
P-value for Relative Risk	0.4880	
Risk difference (95% CI)	7.94 (-9.57, 25.46)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3741	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	7 (11.5%)	2 (5.4%)
Odds ratio (95% CI)	2.177 (0.422, 11.245)	
P-value for Odds Ratio	0.3529	
Relative Risk (95% CI)	1.68 (1.68, 1.68)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	8.97 (-15.33, 33.27)	
P-value for Risk Difference	0.4694	
Improvement	17 (27.9%)	8 (21.6%)
Odds ratio (95% CI)	1.502 (0.556, 4.061)	
P-value for Odds Ratio	0.4224	
Relative Risk (95% CI)	1.31 (0.64, 2.69)	
P-value for Relative Risk	0.4571	
Risk difference (95% CI)	9.01 (-11.02, 29.03)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3780	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	3 (8.6%)	2 (6.7%)
Odds ratio (95% CI)	0.412 (0.033, 5.164)	
P-value for Odds Ratio	0.4922	
Relative Risk (95% CI)	0.48 (0.07, 3.34)	
P-value for Relative Risk	0.4545	
Risk difference (95% CI)	0.04 (-34.03, 34.11)	
P-value for Risk Difference	0.9982	
Improvement	10 (28.6%)	8 (26.7%)
Odds ratio (95% CI)	1.223 (0.371, 4.032)	
P-value for Odds Ratio	0.7411	
Relative Risk (95% CI)	1.12 (0.51, 2.46)	
P-value for Relative Risk	0.7711	
Risk difference (95% CI)	3.24 (-23.05, 29.54)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8091	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	2 (6.9%)	2 (9.5%)
Odds ratio (95% CI)	0.377 (0.031, 4.639)	
P-value for Odds Ratio	0.4466	
Relative Risk (95% CI)	0.39 (0.04, 3.97)	
P-value for Relative Risk	0.4263	
Risk difference (95% CI)	-2.59 (-27.37, 22.20)	
P-value for Risk Difference	0.8379	
Improvement	10 (34.5%)	3 (14.3%)
Odds ratio (95% CI)	3.952 (0.819, 19.054)	
P-value for Odds Ratio	0.0869	
Relative Risk (95% CI)	2.37 (0.78, 7.18)	
P-value for Relative Risk	0.1287	
Risk difference (95% CI)	15.43 (-16.95, 47.81)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3504	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	2 (10.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.33 (0.42, 12.91)	
P-value for Relative Risk	0.3529	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	8 (40.0%)	5 (31.3%)
Odds ratio (95% CI)	2.519 (0.501, 12.662)	
P-value for Odds Ratio	0.2623	
Relative Risk (95% CI)	1.64 (0.74, 3.64)	
P-value for Relative Risk	0.2222	
Risk difference (95% CI)	13.81 (13.81, 13.81)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	2 (40.0%)	3 (42.9%)
Odds ratio (95% CI)	0.895 (0.065, 12.238)	
P-value for Odds Ratio	0.9339	
Relative Risk (95% CI)	1.00 (0.22, 4.52)	
P-value for Relative Risk	0.9996	
Risk difference (95% CI)	-3.08 (-74.05, 67.90)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9323	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (50.0%)	1 (50.0%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-47.50 (-250.77, 155.77)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Appetite loss :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6470	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	15 (9.5%)	18 (11.3%)
Odds ratio (95% CI)	0.839 (0.405, 1.735)	
P-value for Odds Ratio	0.6350	
Relative Risk (95% CI)	0.86 (0.45, 1.64)	
P-value for Relative Risk	0.6414	
Risk difference (95% CI)	-1.79 (-8.49, 4.91)	
P-value for Risk Difference	0.6004	
Improvement	25 (15.8%)	20 (12.6%)
Odds ratio (95% CI)	1.313 (0.694, 2.484)	
P-value for Odds Ratio	0.4025	
Relative Risk (95% CI)	1.24 (0.72, 2.15)	
P-value for Relative Risk	0.4371	
Risk difference (95% CI)	5.18 (-2.91, 13.26)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2094	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	19 (12.5%)	21 (15.2%)
Odds ratio (95% CI)	0.812 (0.415, 1.590)	
P-value for Odds Ratio	0.5439	
Relative Risk (95% CI)	0.84 (0.47, 1.50)	
P-value for Relative Risk	0.5610	
Risk difference (95% CI)	-2.93 (-10.79, 4.93)	
P-value for Risk Difference	0.4646	
Improvement	27 (17.8%)	11 (8.0%)
Odds ratio (95% CI)	2.557 (1.212, 5.395)	
P-value for Odds Ratio	0.0137	
Relative Risk (95% CI)	2.29 (1.18, 4.44)	
P-value for Relative Risk	0.0142	
Risk difference (95% CI)	9.56 (1.69, 17.42)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0172	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	16 (11.1%)	16 (12.6%)
Odds ratio (95% CI)	0.888 (0.421, 1.873)	
P-value for Odds Ratio	0.7542	
Relative Risk (95% CI)	0.90 (0.47, 1.73)	
P-value for Relative Risk	0.7615	
Risk difference (95% CI)	-2.81 (-11.27, 5.64)	
P-value for Risk Difference	0.5146	
Improvement	23 (16.0%)	11 (8.7%)
Odds ratio (95% CI)	1.981 (0.921, 4.263)	
P-value for Odds Ratio	0.0804	
Relative Risk (95% CI)	1.81 (0.92, 3.58)	
P-value for Relative Risk	0.0876	
Risk difference (95% CI)	7.81 (0.17, 15.45)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0452	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	24 (15.1%)	20 (13.3%)
Odds ratio (95% CI)	1.170 (0.615, 2.227)	
P-value for Odds Ratio	0.6325	
Relative Risk (95% CI)	1.15 (0.66, 1.99)	
P-value for Relative Risk	0.6240	
Risk difference (95% CI)	1.69 (-6.38, 9.76)	
P-value for Risk Difference	0.6811	
Improvement	24 (15.1%)	19 (12.7%)
Odds ratio (95% CI)	1.220 (0.636, 2.343)	
P-value for Odds Ratio	0.5494	
Relative Risk (95% CI)	1.17 (0.67, 2.06)	
P-value for Relative Risk	0.5753	
Risk difference (95% CI)	3.17 (-4.57, 10.91)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4224	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	14 (10.4%)	11 (11.2%)
Odds ratio (95% CI)	0.898 (0.384, 2.098)	
P-value for Odds Ratio	0.8038	
Relative Risk (95% CI)	0.93 (0.44, 1.95)	
P-value for Relative Risk	0.8418	
Risk difference (95% CI)	-1.91 (-10.40, 6.57)	
P-value for Risk Difference	0.6585	
Improvement	25 (18.7%)	10 (10.2%)
Odds ratio (95% CI)	2.203 (0.992, 4.894)	
P-value for Odds Ratio	0.0524	
Relative Risk (95% CI)	1.93 (0.98, 3.82)	
P-value for Relative Risk	0.0588	
Risk difference (95% CI)	8.82 (0.25, 17.39)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0438	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	13 (11.1%)	9 (10.8%)
Odds ratio (95% CI)	1.049 (0.424, 2.594)	
P-value for Odds Ratio	0.9180	
Relative Risk (95% CI)	1.05 (0.47, 2.34)	
P-value for Relative Risk	0.9123	
Risk difference (95% CI)	0.20 (-10.44, 10.83)	
P-value for Risk Difference	0.9712	
Improvement	18 (15.4%)	7 (8.4%)
Odds ratio (95% CI)	2.166 (0.848, 5.532)	
P-value for Odds Ratio	0.1061	
Relative Risk (95% CI)	1.94 (0.85, 4.39)	
P-value for Relative Risk	0.1134	
Risk difference (95% CI)	6.58 (-4.39, 17.56)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2398	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	15 (15.2%)	9 (14.1%)
Odds ratio (95% CI)	1.033 (0.414, 2.580)	
P-value for Odds Ratio	0.9439	
Relative Risk (95% CI)	1.03 (0.48, 2.18)	
P-value for Relative Risk	0.9418	
Risk difference (95% CI)	-0.37 (-12.19, 11.44)	
P-value for Risk Difference	0.9505	
Improvement	17 (17.2%)	7 (10.9%)
Odds ratio (95% CI)	1.764 (0.679, 4.579)	
P-value for Odds Ratio	0.2438	
Relative Risk (95% CI)	1.63 (0.71, 3.72)	
P-value for Relative Risk	0.2473	
Risk difference (95% CI)	6.56 (-3.99, 17.11)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2229	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	15 (17.2%)	9 (16.4%)
Odds ratio (95% CI)	1.067 (0.425, 2.679)	
P-value for Odds Ratio	0.8895	
Relative Risk (95% CI)	1.05 (0.50, 2.20)	
P-value for Relative Risk	0.9037	
Risk difference (95% CI)	0.85 (-11.89, 13.60)	
P-value for Risk Difference	0.8955	
Improvement	14 (16.1%)	5 (9.1%)
Odds ratio (95% CI)	1.931 (0.649, 5.747)	
P-value for Odds Ratio	0.2369	
Relative Risk (95% CI)	1.81 (0.69, 4.73)	
P-value for Relative Risk	0.2279	
Risk difference (95% CI)	5.48 (-5.78, 16.75)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3401	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	9 (11.7%)	5 (11.6%)
Odds ratio (95% CI)	0.916 (0.274, 3.063)	
P-value for Odds Ratio	0.8867	
Relative Risk (95% CI)	0.89 (0.32, 2.45)	
P-value for Relative Risk	0.8182	
Risk difference (95% CI)	-0.01 (-16.42, 16.40)	
P-value for Risk Difference	0.9992	
Improvement	14 (18.2%)	4 (9.3%)
Odds ratio (95% CI)	2.558 (0.763, 8.578)	
P-value for Odds Ratio	0.1281	
Relative Risk (95% CI)	2.25 (0.81, 6.27)	
P-value for Relative Risk	0.1210	
Risk difference (95% CI)	6.45 (-11.42, 24.32)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4792	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	5 (8.2%)	3 (8.1%)
Odds ratio (95% CI)	1.029 (0.209, 5.059)	
P-value for Odds Ratio	0.9717	
Relative Risk (95% CI)	0.92 (0.25, 3.36)	
P-value for Relative Risk	0.9049	
Risk difference (95% CI)	1.29 (-23.74, 26.32)	
P-value for Risk Difference	0.9193	
Improvement	13 (21.3%)	3 (8.1%)
Odds ratio (95% CI)	3.422 (0.886, 13.212)	
P-value for Odds Ratio	0.0743	
Relative Risk (95% CI)	2.80 (0.86, 9.13)	
P-value for Relative Risk	0.0870	
Risk difference (95% CI)	11.25 (-8.61, 31.10)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2670	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	7 (20.0%)	3 (10.0%)
Odds ratio (95% CI)	1.997 (0.457, 8.730)	
P-value for Odds Ratio	0.3583	
Relative Risk (95% CI)	1.80 (0.51, 6.30)	
P-value for Relative Risk	0.3584	
Risk difference (95% CI)	8.67 (8.67, 8.67)*	
P-value for Risk Difference	NE	
Improvement	7 (20.0%)	2 (6.7%)
Odds ratio (95% CI)	3.081 (0.563, 16.876)	
P-value for Odds Ratio	0.1946	
Relative Risk (95% CI)	2.53 (0.57, 11.19)	
P-value for Relative Risk	0.2225	
Risk difference (95% CI)	12.29 (12.29, 12.29)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	5 (17.2%)	2 (9.5%)
Odds ratio (95% CI)	2.246 (0.381, 13.244)	
P-value for Odds Ratio	0.3715	
Relative Risk (95% CI)	1.99 (0.43, 9.15)	
P-value for Relative Risk	0.3772	
Risk difference (95% CI)	7.78 (-21.59, 37.14)	
P-value for Risk Difference	0.6038	
Improvement	7 (24.1%)	3 (14.3%)
Odds ratio (95% CI)	1.449 (0.291, 7.206)	
P-value for Odds Ratio	0.6505	
Relative Risk (95% CI)	1.02 (1.02, 1.02)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	5.38 (-19.92, 30.67)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6770	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	3 (15.0%)	4 (25.0%)
Odds ratio (95% CI)	0.873 (0.149, 5.124)	
P-value for Odds Ratio	0.8808	
Relative Risk (95% CI)	0.93 (0.25, 3.49)	
P-value for Relative Risk	0.9110	
Risk difference (95% CI)	-1.90 (-1.90, -1.90)*	
P-value for Risk Difference	NE	
Improvement	7 (35.0%)	2 (12.5%)
Odds ratio (95% CI)	3.036 (0.428, 21.516)	
P-value for Odds Ratio	0.2664	
Relative Risk (95% CI)	1.88 (0.57, 6.12)	
P-value for Relative Risk	0.2970	
Risk difference (95% CI)	11.27 (-14.75, 37.28)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3960	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	1 (20.0%)	3 (42.9%)
Odds ratio (95% CI)	0.256 (0.010, 6.452)	
P-value for Odds Ratio	0.4077	
Relative Risk (95% CI)	0.26 (0.00, 23.82)	
P-value for Relative Risk	0.5617	
Risk difference (95% CI)	-18.09 (-84.40, 48.23)	
P-value for Risk Difference	0.5930	
Improvement	2 (40.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.14 (0.42, 10.98)	
P-value for Relative Risk	0.3711	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.50 (0.32, 63.94)	
P-value for Relative Risk	0.2433	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.50 (0.18, 12.46)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Constipation :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	159
Deterioration	17 (10.8%)	22 (13.8%)
Odds ratio (95% CI)	0.752 (0.382, 1.481)	
P-value for Odds Ratio	0.4100	
Relative Risk (95% CI)	0.78 (0.43, 1.42)	
P-value for Relative Risk	0.4164	
Risk difference (95% CI)	-3.66 (-11.13, 3.80)	
P-value for Risk Difference	0.3363	
Improvement	8 (5.1%)	13 (8.2%)
Odds ratio (95% CI)	0.627 (0.250, 1.576)	
P-value for Odds Ratio	0.3214	
Relative Risk (95% CI)	0.65 (0.28, 1.52)	
P-value for Relative Risk	0.3240	
Risk difference (95% CI)	-2.34 (-10.73, 6.05)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5849	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	138
Deterioration	16 (10.5%)	11 (8.0%)
Odds ratio (95% CI)	1.259 (0.555, 2.856)	
P-value for Odds Ratio	0.5808	
Relative Risk (95% CI)	1.24 (0.59, 2.57)	
P-value for Relative Risk	0.5702	
Risk difference (95% CI)	1.03 (-5.31, 7.37)	
P-value for Risk Difference	0.7500	
Improvement	8 (5.3%)	10 (7.2%)
Odds ratio (95% CI)	0.703 (0.267, 1.856)	
P-value for Odds Ratio	0.4775	
Relative Risk (95% CI)	0.72 (0.29, 1.77)	
P-value for Relative Risk	0.4753	
Risk difference (95% CI)	-1.47 (-6.89, 3.94)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5937	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	127
Deterioration	22 (15.3%)	15 (11.8%)
Odds ratio (95% CI)	1.349 (0.664, 2.741)	
P-value for Odds Ratio	0.4085	
Relative Risk (95% CI)	1.28 (0.69, 2.36)	
P-value for Relative Risk	0.4289	
Risk difference (95% CI)	4.25 (-3.75, 12.26)	
P-value for Risk Difference	0.2978	
Improvement	10 (6.9%)	7 (5.5%)
Odds ratio (95% CI)	1.279 (0.468, 3.497)	
P-value for Odds Ratio	0.6316	
Relative Risk (95% CI)	1.25 (0.49, 3.18)	
P-value for Relative Risk	0.6380	
Risk difference (95% CI)	1.59 (-4.07, 7.24)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5828	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	159	150
Deterioration	17 (10.7%)	15 (10.0%)
Odds ratio (95% CI)	1.033 (0.493, 2.163)	
P-value for Odds Ratio	0.9309	
Relative Risk (95% CI)	1.02 (0.53, 1.97)	
P-value for Relative Risk	0.9617	
Risk difference (95% CI)	1.07 (-5.56, 7.69)	
P-value for Risk Difference	0.7526	
Improvement	8 (5.0%)	9 (6.0%)
Odds ratio (95% CI)	0.870 (0.324, 2.337)	
P-value for Odds Ratio	0.7830	
Relative Risk (95% CI)	0.87 (0.35, 2.18)	
P-value for Relative Risk	0.7649	
Risk difference (95% CI)	0.02 (-5.15, 5.19)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9931	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	98
Deterioration	14 (10.4%)	8 (8.2%)
Odds ratio (95% CI)	1.329 (0.530, 3.334)	
P-value for Odds Ratio	0.5439	
Relative Risk (95% CI)	1.26 (0.55, 2.90)	
P-value for Relative Risk	0.5870	
Risk difference (95% CI)	4.55 (-3.38, 12.48)	
P-value for Risk Difference	0.2607	
Improvement	5 (3.7%)	7 (7.1%)
Odds ratio (95% CI)	0.543 (0.163, 1.809)	
P-value for Odds Ratio	0.3196	
Relative Risk (95% CI)	0.55 (0.18, 1.66)	
P-value for Relative Risk	0.2899	
Risk difference (95% CI)	-0.44 (-6.21, 5.34)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8818	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	83
Deterioration	9 (7.7%)	9 (10.8%)
Odds ratio (95% CI)	0.746 (0.281, 1.984)	
P-value for Odds Ratio	0.5575	
Relative Risk (95% CI)	0.77 (0.32, 1.86)	
P-value for Relative Risk	0.5625	
Risk difference (95% CI)	-2.27 (-13.47, 8.92)	
P-value for Risk Difference	0.6903	
Improvement	4 (3.4%)	8 (9.6%)
Odds ratio (95% CI)	0.316 (0.090, 1.107)	
P-value for Odds Ratio	0.0717	
Relative Risk (95% CI)	0.33 (0.10, 1.08)	
P-value for Relative Risk	0.0677	
Risk difference (95% CI)	-6.28 (-14.78, 2.22)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1476	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	10 (10.1%)	11 (17.2%)
Odds ratio (95% CI)	0.560 (0.220, 1.422)	
P-value for Odds Ratio	0.2225	
Relative Risk (95% CI)	0.60 (0.27, 1.33)	
P-value for Relative Risk	0.2081	
Risk difference (95% CI)	-4.57 (-16.62, 7.48)	
P-value for Risk Difference	0.4577	
Improvement	4 (4.0%)	6 (9.4%)
Odds ratio (95% CI)	0.454 (0.118, 1.748)	
P-value for Odds Ratio	0.2511	
Relative Risk (95% CI)	0.49 (0.14, 1.67)	
P-value for Relative Risk	0.2535	
Risk difference (95% CI)	-1.81 (-14.67, 11.04)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7820	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	11 (12.6%)	8 (14.5%)
Odds ratio (95% CI)	0.900 (0.335, 2.418)	
P-value for Odds Ratio	0.8341	
Relative Risk (95% CI)	0.91 (0.39, 2.11)	
P-value for Relative Risk	0.8201	
Risk difference (95% CI)	-0.34 (-12.69, 12.00)	
P-value for Risk Difference	0.9565	
Improvement	6 (6.9%)	4 (7.3%)
Odds ratio (95% CI)	1.058 (0.277, 4.046)	
P-value for Odds Ratio	0.9345	
Relative Risk (95% CI)	0.98 (0.30, 3.26)	
P-value for Relative Risk	0.9745	
Risk difference (95% CI)	0.99 (-14.60, 16.58)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9013	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	8 (10.4%)	4 (9.3%)
Odds ratio (95% CI)	1.112 (0.310, 3.995)	
P-value for Odds Ratio	0.8702	
Relative Risk (95% CI)	1.10 (0.35, 3.47)	
P-value for Relative Risk	0.8670	
Risk difference (95% CI)	0.46 (-10.87, 11.79)	
P-value for Risk Difference	0.9368	
Improvement	5 (6.5%)	7 (16.3%)
Odds ratio (95% CI)	0.318 (0.087, 1.160)	
P-value for Odds Ratio	0.0827	
Relative Risk (95% CI)	0.37 (0.12, 1.07)	
P-value for Relative Risk	0.0675	
Risk difference (95% CI)	-2.61 (-17.87, 12.65)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7373	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	3 (4.9%)	3 (8.1%)
Odds ratio (95% CI)	0.683 (0.127, 3.678)	
P-value for Odds Ratio	0.6568	
Relative Risk (95% CI)	0.71 (0.15, 3.33)	
P-value for Relative Risk	0.6640	
Risk difference (95% CI)	-2.17 (-22.64, 18.31)	
P-value for Risk Difference	0.8358	
Improvement	3 (4.9%)	2 (5.4%)
Odds ratio (95% CI)	0.768 (0.109, 5.396)	
P-value for Odds Ratio	0.7903	
Relative Risk (95% CI)	0.78 (0.14, 4.33)	
P-value for Relative Risk	0.7735	
Risk difference (95% CI)	-0.15 (-26.64, 26.34)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9911	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	4 (11.4%)	3 (10.0%)
Odds ratio (95% CI)	1.045 (0.209, 5.214)	
P-value for Odds Ratio	0.9575	
Relative Risk (95% CI)	1.04 (0.25, 4.38)	
P-value for Relative Risk	0.9536	
Risk difference (95% CI)	0.31 (0.31, 0.31)*	
P-value for Risk Difference	NE	
Improvement	2 (5.7%)	5 (16.7%)
Odds ratio (95% CI)	0.208 (0.027, 1.578)	
P-value for Odds Ratio	0.1289	
Relative Risk (95% CI)	0.81 (0.81, 0.81)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-6.85 (-36.39, 22.70)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6498	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	3 (10.3%)	3 (14.3%)
Odds ratio (95% CI)	0.742 (0.130, 4.245)	
P-value for Odds Ratio	0.7372	
Relative Risk (95% CI)	0.76 (0.17, 3.36)	
P-value for Relative Risk	0.7172	
Risk difference (95% CI)	-2.51 (-24.94, 19.92)	
P-value for Risk Difference	0.8264	
Improvement	2 (6.9%)	2 (9.5%)
Odds ratio (95% CI)	0.923 (0.087, 9.777)	
P-value for Odds Ratio	0.9466	
Relative Risk (95% CI)	0.82 (0.16, 4.06)	
P-value for Relative Risk	0.8033	
Risk difference (95% CI)	-0.75 (-39.95, 38.46)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9702	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	1 (5.0%)	1 (6.3%)
Odds ratio (95% CI)	1.000 (0.054, 18.573)	
P-value for Odds Ratio	1.0000	
Relative Risk (95% CI)	1.00 (0.07, 13.87)	
P-value for Relative Risk	1.0000	
Risk difference (95% CI)	-0.27 (-28.52, 27.99)	
P-value for Risk Difference	0.9851	
Improvement	3 (15.0%)	1 (6.3%)
Odds ratio (95% CI)	2.680 (0.077, 93.134)	
P-value for Odds Ratio	0.5860	
Relative Risk (95% CI)	1.25 (1.25, 1.25)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	1.23 (-51.04, 53.51)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9632	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	1 (20.0%)	1 (14.3%)
Odds ratio (95% CI)	1.689 (0.054, 53.149)	
P-value for Odds Ratio	0.7659	
Relative Risk (95% CI)	0.51 (0.51, 0.51)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	0.61 (-84.48, 85.70)	
P-value for Risk Difference	0.9888	
Improvement	0	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.33 (0.03, 4.19)	
P-value for Relative Risk	0.3865	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.50 (0.32, 63.94)	
P-value for Relative Risk	0.2433	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Diarhoea :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	158
Deterioration	14 (8.9%)	10 (6.3%)
Odds ratio (95% CI)	1.472 (0.630, 3.440)	
P-value for Odds Ratio	0.3721	
Relative Risk (95% CI)	1.46 (0.67, 3.19)	
P-value for Relative Risk	0.3455	
Risk difference (95% CI)	1.82 (-4.80, 8.44)	
P-value for Risk Difference	0.5896	
Improvement	19 (12.0%)	15 (9.5%)
Odds ratio (95% CI)	1.198 (0.575, 2.497)	
P-value for Odds Ratio	0.6292	
Relative Risk (95% CI)	0.93 (0.93, 0.93)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-3.81 (-12.39, 4.78)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3849	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	152	137
Deterioration	16 (10.5%)	10 (7.3%)
Odds ratio (95% CI)	1.516 (0.661, 3.475)	
P-value for Odds Ratio	0.3261	
Relative Risk (95% CI)	1.46 (0.69, 3.11)	
P-value for Relative Risk	0.3237	
Risk difference (95% CI)	3.61 (-2.97, 10.20)	
P-value for Risk Difference	0.2824	
Improvement	17 (11.2%)	17 (12.4%)
Odds ratio (95% CI)	0.821 (0.395, 1.711)	
P-value for Odds Ratio	0.5993	
Relative Risk (95% CI)	0.89 (0.47, 1.66)	
P-value for Relative Risk	0.7030	
Risk difference (95% CI)	-6.16 (-14.92, 2.60)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1681	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	144	126
Deterioration	15 (10.4%)	8 (6.3%)
Odds ratio (95% CI)	1.804 (0.734, 4.434)	
P-value for Odds Ratio	0.1986	
Relative Risk (95% CI)	1.25 (1.25, 1.25)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	4.46 (-4.39, 13.31)	
P-value for Risk Difference	0.3235	
Improvement	17 (11.8%)	15 (11.9%)
Odds ratio (95% CI)	0.914 (0.429, 1.945)	
P-value for Odds Ratio	0.8146	
Relative Risk (95% CI)	0.94 (0.49, 1.80)	
P-value for Relative Risk	0.8620	
Risk difference (95% CI)	-2.76 (-10.20, 4.68)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4674	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	158	149
Deterioration	14 (8.9%)	14 (9.4%)
Odds ratio (95% CI)	0.942 (0.430, 2.061)	
P-value for Odds Ratio	0.8810	
Relative Risk (95% CI)	0.93 (0.46, 1.89)	
P-value for Relative Risk	0.8444	
Risk difference (95% CI)	0.31 (-5.89, 6.51)	
P-value for Risk Difference	0.9221	
Improvement	21 (13.3%)	22 (14.8%)
Odds ratio (95% CI)	0.829 (0.430, 1.595)	
P-value for Odds Ratio	0.5737	
Relative Risk (95% CI)	0.89 (0.51, 1.53)	
P-value for Relative Risk	0.6655	
Risk difference (95% CI)	-4.67 (-12.07, 2.74)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2171	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	134	97
Deterioration	12 (9.0%)	8 (8.2%)
Odds ratio (95% CI)	1.162 (0.453, 2.982)	
P-value for Odds Ratio	0.7541	
Relative Risk (95% CI)	1.14 (0.48, 2.67)	
P-value for Relative Risk	0.7718	
Risk difference (95% CI)	3.02 (-5.27, 11.30)	
P-value for Risk Difference	0.4753	
Improvement	27 (20.1%)	11 (11.3%)
Odds ratio (95% CI)	1.916 (0.884, 4.150)	
P-value for Odds Ratio	0.0993	
Relative Risk (95% CI)	1.81 (0.95, 3.44)	
P-value for Relative Risk	0.0700	
Risk difference (95% CI)	5.13 (-5.46, 15.73)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3425	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	117	82
Deterioration	12 (10.3%)	6 (7.3%)
Odds ratio (95% CI)	1.642 (0.582, 4.632)	
P-value for Odds Ratio	0.3487	
Relative Risk (95% CI)	1.53 (0.60, 3.88)	
P-value for Relative Risk	0.3687	
Risk difference (95% CI)	3.16 (-7.87, 14.19)	
P-value for Risk Difference	0.5743	
Improvement	14 (12.0%)	12 (14.6%)
Odds ratio (95% CI)	0.753 (0.321, 1.770)	
P-value for Odds Ratio	0.5158	
Relative Risk (95% CI)	0.83 (0.41, 1.67)	
P-value for Relative Risk	0.5944	
Risk difference (95% CI)	-5.66 (-15.20, 3.89)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2453	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	99	64
Deterioration	8 (8.1%)	4 (6.3%)
Odds ratio (95% CI)	1.454 (0.412, 5.131)	
P-value for Odds Ratio	0.5611	
Relative Risk (95% CI)	1.39 (0.44, 4.39)	
P-value for Relative Risk	0.5790	
Risk difference (95% CI)	2.49 (-13.51, 18.50)	
P-value for Risk Difference	0.7600	
Improvement	17 (17.2%)	7 (10.9%)
Odds ratio (95% CI)	1.954 (0.729, 5.236)	
P-value for Odds Ratio	0.1828	
Relative Risk (95% CI)	1.92 (0.85, 4.31)	
P-value for Relative Risk	0.1142	
Risk difference (95% CI)	5.94 (-5.35, 17.22)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3023	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	87	55
Deterioration	8 (9.2%)	1 (1.8%)
Odds ratio (95% CI)	5.879 (0.707, 48.866)	
P-value for Odds Ratio	0.1011	
Relative Risk (95% CI)	2.69 (2.69, 2.69)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	6.35 (-18.06, 30.76)	
P-value for Risk Difference	0.6102	
Improvement	13 (14.9%)	6 (10.9%)
Odds ratio (95% CI)	1.347 (0.471, 3.854)	
P-value for Odds Ratio	0.5788	
Relative Risk (95% CI)	1.33 (0.54, 3.28)	
P-value for Relative Risk	0.5424	
Risk difference (95% CI)	0.73 (-12.28, 13.74)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9126	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	77	43
Deterioration	8 (10.4%)	2 (4.7%)
Odds ratio (95% CI)	2.479 (0.497, 12.354)	
P-value for Odds Ratio	0.2679	
Relative Risk (95% CI)	2.33 (0.51, 10.58)	
P-value for Relative Risk	0.2728	
Risk difference (95% CI)	7.44 (-11.55, 26.44)	
P-value for Risk Difference	0.4424	
Improvement	14 (18.2%)	7 (16.3%)
Odds ratio (95% CI)	0.984 (0.332, 2.918)	
P-value for Odds Ratio	0.9764	
Relative Risk (95% CI)	1.12 (0.50, 2.49)	
P-value for Relative Risk	0.7892	
Risk difference (95% CI)	-8.24 (-23.60, 7.12)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2931	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	61	37
Deterioration	13 (21.3%)	1 (2.7%)
Odds ratio (95% CI)	10.904 (1.340, 88.744)	
P-value for Odds Ratio	0.0255	
Relative Risk (95% CI)	1.98 (1.98, 1.98)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	15.68 (15.68, 15.68)*	
P-value for Risk Difference	NE	
Improvement	12 (19.7%)	6 (16.2%)
Odds ratio (95% CI)	1.003 (0.317, 3.172)	
P-value for Odds Ratio	0.9961	
Relative Risk (95% CI)	0.90 (0.90, 0.90)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-6.09 (-23.03, 10.84)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4806	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	30
Deterioration	6 (17.1%)	3 (10.0%)
Odds ratio (95% CI)	1.543 (0.338, 7.037)	
P-value for Odds Ratio	0.5751	
Relative Risk (95% CI)	1.45 (0.39, 5.39)	
P-value for Relative Risk	0.5790	
Risk difference (95% CI)	4.64 (4.64, 4.64)*	
P-value for Risk Difference	NE	
Improvement	5 (14.3%)	6 (20.0%)
Odds ratio (95% CI)	0.458 (0.112, 1.869)	
P-value for Odds Ratio	0.2767	
Relative Risk (95% CI)	0.85 (0.85, 0.85)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-11.21 (-11.21, -11.21)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	29	21
Deterioration	4 (13.8%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.27 (0.55, 33.04)	
P-value for Relative Risk	0.1257	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	6 (20.7%)	3 (14.3%)
Odds ratio (95% CI)	1.278 (0.236, 6.929)	
P-value for Odds Ratio	0.7758	
Relative Risk (95% CI)	1.05 (0.30, 3.60)	
P-value for Relative Risk	0.9423	
Risk difference (95% CI)	5.31 (-14.98, 25.59)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6082	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	16
Deterioration	2 (10.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.33 (0.42, 12.91)	
P-value for Relative Risk	0.3529	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	3 (15.0%)	2 (12.5%)
Odds ratio (95% CI)	0.814 (0.092, 7.193)	
P-value for Odds Ratio	0.8528	
Relative Risk (95% CI)	0.85 (0.14, 5.11)	
P-value for Relative Risk	0.8604	
Risk difference (95% CI)	-1.28 (-36.83, 34.27)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9438	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	1 (20.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.00 (0.24, 37.67)	
P-value for Relative Risk	0.3865	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.56 (0.03, 9.73)	
P-value for Relative Risk	0.6933	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 14.2.6.1 Response status over time-EORTC QLQ-C30 scales
(Full Analysis Set)

Financial Problems :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For functional scales the following was used: deterioration is defined as a decrease of 10 or more points with respect to Baseline; improvement is defined as an increase of 10 or more points with respect to Baseline.
For symptom scales the following was used: deterioration is defined as an increase of 10 or more points with respect to Baseline; improvement is defined as a decrease of 10 or more points with respect to Baseline; any change from Baseline between (-10, 10) points is considered as Stable.

Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Global health status/QoL (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	79 (37.8 %)	59 (28.6 %)
Number of censored cases	n (%)	130 (62.2 %)	147 (71.4 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	0	1 (0.5 %)
No confirmed deterioration	n (%)	110 (52.6 %)	126 (61.2 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	10.78 [7.85, 14.59]	8.41 [5.78, 18.33]
	Median [95% CI]	34.66 [25.79, 51.61]	50.92 [34.92, NC]
	Q3 [95% CI]	NYR [51.61, NC]	NYR [57.76, NC]
	p-value[b]		0.367
	HR [95 % CI][c]		1.17 [0.83, 1.65]
Physical Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	56 (26.8 %)	46 (22.3 %)
Number of censored cases	n (%)	153 (73.2 %)	160 (77.7 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	1 (0.5 %)	0
No confirmed deterioration	n (%)	132 (63.2 %)	140 (68.0 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	17.68 [11.20, 33.87]	13.50 [8.38, 25.53]
	Median [95% CI]	NYR [37.98, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.661
	HR [95 % CI][c]		0.91 [0.61, 1.36]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Role Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	84 (40.2 %)	67 (32.5 %)
Number of censored cases	n (%)	125 (59.8 %)	139 (67.5 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	5 (2.4 %)	0
No confirmed deterioration	n (%)	100 (47.8 %)	119 (57.8 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.34 [5.62, 11.20]	8.34 [5.62, 10.61]
	Median [95% CI]	29.31 [17.58, 46.49]	33.84 [27.47, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.462
	HR [95 % CI][c]		1.13 [0.82, 1.56]
Emotional Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	60 (28.7 %)	49 (23.8 %)
Number of censored cases	n (%)	149 (71.3 %)	157 (76.2 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	1 (0.5 %)	1 (0.5 %)
No confirmed deterioration	n (%)	128 (61.2 %)	136 (66.0 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	14.98 [10.64, 21.91]	17.74 [8.48, 25.53]
	Median [95% CI]	52.30 [38.87, NC]	NYR [34.30, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.906
	HR [95 % CI][c]		1.02 [0.70, 1.50]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Cognitive Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	81 (38.8 %)	64 (31.1 %)
Number of censored cases	n (%)	128 (61.2 %)	142 (68.9 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	0	1 (0.5 %)
No confirmed deterioration	n (%)	108 (51.7 %)	121 (58.7 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.48 [5.68, 13.90]	10.74 [8.34, 14.55]
	Median [95% CI]	34.46 [24.08, 46.03]	51.12 [21.26, NC]
	Q3 [95% CI]	NYR [46.03, NC]	NYR [52.44, NC]
	p-value[b]		0.587
	HR [95 % CI][c]		1.09 [0.78, 1.52]
Social Functioning (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	73 (34.9 %)	47 (22.8 %)
Number of censored cases	n (%)	136 (65.1 %)	159 (77.2 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	0	2 (1.0 %)
No confirmed deterioration	n (%)	116 (55.5 %)	137 (66.5 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.54 [8.34, 16.53]	13.90 [8.31, 25.86]
	Median [95% CI]	39.49 [28.65, NC]	NYR [44.68, NC]
	Q3 [95% CI]	NYR [52.53, NC]	NYR [NC, NC]
	p-value[b]		0.157
	HR [95 % CI][c]		1.31 [0.90, 1.90]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Fatigue (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	106 (50.7 %)	86 (41.7 %)
Number of censored cases	n (%)	103 (49.3 %)	120 (58.3 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	1 (0.5 %)	1 (0.5 %)
No confirmed deterioration	n (%)	82 (39.2 %)	99 (48.1 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	5.52 [2.92, 5.68]	5.09 [2.89, 6.51]
	Median [95% CI]	16.53 [10.35, 27.07]	13.50 [8.41, 34.07]
	Q3 [95% CI]	52.30 [39.46, NC]	NYR [NC, NC]
	p-value[b]		0.984
	HR [95 % CI][c]		1.00 [0.75, 1.33]
Pain (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	79 (37.8 %)	64 (31.1 %)
Number of censored cases	n (%)	130 (62.2 %)	142 (68.9 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	2 (1.0 %)	2 (1.0 %)
No confirmed deterioration	n (%)	108 (51.7 %)	120 (58.3 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.54 [6.67, 14.75]	8.38 [5.62, 13.90]
	Median [95% CI]	35.45 [26.02, NC]	49.74 [39.16, NC]
	Q3 [95% CI]	58.61 [58.61, NC]	NYR [52.44, NC]
	p-value[b]		0.956
	HR [95 % CI][c]		1.01 [0.72, 1.41]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Financial Difficulties (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	35 (16.7 %)	23 (11.2 %)
Number of censored cases	n (%)	174 (83.3 %)	183 (88.8 %)
No baseline score	n (%)	17 (8.1 %)	16 (7.8 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	6 (2.9 %)	2 (1.0 %)
No confirmed deterioration	n (%)	148 (70.8 %)	160 (77.7 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	35.84 [25.13, 57.99]	NYR [40.80, NC]
	Median [95% CI]	57.99 [57.99, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b]		0.321
	HR [95 % CI][c]		1.31 [0.77, 2.22]
Nausea/Vomiting (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	37 (17.7 %)	24 (11.7 %)
Number of censored cases	n (%)	172 (82.3 %)	182 (88.3 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	0	0
No confirmed deterioration	n (%)	152 (72.7 %)	162 (78.6 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	34.37 [17.58, NC]	NYR [25.63, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.512
	HR [95 % CI][c]		1.19 [0.71, 1.99]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Dyspnoea (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	54 (25.8 %)	37 (18.0 %)
Number of censored cases	n (%)	155 (74.2 %)	169 (82.0 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	3 (1.4 %)	0
No confirmed deterioration	n (%)	132 (63.2 %)	149 (72.3 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	22.14 [15.38, 33.91]	20.73 [13.83, NC]
	Median [95% CI]	52.60 [34.37, NC]	NYR [NC, NC]
	Q3 [95% CI]	62.26 [52.60, NC]	NYR [NC, NC]
	p-value[b]		0.552
	HR [95 % CI][c]		1.14 [0.74, 1.74]
Insomnia (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	61 (29.2 %)	68 (33.0 %)
Number of censored cases	n (%)	148 (70.8 %)	138 (67.0 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	5 (2.4 %)	6 (2.9 %)
No confirmed deterioration	n (%)	123 (58.9 %)	112 (54.4 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	10.91 [8.25, 24.08]	8.31 [5.62, 8.54]
	Median [95% CI]	NYR [39.49, NC]	38.01 [21.72, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [57.76, NC]
	p-value[b]		0.088
	HR [95 % CI][c]		0.73 [0.51, 1.05]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Appetite Loss (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	41 (19.6 %)	21 (10.2 %)
Number of censored cases	n (%)	168 (80.4 %)	185 (89.8 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	5 (2.4 %)	5 (2.4 %)
No confirmed deterioration	n (%)	143 (68.4 %)	160 (77.7 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	35.45 [14.59, NC]	NYR [32.00, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.150
	HR [95 % CI][c]		1.47 [0.87, 2.51]
Constipation (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	43 (20.6 %)	42 (20.4 %)
Number of censored cases	n (%)	166 (79.4 %)	164 (79.6 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	2 (1.0 %)	3 (1.5 %)
No confirmed deterioration	n (%)	144 (68.9 %)	141 (68.4 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	29.73 [14.59, 46.49]	22.34 [10.81, 49.97]
	Median [95% CI]	NYR [52.53, NC]	52.60 [49.97, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [58.68, NC]
	p-value[b]		0.356
	HR [95 % CI][c]		0.81 [0.53, 1.26]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 6.2.1.1: Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death) *[cont'd]*
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Diarrhoea (Deterioration threshold = 10)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	31 (14.8 %)	25 (12.1 %)
Number of censored cases	n (%)	178 (85.2 %)	181 (87.9 %)
No baseline score	n (%)	17 (8.1 %)	15 (7.3 %)
No post-baseline score	n (%)	3 (1.4 %)	5 (2.4 %)
No deterioration possible	n (%)	1 (0.5 %)	0
No confirmed deterioration	n (%)	157 (75.1 %)	161 (78.2 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	52.60 [25.79, NC]	NYR [25.66, NC]
	Median [95% CI]	62.26 [52.60, NC]	NYR [NC, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b]		0.949
	HR [95 % CI][c]		0.98 [0.58, 1.67]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	79 (37.8%)	59 (28.6%)
Number of censored participants, n (%)	130 (62.2%)	147 (71.4%)
Proportionality Test p-value[a][b]	0.0429	
Hazard ratio(interaction)	0.655 (0.435, 0.987)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	56 (26.8%)	46 (22.3%)
Number of censored participants, n (%)	153 (73.2%)	160 (77.7%)
Proportionality Test p-value[a][b]	0.1196	
Hazard ratio(interaction)	0.683 (0.423, 1.104)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	84 (40.2%)	67 (32.5%)
Number of censored participants, n (%)	125 (59.8%)	139 (67.5%)
Proportionality Test p-value[a][b]	0.1595	
Hazard ratio(interaction)	0.745 (0.495, 1.123)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	60 (28.7%)	49 (23.8%)
Number of censored participants, n (%)	149 (71.3%)	157 (76.2%)
Proportionality Test p-value[a][b]	0.7852	
Hazard ratio(interaction)	1.065 (0.677, 1.675)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	81 (38.8%)	64 (31.1%)
Number of censored participants, n (%)	128 (61.2%)	142 (68.9%)
Proportionality Test p-value[a][b]	0.9001	
Hazard ratio(interaction)	1.025 (0.697, 1.508)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	73 (34.9%)	47 (22.8%)
Number of censored participants, n (%)	136 (65.1%)	159 (77.2%)
Proportionality Test p-value[a][b]	0.2423	
Hazard ratio(interaction)	0.777 (0.508, 1.187)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	106 (50.7%)	86 (41.7%)
Number of censored participants, n (%)	103 (49.3%)	120 (58.3%)
Proportionality Test p-value[a][b]	0.1812	
Hazard ratio(interaction)	0.777 (0.537, 1.125)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	37 (17.7%)	24 (11.7%)
Number of censored participants, n (%)	172 (82.3%)	182 (88.3%)
Proportionality Test p-value[a][b]	0.3851	
Hazard ratio(interaction)	0.769 (0.425, 1.392)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Pain (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	79 (37.8%)	64 (31.1%)
Number of censored participants, n (%)	130 (62.2%)	142 (68.9%)
Proportionality Test p-value[a][b]	0.0443	
Hazard ratio(interaction)	0.662 (0.443, 0.990)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	54 (25.8%)	37 (18.0%)
Number of censored participants, n (%)	155 (74.2%)	169 (82.0%)
Proportionality Test p-value[a][b]	0.0139	
Hazard ratio(interaction)	0.555 (0.348, 0.887)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	61 (29.2%)	68 (33.0%)
Number of censored participants, n (%)	148 (70.8%)	138 (67.0%)
Proportionality Test p-value[a][b]	0.9142	
Hazard ratio(interaction)	1.024 (0.665, 1.578)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	41 (19.6%)	21 (10.2%)
Number of censored participants, n (%)	168 (80.4%)	185 (89.8%)
Proportionality Test p-value[a][b]	0.9989	
Hazard ratio(interaction)	1.000 (0.520, 1.926)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Constipation (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	43 (20.6%)	42 (20.4%)
Number of censored participants, n (%)	166 (79.4%)	164 (79.6%)
Proportionality Test p-value[a][b]	0.8665	
Hazard ratio(interaction)	1.045 (0.628, 1.737)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	31 (14.8%)	25 (12.1%)
Number of censored participants, n (%)	178 (85.2%)	181 (87.9%)
Proportionality Test p-value[a][b]	0.2619	
Hazard ratio(interaction)	0.705 (0.382, 1.299)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

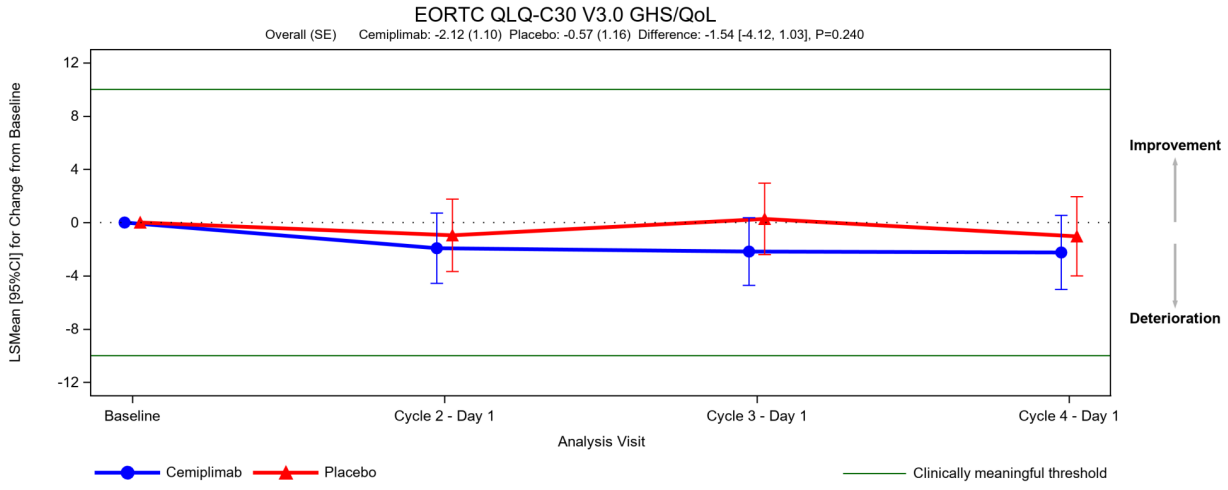
Table 14.2.8.3 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EORTC QLQ-C30 scales (excluding death)
(Full Analysis Set)

Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	35 (16.7%)	23 (11.2%)
Number of censored participants, n (%)	174 (83.3%)	183 (88.8%)
Proportionality Test p-value[a][b]	0.0510	
Hazard ratio(interaction)	0.566 (0.320, 1.003)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Figure 4.1.1: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 GHS/QoL scale
FAS (N=415)

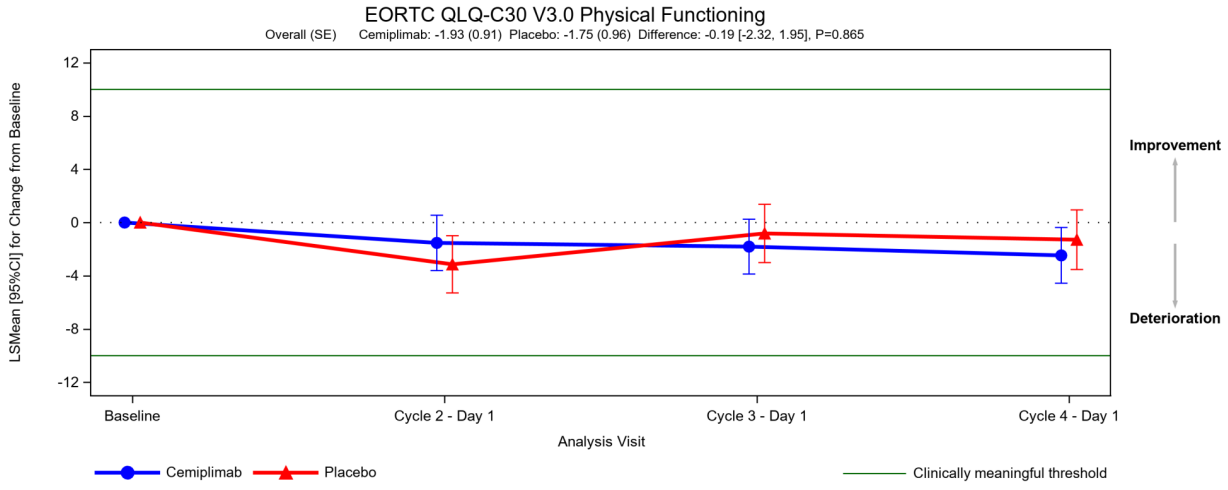


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.2: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Physical Functioning scale
FAS (N=415)

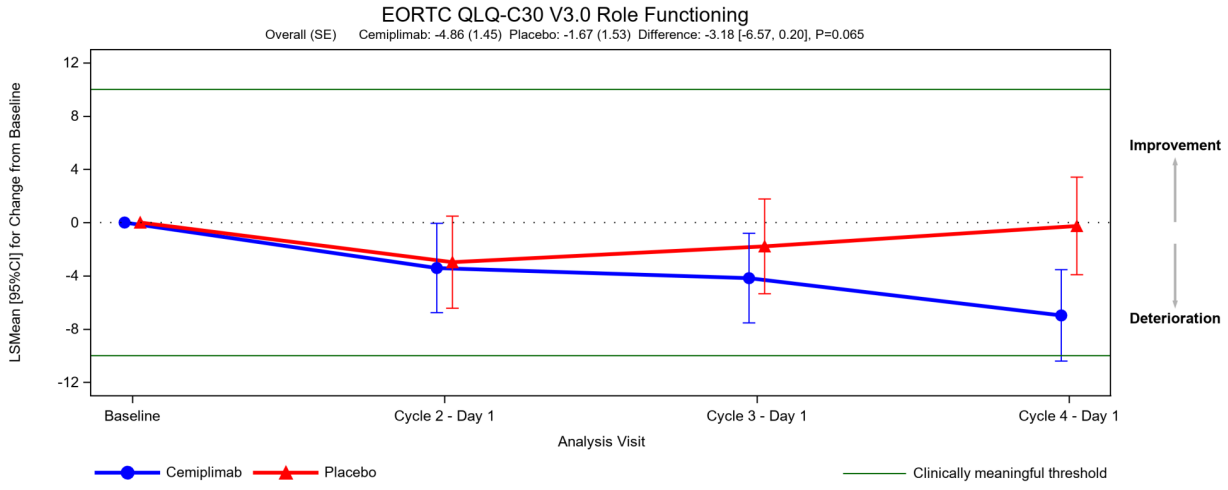


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.3: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Role Functioning scale
FAS (N=415)

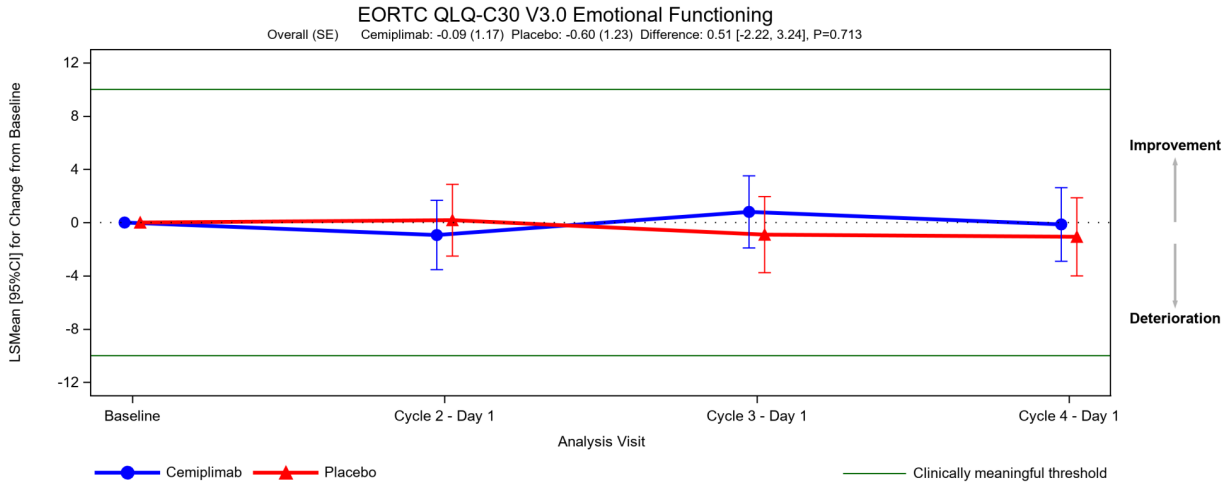


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.4: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Emotional Functioning scale
FAS (N=415)

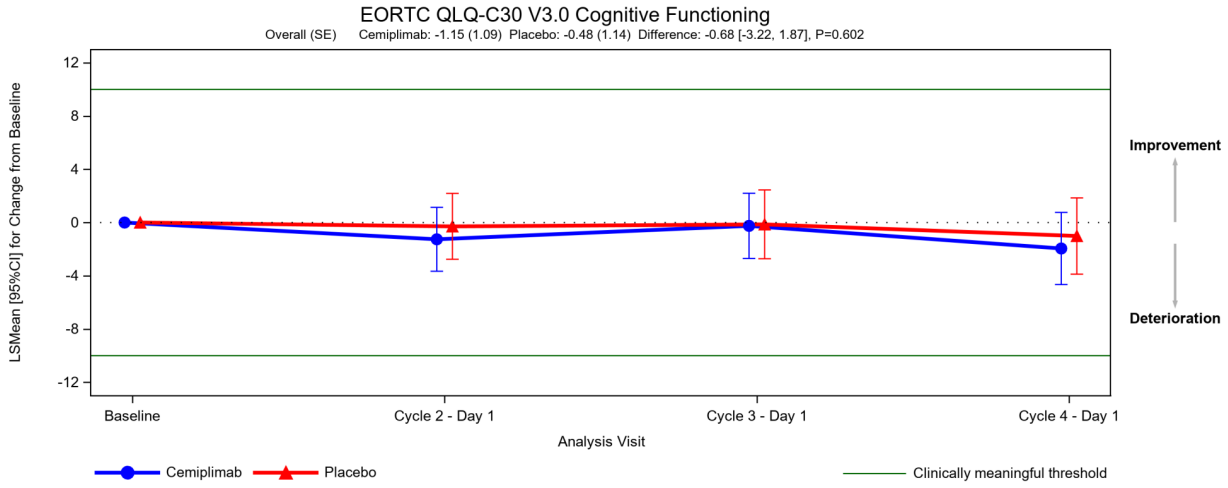


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.5: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Cognitive Functioning scale
FAS (N=415)

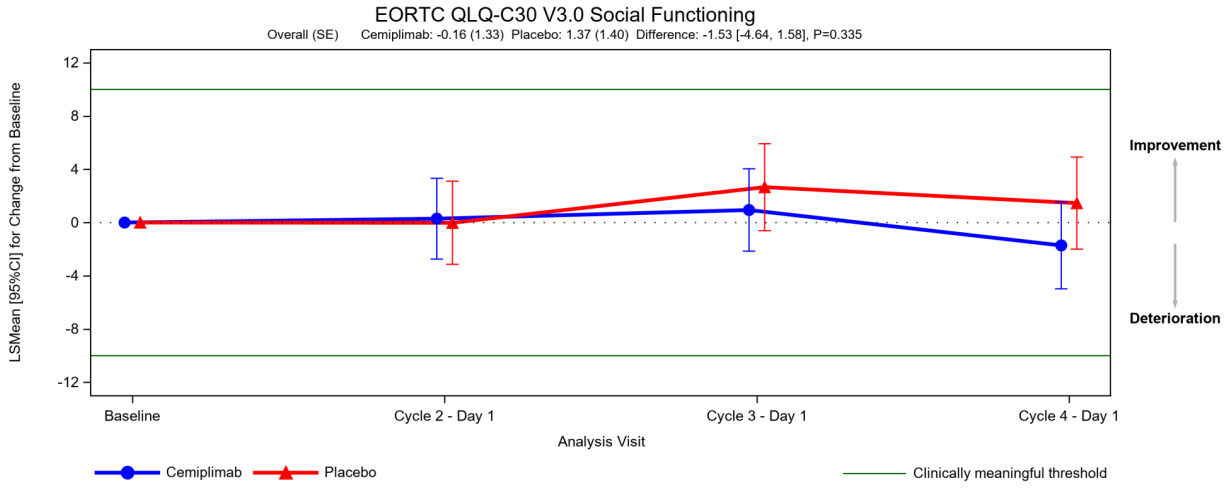


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.6: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Social Functioning scale
FAS (N=415)

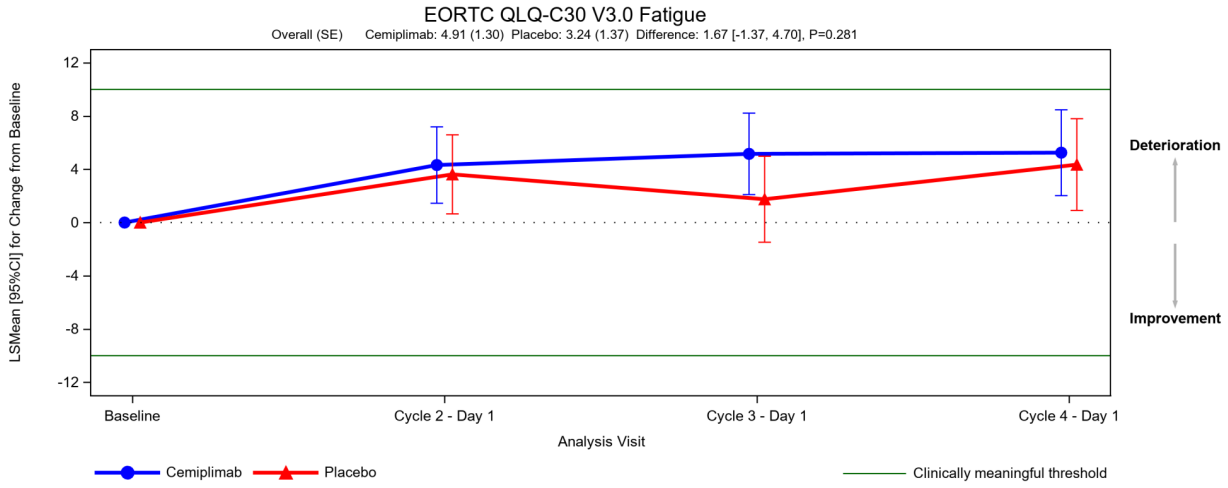


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.7: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Fatigue scale
FAS (N=415)

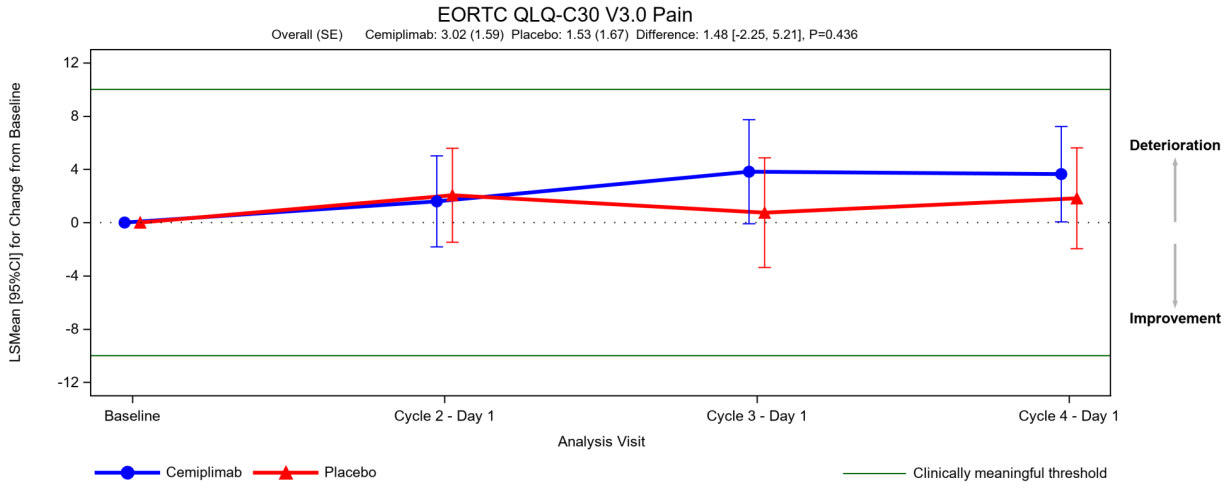


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.8: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Pain scale
FAS (N=415)

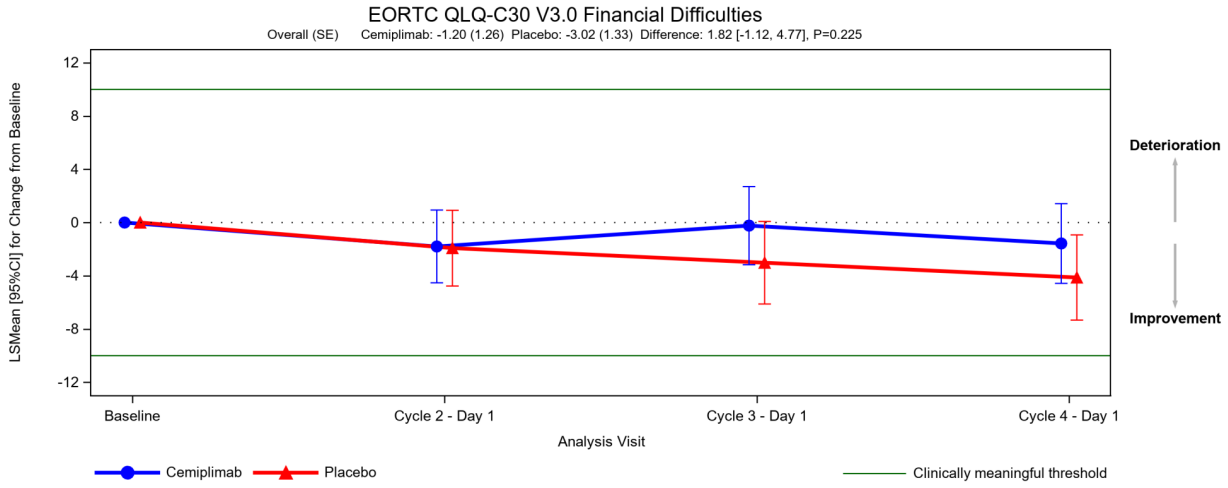


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.9: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Financial Difficulties scale
FAS (N=415)

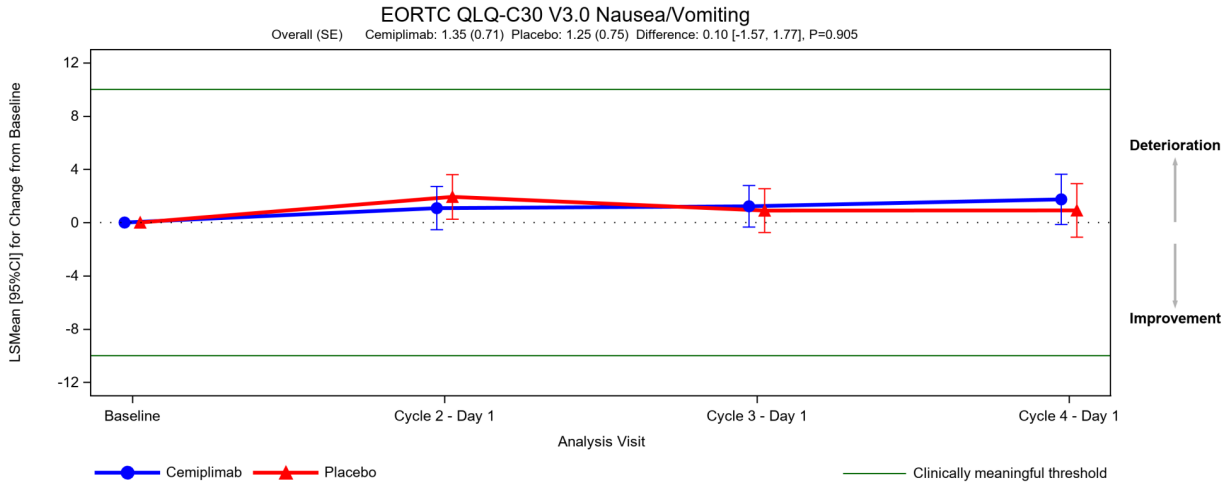


Number of patients

Cemiplimab	158	152	144
Placebo	158	137	126

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.10: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Nausea/Vomiting scale
FAS (N=415)

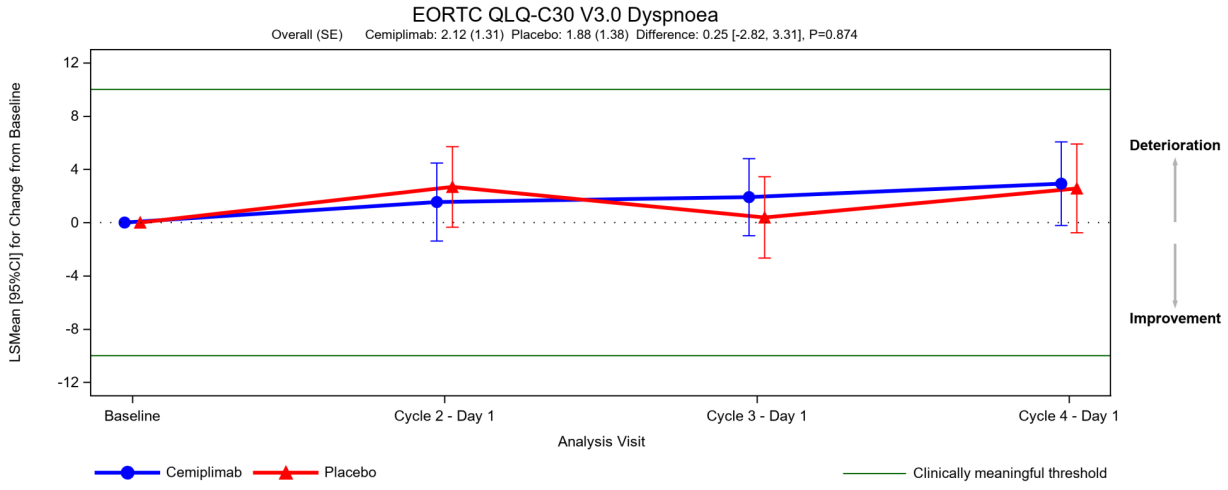


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.11: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Dyspnoea scale
FAS (N=415)

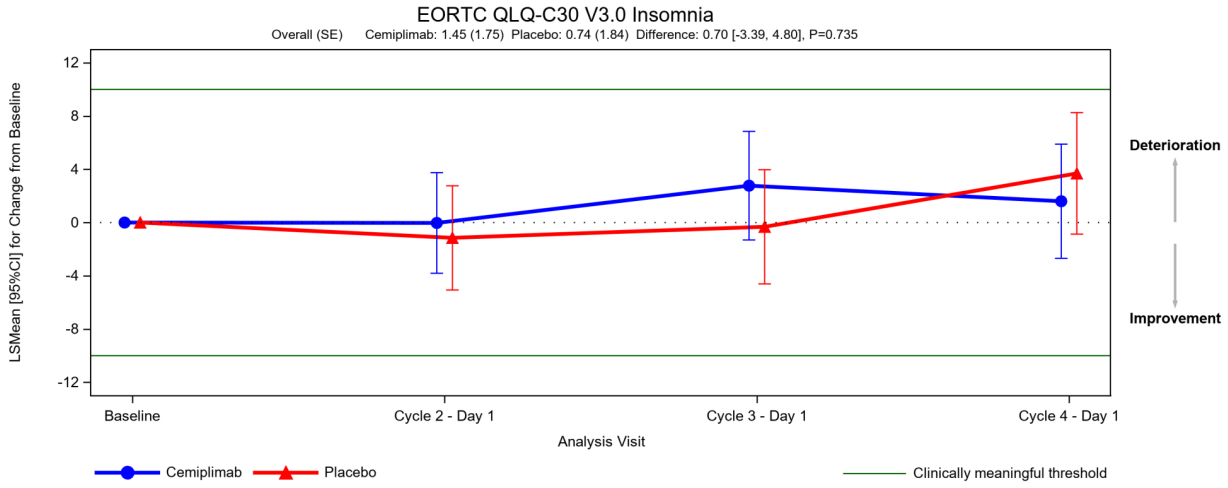


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.12: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Insomnia scale
FAS (N=415)

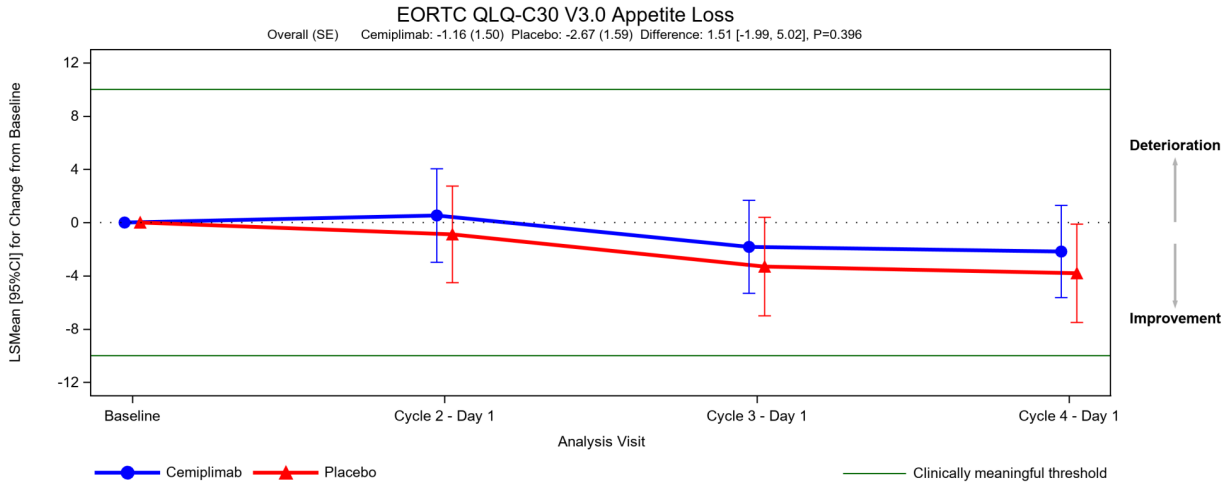


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.13: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Appetite Loss scale
FAS (N=415)

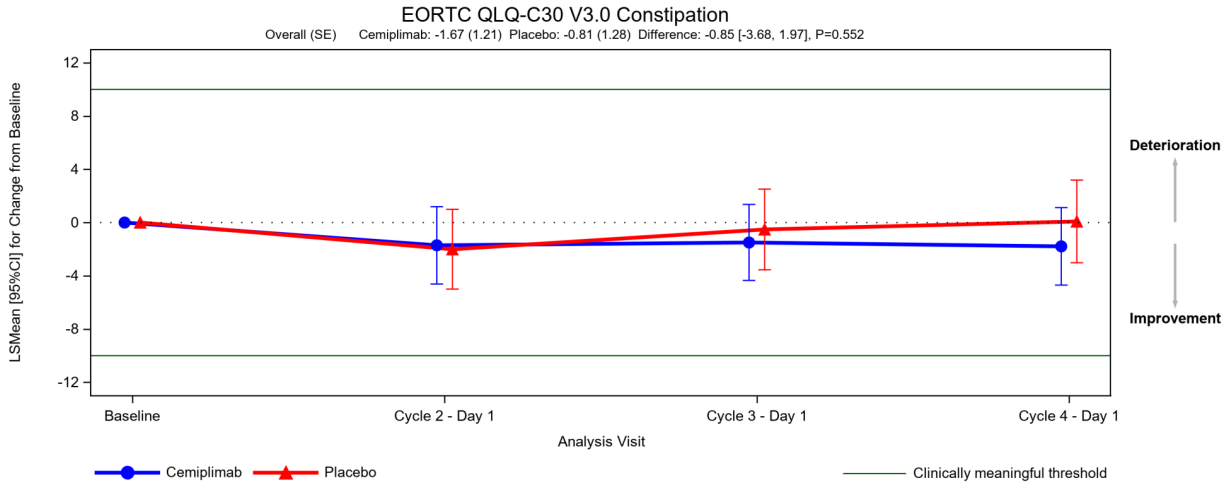


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.14: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Constipation scale
FAS (N=415)

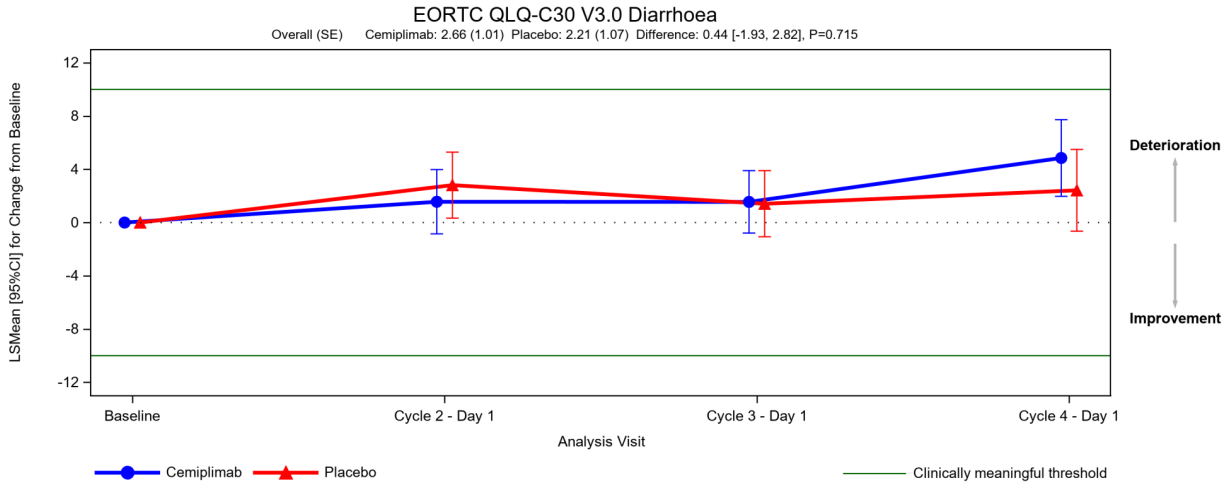


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure 4.1.15: Mixed Model Repeated Measures: Change from Baseline - EORTC QLQ-C30 Diarrhoea scale
FAS (N=415)

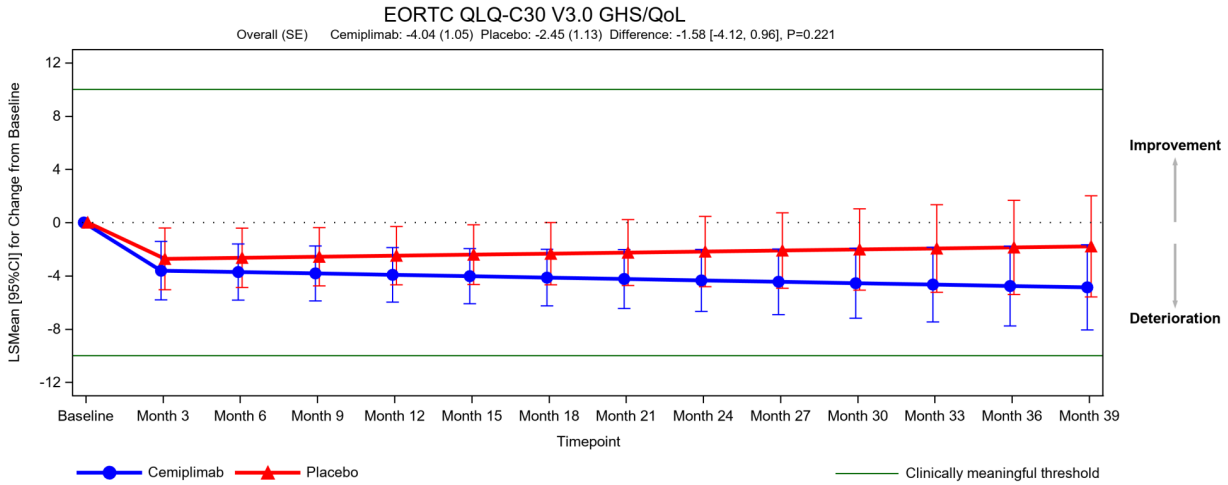


Number of patients

Cemiplimab	158	152	144
Placebo	159	138	127

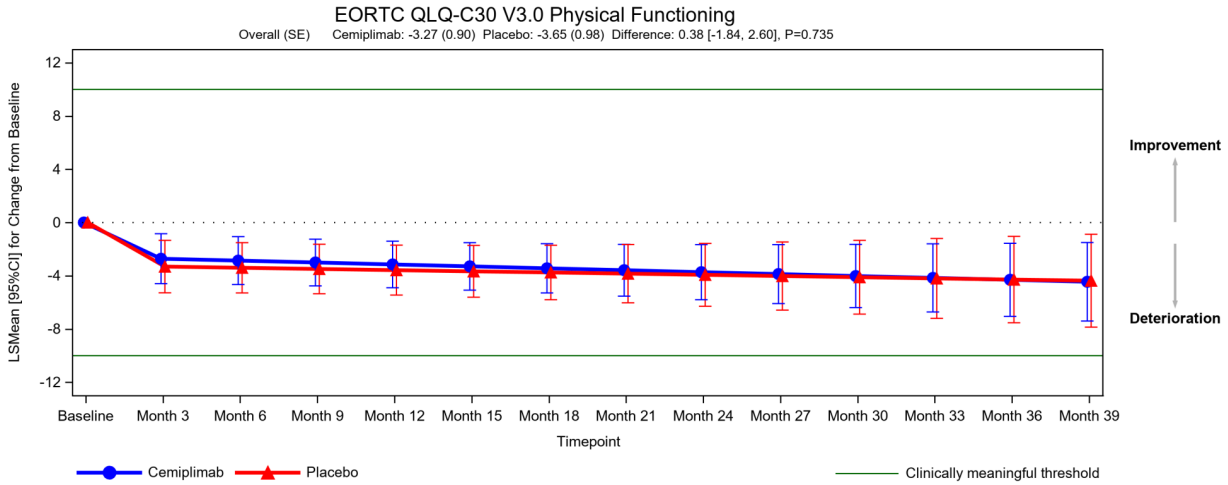
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full Analysis Set.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure A3.1.1: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 GHS/QoL
FAS (N=415)



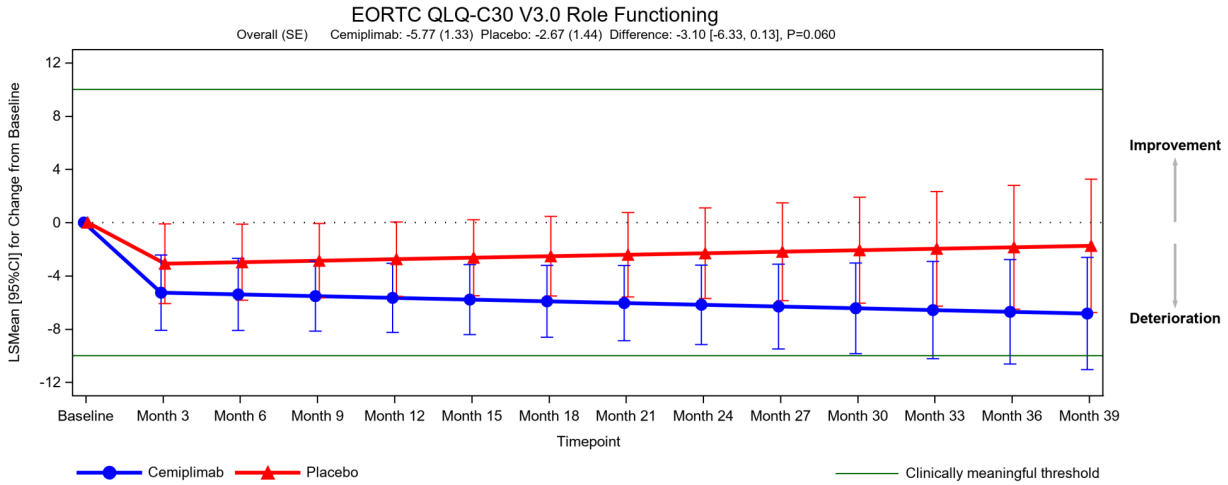
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; QoL: Quality of Life.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.2: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Physical Functioning scale
FAS (N=415)



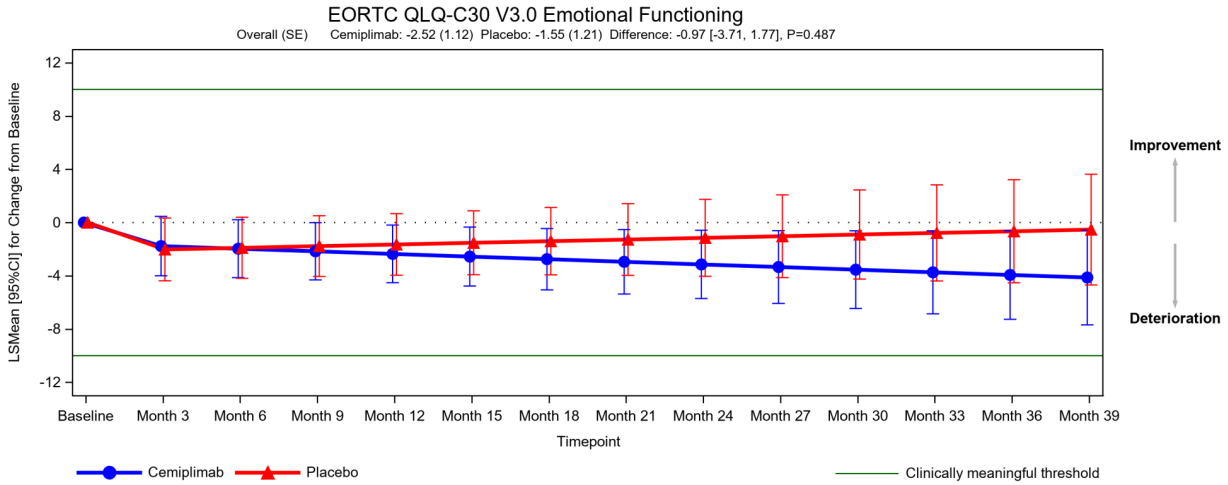
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.3: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Role Functioning scale
FAS (N=415)



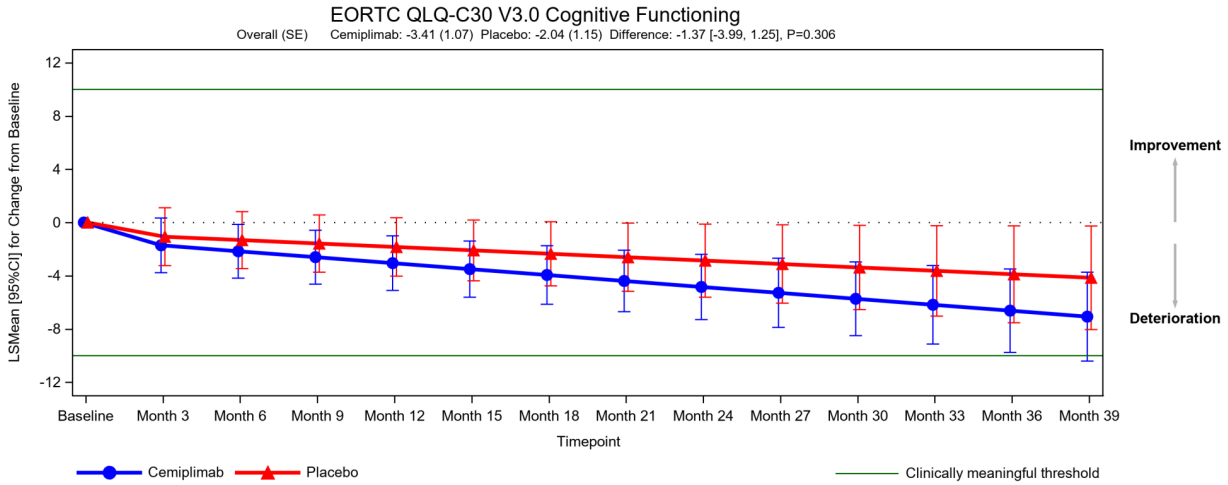
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.4: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Emotional Functioning scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.5: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Cognitive Functioning scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
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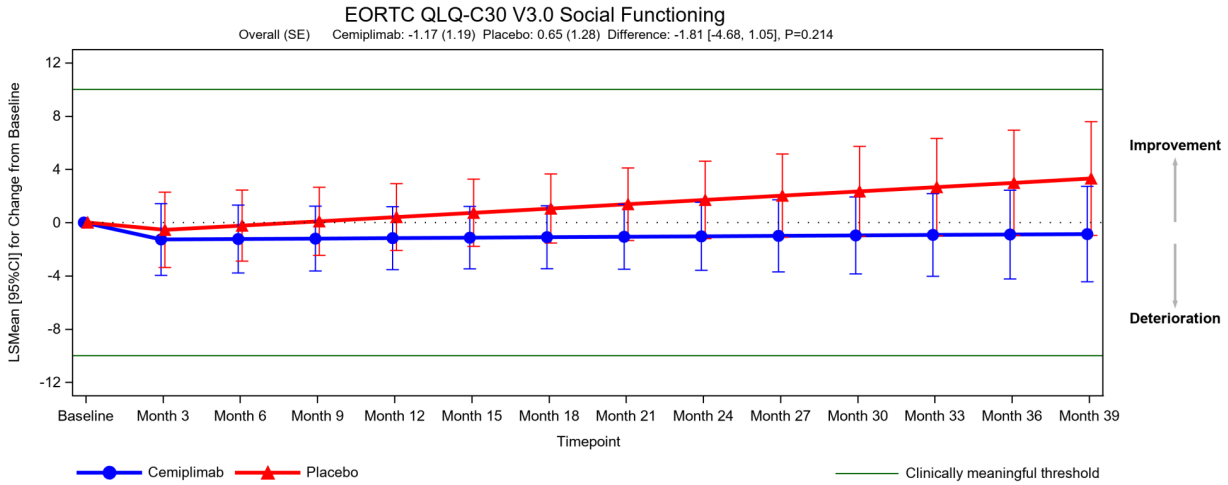
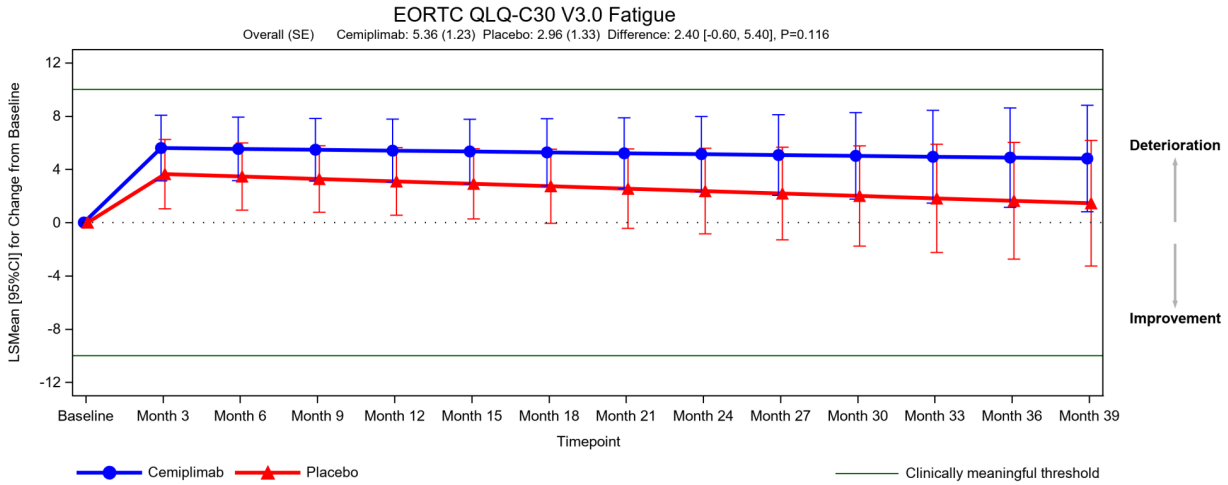
Figure A3.1.6: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Social Functioning scale
FAS (N=415)



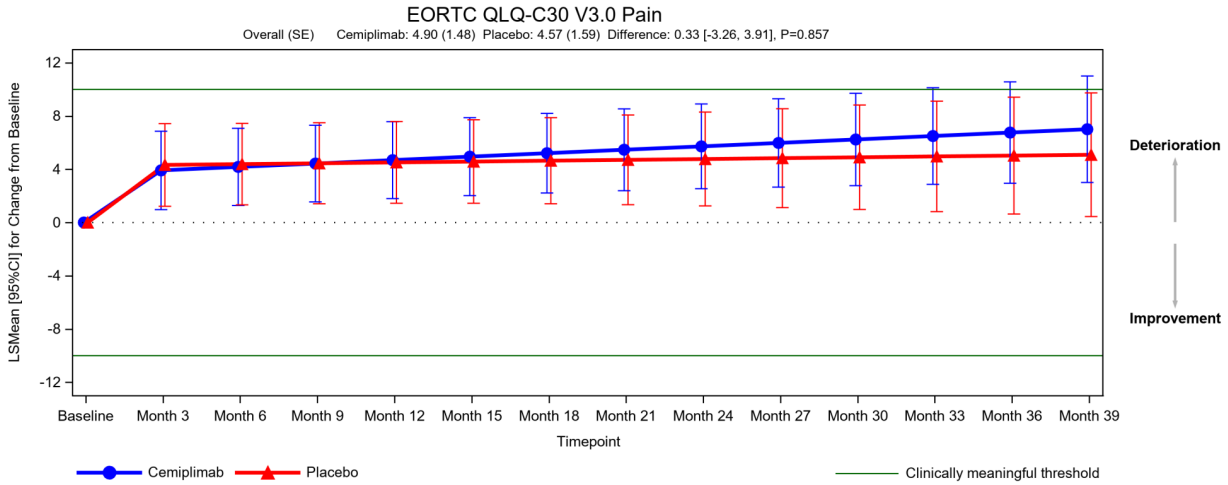
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.7: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Fatigue scale
FAS (N=415)



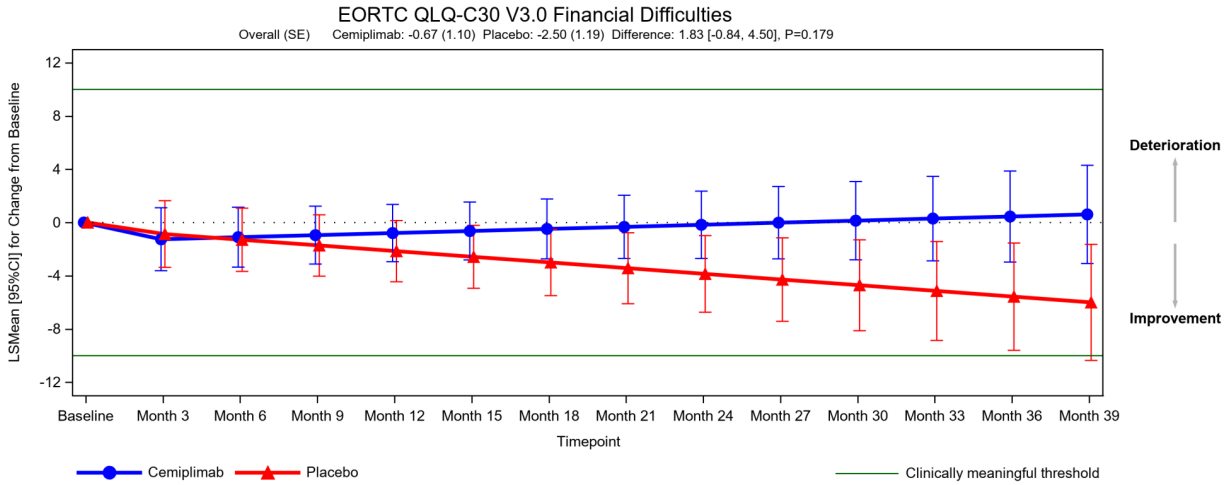
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.8: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Pain scale
FAS (N=415)



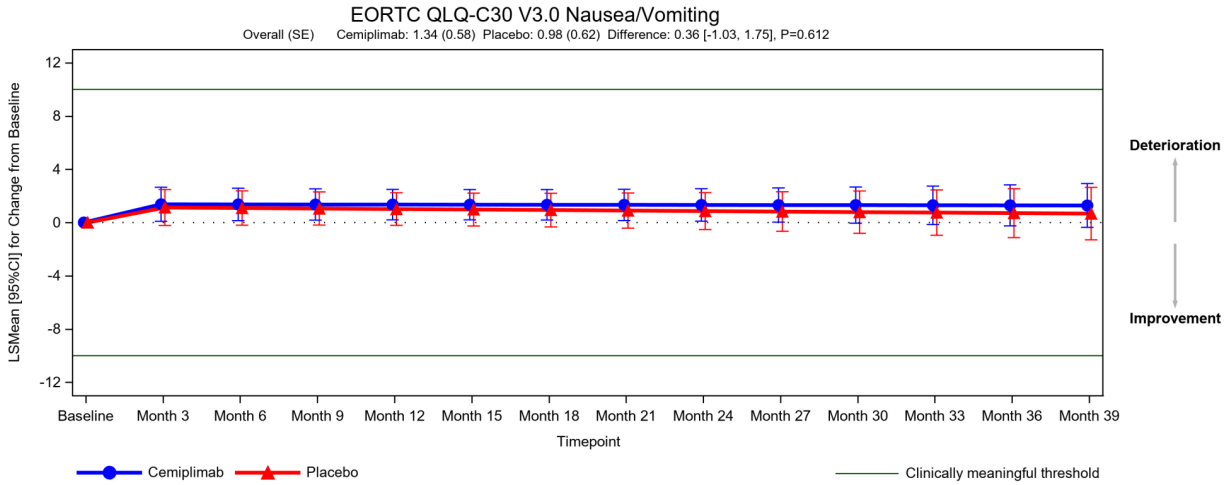
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.9: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Financial Difficulties scale
FAS (N=415)



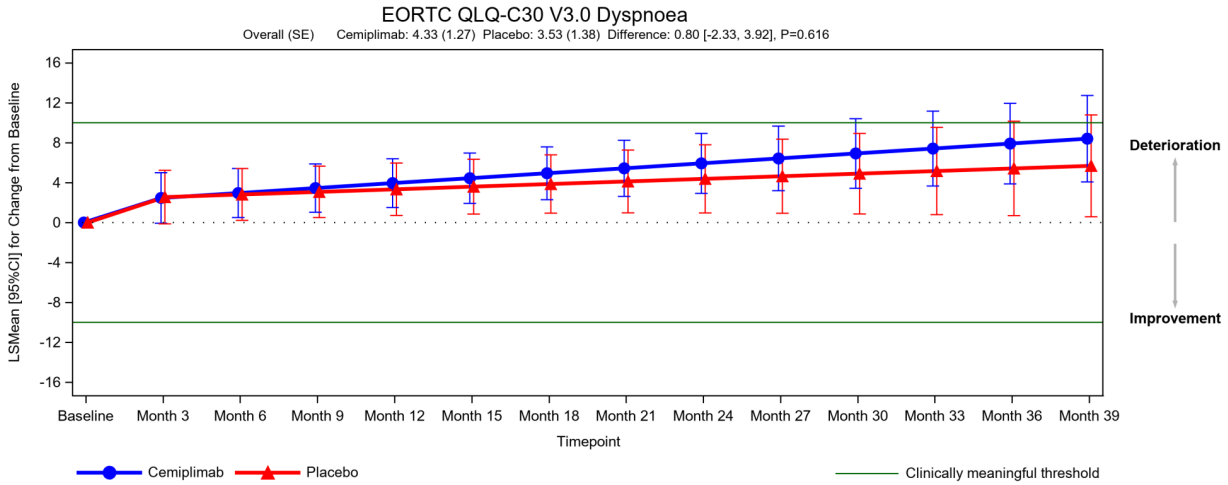
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.10: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Nausea/Vomiting scale
FAS (N=415)



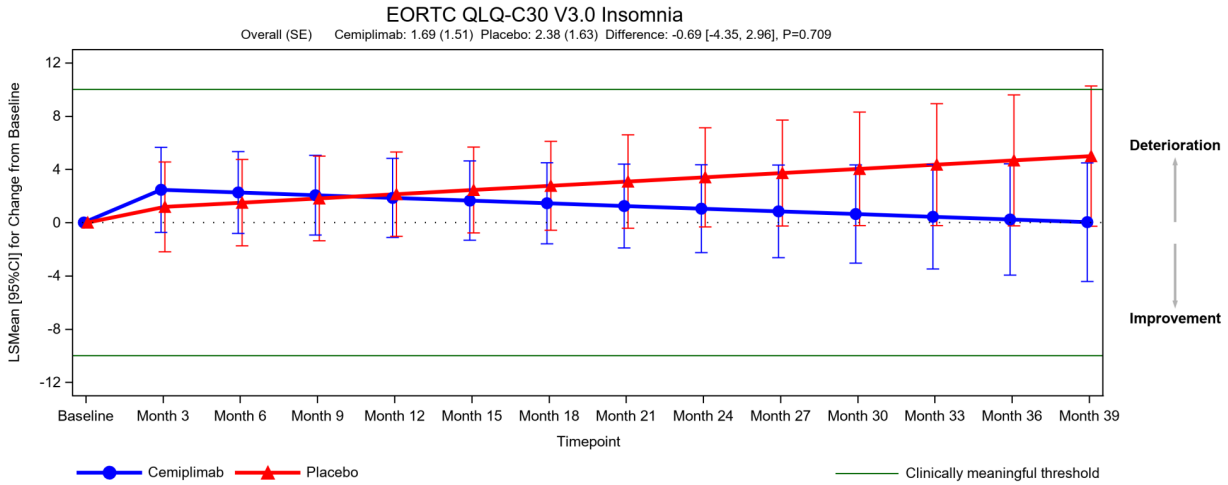
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.11: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Dyspnoea scale
FAS (N=415)



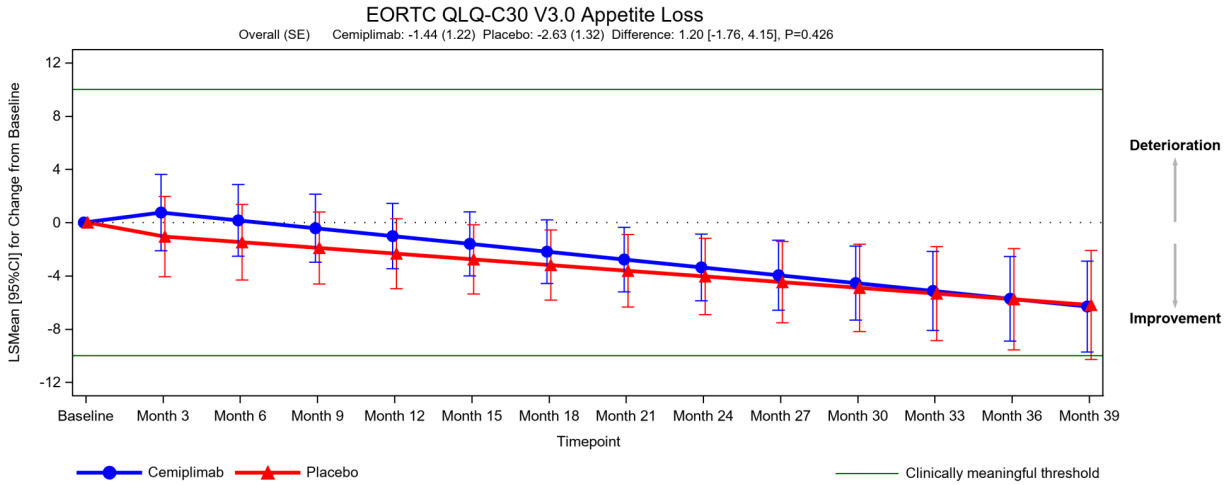
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.12: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Insomnia scale
FAS (N=415)



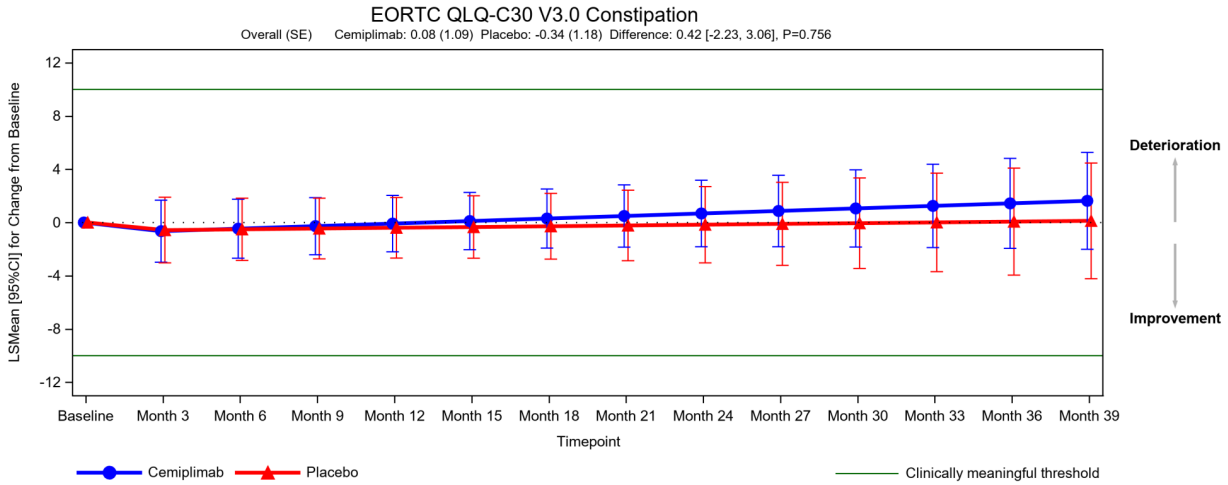
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.13: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Appetite Loss scale
FAS (N=415)



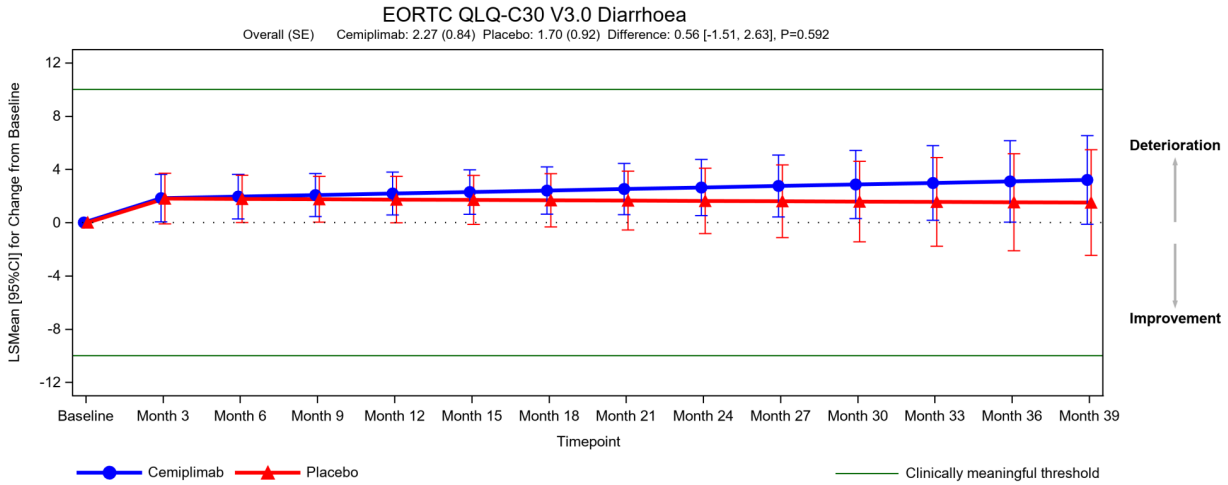
Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure A3.1.14: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Constipation scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

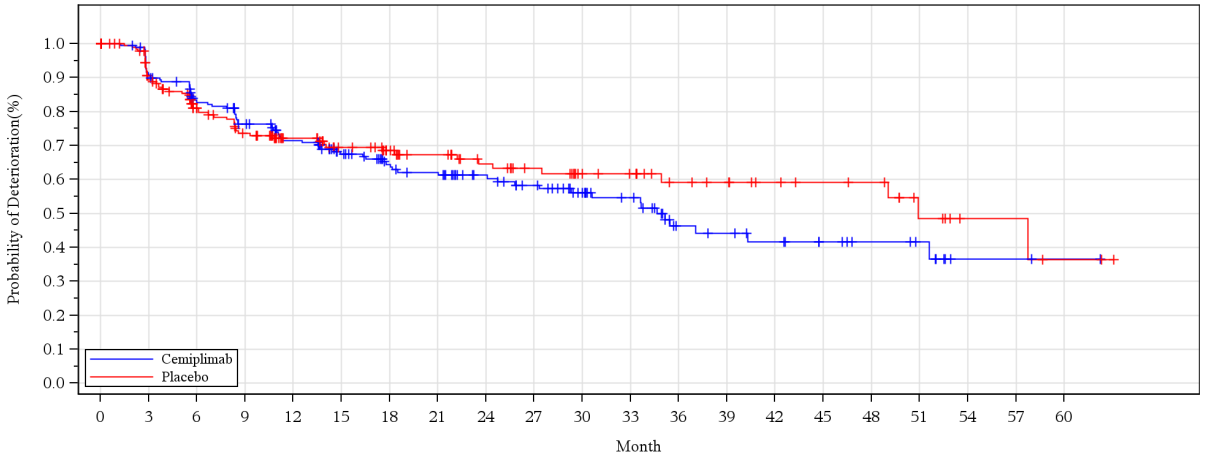
Figure A3.1.15: Mixed model repeated measures: Change from Baseline - EORTC QLQ-C30 Diarrhoea scale
FAS (N=415)



Note(s): EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

1.1.2.1 Figures KM EORTC

Figure 14.2.11.1 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale
(Full Analysis Set)



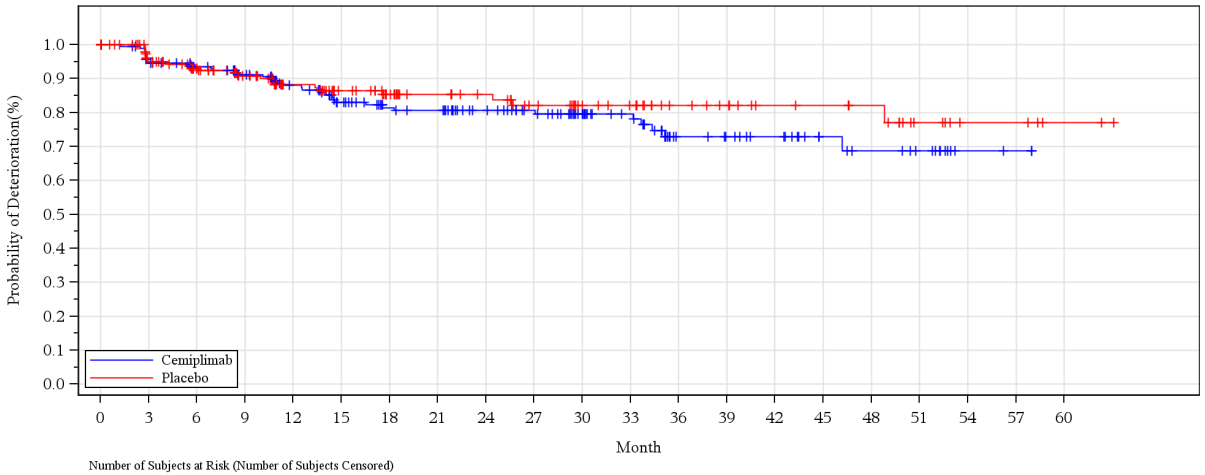
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	170 (22)	147 (30)	130 (36)	115 (43)	96 (56)	81 (67)	76 (69)	64 (80)	56 (85)	44 (95)	37 (101)	22 (111)	20 (112)	17 (114)	13 (118)	10 (121)	8 (123)	2 (128)	2 (128)	1 (129)
Placebo	206 (0)	157 (30)	123 (50)	106 (56)	86 (74)	73 (84)	63 (93)	55 (100)	46 (107)	40 (112)	32 (119)	30 (121)	23 (127)	21 (129)	17 (133)	15 (135)	14 (136)	8 (140)	4 (144)	4 (144)	2 (145)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km2.sas' (wenju.shi 10DEC2025 12:03 SAS Linux 9.4)

Figure 14.2.11.10 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	176 (23)	164 (33)	149 (44)	132 (56)	112 (69)	99 (80)	96 (82)	84 (94)	75 (103)	61 (116)	52 (125)	32 (141)	29 (144)	25 (148)	17 (156)	14 (158)	11 (161)	3 (169)	2 (170)	0 (172)
Placebo	206 (0)	163 (34)	136 (58)	116 (75)	94 (94)	81 (105)	69 (116)	60 (125)	55 (130)	47 (136)	39 (144)	36 (147)	27 (156)	24 (159)	19 (164)	18 (165)	16 (167)	9 (173)	5 (177)	5 (177)	2 (180)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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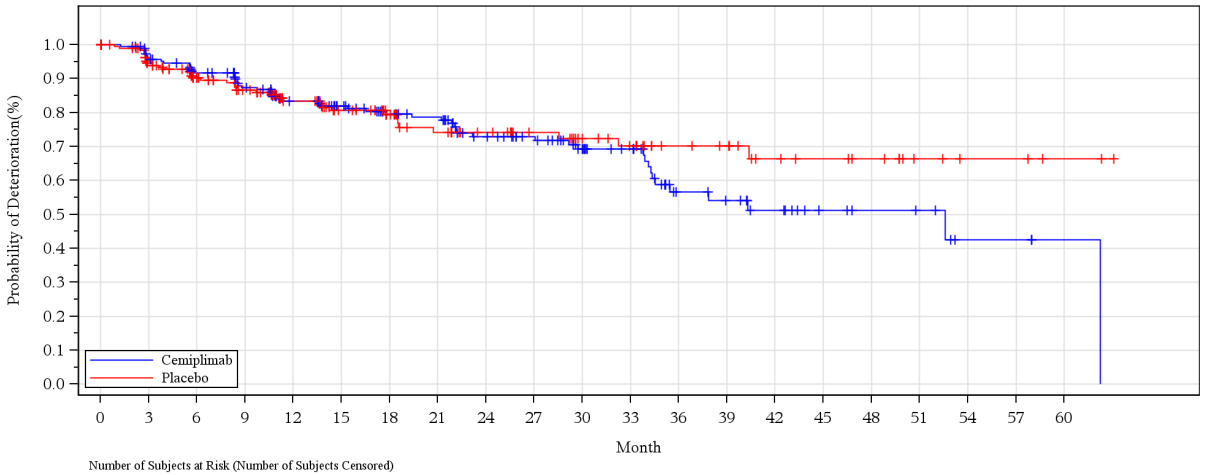
Figure 14.2.11.11 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale
(Full Analysis Set)



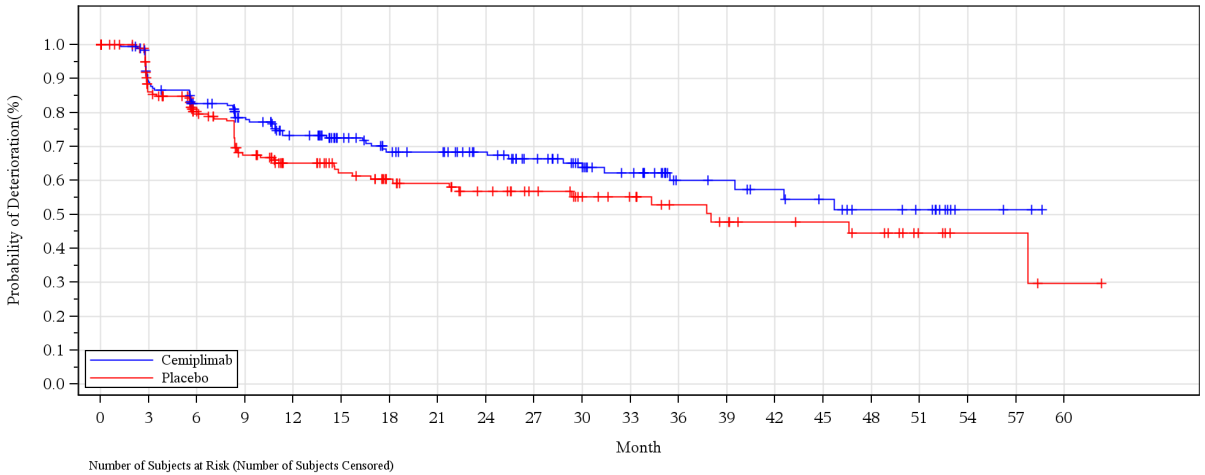
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	173 (28)	158 (36)	140 (47)	121 (60)	105 (74)	92 (84)	88 (87)	72 (97)	64 (105)	51 (115)	44 (122)	24 (135)	21 (137)	16 (141)	10 (147)	8 (149)	7 (150)	3 (153)	3 (153)	1 (155)
Placebo	206 (0)	164 (31)	136 (53)	117 (67)	93 (87)	79 (98)	66 (110)	55 (117)	49 (123)	42 (130)	35 (136)	31 (139)	23 (147)	21 (149)	15 (154)	13 (156)	11 (158)	6 (163)	4 (165)	4 (165)	2 (167)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km2.sas' (wenju.shi 10DEC2025 12:03 SAS Linux 9.4)

Figure 14.2.11.12 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	159 (30)	142 (36)	125 (46)	108 (55)	93 (69)	81 (76)	77 (80)	68 (89)	58 (97)	46 (107)	40 (112)	24 (127)	23 (128)	20 (130)	17 (132)	13 (135)	11 (137)	3 (145)	2 (146)	0 (148)
Placebo	206 (0)	144 (38)	117 (56)	92 (63)	75 (77)	65 (84)	54 (93)	50 (96)	43 (101)	37 (107)	30 (113)	27 (116)	21 (121)	18 (122)	15 (125)	14 (126)	12 (127)	6 (133)	3 (136)	3 (136)	1 (137)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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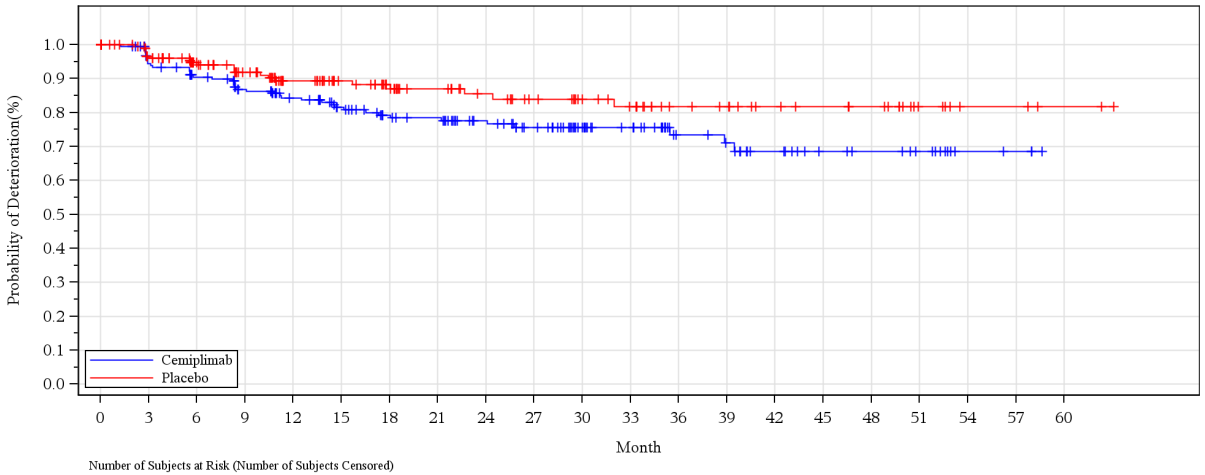
Figure 14.2.11.13 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale
(Full Analysis Set)



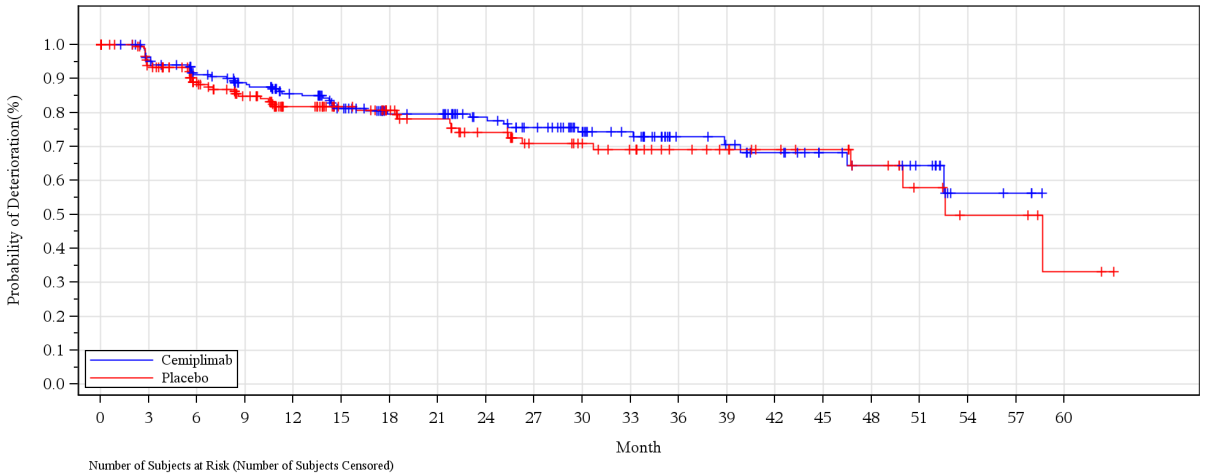
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	169 (30)	155 (37)	140 (46)	126 (56)	111 (67)	97 (78)	93 (81)	80 (93)	70 (101)	55 (116)	48 (123)	32 (138)	29 (140)	22 (146)	16 (152)	14 (154)	11 (157)	4 (164)	3 (165)	0 (168)
Placebo	206 (0)	164 (36)	137 (60)	119 (74)	96 (94)	82 (108)	71 (118)	61 (127)	54 (133)	47 (139)	40 (146)	36 (149)	27 (158)	25 (160)	20 (165)	18 (167)	16 (169)	8 (177)	4 (181)	4 (181)	2 (183)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km2.sas' (wenju.shi 10DEC2025 12:03 SAS Linux 9.4)

Figure 14.2.11.14 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	173 (27)	158 (35)	143 (46)	127 (57)	109 (69)	94 (82)	93 (83)	79 (96)	70 (102)	57 (114)	50 (121)	33 (137)	30 (139)	25 (143)	19 (149)	16 (151)	13 (154)	4 (162)	3 (163)	0 (166)
Placebo	206 (0)	164 (31)	135 (52)	116 (65)	92 (85)	78 (99)	67 (109)	59 (115)	50 (121)	41 (128)	37 (132)	33 (135)	26 (142)	23 (145)	19 (149)	17 (151)	13 (154)	8 (158)	5 (160)	5 (160)	2 (162)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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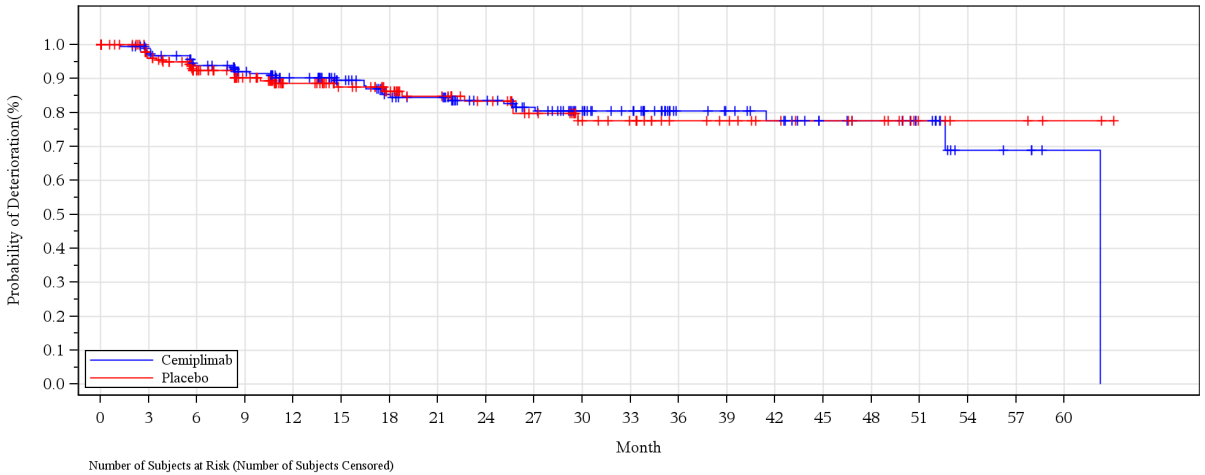
Figure 14.2.11.15 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	178 (26)	164 (34)	148 (47)	132 (60)	115 (76)	101 (85)	96 (89)	83 (101)	73 (109)	59 (122)	52 (129)	34 (147)	31 (150)	27 (153)	20 (160)	18 (162)	14 (166)	5 (174)	4 (175)	1 (178)
Placebo	206 (0)	167 (32)	138 (55)	117 (73)	95 (93)	82 (105)	69 (117)	60 (125)	52 (132)	43 (139)	34 (147)	31 (150)	23 (158)	21 (160)	17 (164)	15 (166)	13 (168)	6 (175)	4 (177)	4 (177)	2 (179)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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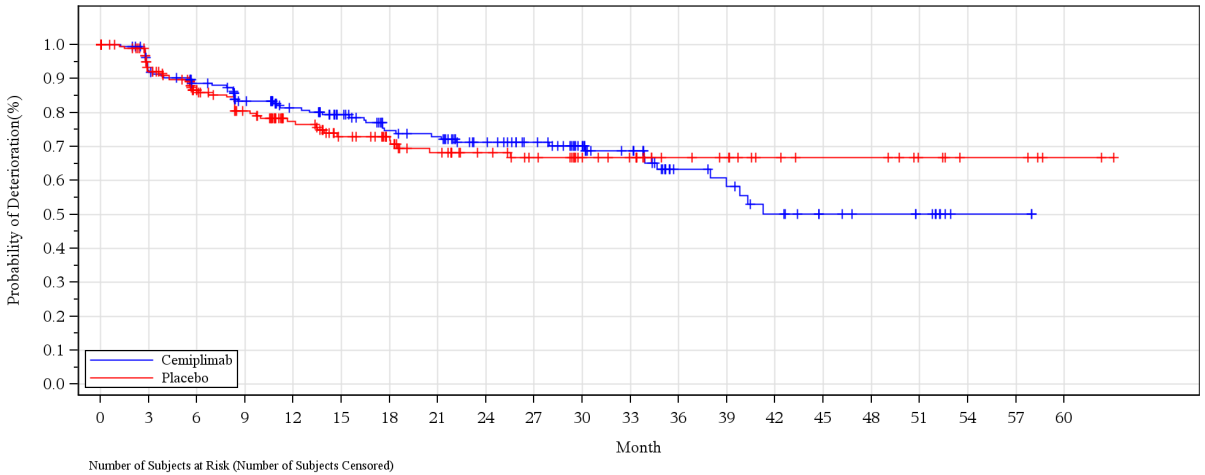
Figure 14.2.11.2 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	170 (25)	156 (32)	137 (42)	122 (54)	108 (65)	92 (75)	88 (77)	74 (89)	65 (98)	52 (110)	43 (118)	26 (132)	23 (133)	18 (135)	13 (140)	11 (142)	9 (144)	2 (151)	2 (151)	0 (153)
Placebo	206 (0)	160 (32)	130 (53)	112 (62)	91 (79)	75 (90)	64 (101)	54 (107)	46 (115)	40 (120)	32 (128)	29 (131)	21 (139)	19 (141)	14 (146)	12 (148)	12 (148)	8 (152)	5 (155)	5 (155)	2 (158)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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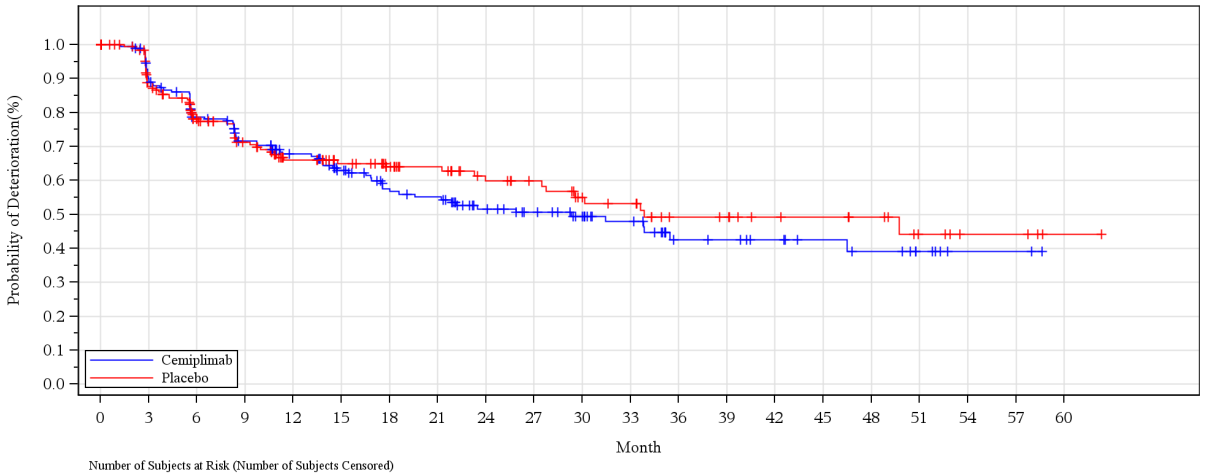
Figure 14.2.11.3 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	162 (29)	135 (36)	117 (42)	102 (51)	87 (59)	72 (67)	68 (68)	53 (79)	46 (85)	38 (92)	32 (97)	19 (107)	18 (108)	15 (111)	12 (114)	10 (115)	6 (119)	2 (123)	2 (123)	0 (125)
Placebo	206 (0)	154 (30)	120 (48)	100 (58)	79 (72)	69 (81)	58 (91)	52 (97)	42 (104)	38 (108)	30 (113)	28 (114)	20 (120)	19 (121)	15 (125)	14 (126)	12 (128)	7 (132)	4 (135)	4 (135)	1 (138)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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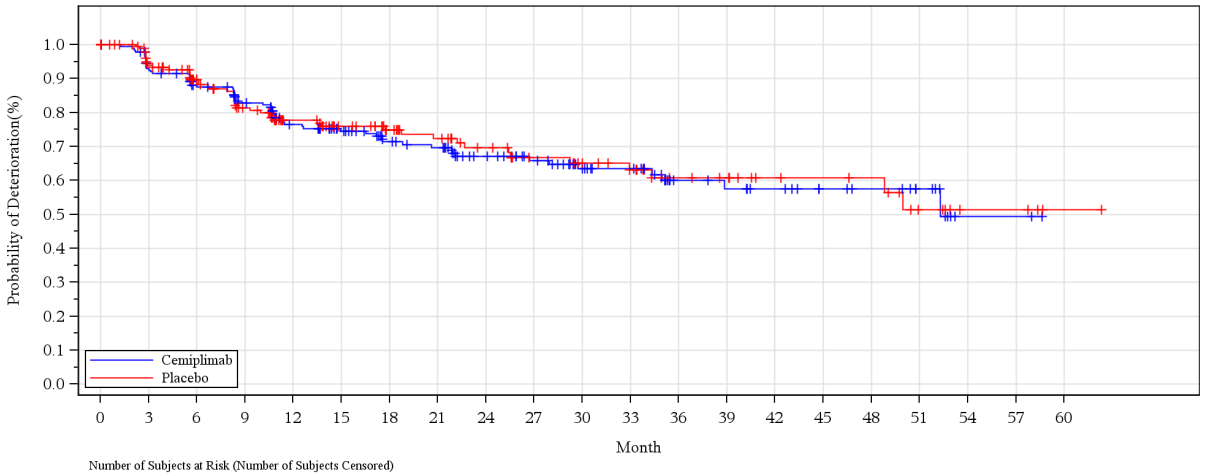
Figure 14.2.11.4 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	172 (24)	154 (32)	137 (41)	117 (51)	103 (62)	88 (73)	83 (76)	68 (88)	59 (96)	46 (107)	42 (111)	26 (125)	24 (126)	21 (129)	16 (134)	14 (136)	10 (140)	2 (147)	2 (147)	0 (149)
Placebo	206 (0)	164 (31)	135 (53)	114 (62)	91 (80)	77 (92)	65 (103)	58 (108)	49 (115)	41 (121)	36 (125)	32 (128)	23 (136)	21 (138)	16 (143)	15 (144)	14 (145)	8 (149)	4 (153)	4 (153)	1 (156)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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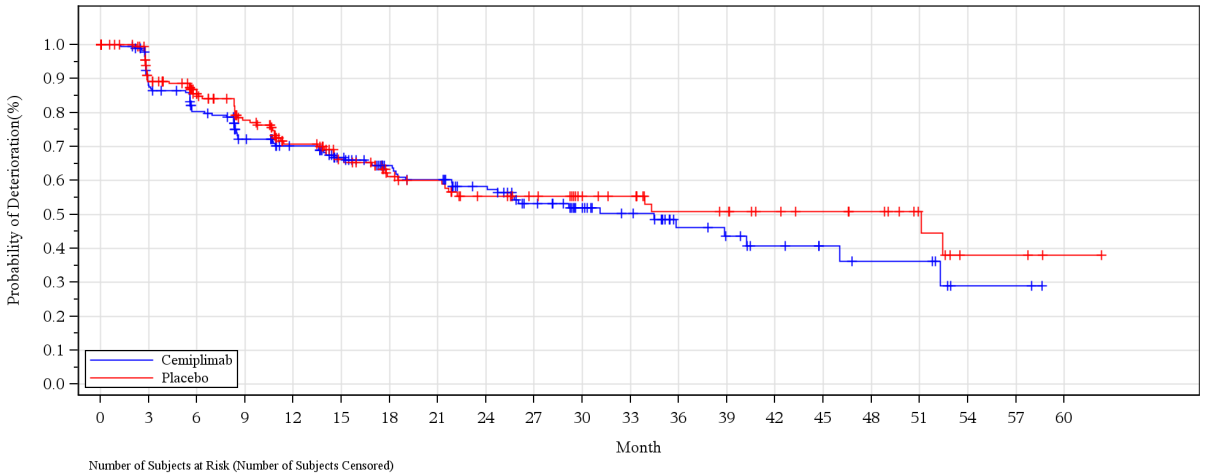
Figure 14.2.11.5 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	162 (25)	142 (31)	118 (41)	106 (50)	91 (60)	75 (73)	69 (74)	59 (82)	47 (89)	36 (99)	30 (104)	19 (113)	16 (115)	12 (118)	9 (121)	7 (122)	7 (122)	2 (126)	2 (126)	0 (128)
Placebo	206 (0)	154 (33)	129 (52)	107 (63)	84 (77)	71 (85)	56 (95)	52 (98)	43 (103)	38 (108)	31 (115)	29 (117)	22 (122)	21 (123)	17 (127)	15 (129)	13 (131)	8 (136)	3 (139)	3 (139)	1 (141)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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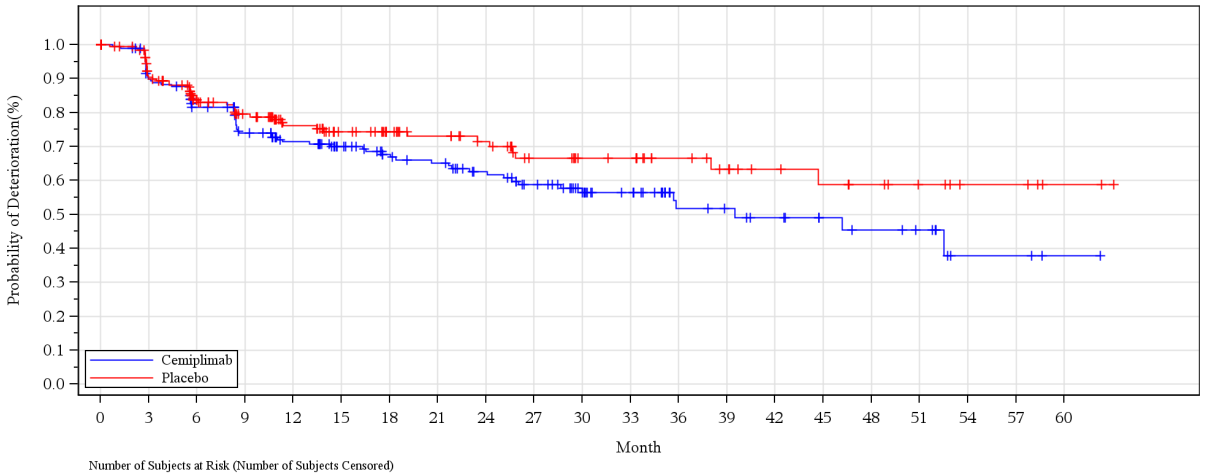
Figure 14.2.11.6 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	166 (24)	145 (30)	124 (38)	110 (48)	95 (61)	82 (71)	77 (73)	67 (80)	57 (86)	44 (97)	37 (104)	22 (117)	20 (119)	17 (121)	13 (125)	11 (126)	9 (128)	3 (133)	3 (133)	1 (135)
Placebo	206 (0)	157 (32)	125 (53)	108 (64)	86 (82)	71 (95)	60 (106)	53 (112)	47 (117)	36 (125)	31 (130)	30 (131)	23 (138)	19 (141)	15 (145)	13 (146)	11 (148)	8 (151)	5 (154)	5 (154)	2 (157)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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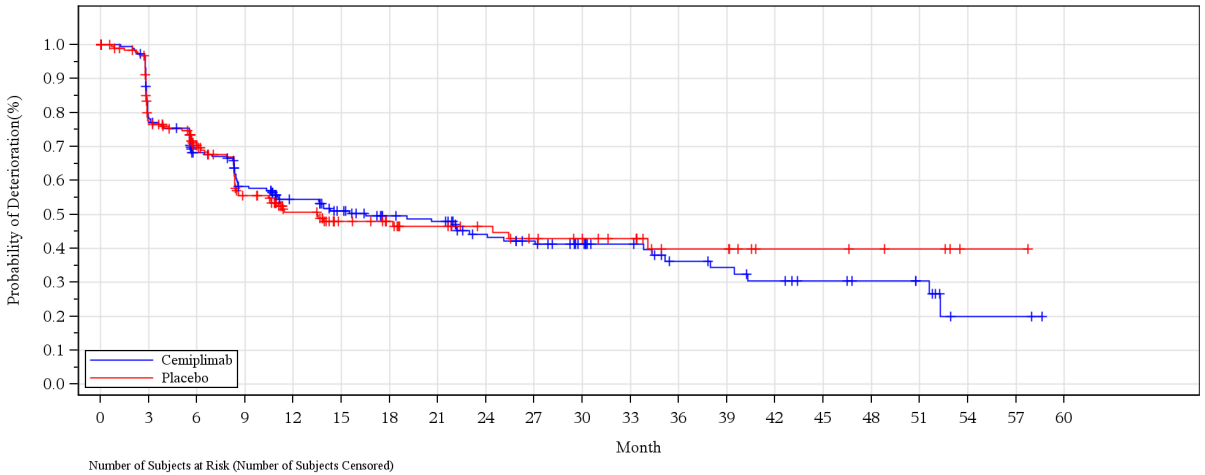
Figure 14.2.11.7 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	146 (23)	120 (30)	97 (36)	82 (45)	71 (51)	60 (60)	57 (61)	45 (69)	40 (72)	32 (79)	27 (84)	20 (88)	18 (89)	15 (90)	12 (93)	10 (95)	8 (97)	2 (101)	2 (101)	0 (103)
Placebo	206 (0)	136 (30)	105 (49)	76 (57)	56 (71)	42 (82)	36 (88)	31 (92)	26 (97)	22 (99)	19 (102)	17 (104)	11 (109)	11 (109)	6 (114)	6 (114)	5 (115)	4 (116)	1 (119)	1 (119)	0 (120)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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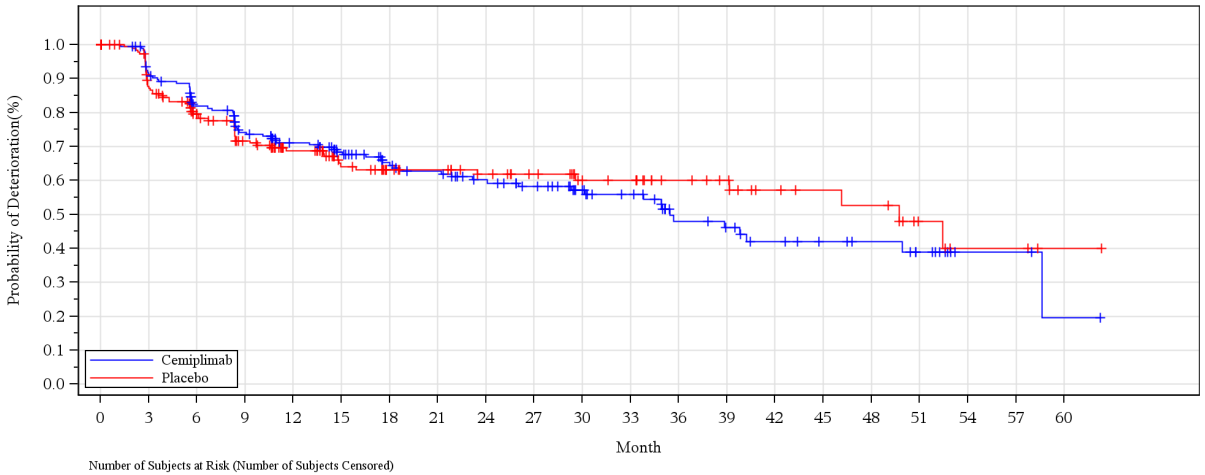
Figure 14.2.11.8 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	167 (26)	143 (33)	123 (40)	108 (50)	94 (60)	80 (70)	74 (73)	65 (79)	58 (84)	47 (94)	41 (99)	27 (108)	24 (110)	19 (113)	16 (116)	14 (118)	10 (121)	3 (128)	3 (128)	1 (129)
Placebo	206 (0)	156 (28)	125 (45)	104 (54)	85 (69)	66 (83)	55 (93)	52 (96)	46 (101)	41 (106)	33 (113)	32 (114)	24 (122)	21 (125)	15 (130)	13 (132)	12 (132)	6 (137)	3 (139)	3 (139)	1 (141)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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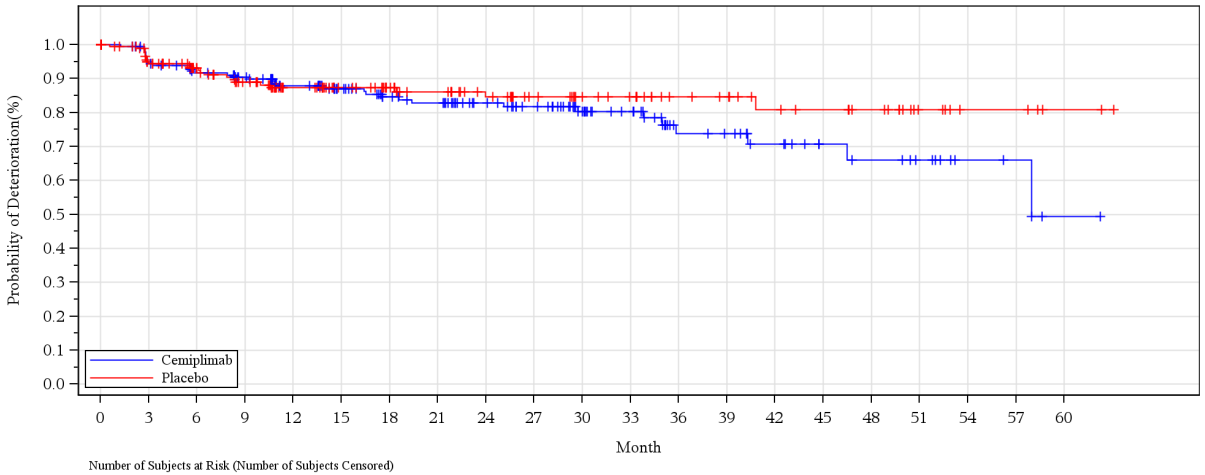
Figure 14.2.11.9 Time to Confirmed Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	170 (29)	158 (36)	145 (47)	127 (61)	111 (76)	97 (87)	92 (90)	79 (103)	70 (111)	55 (125)	47 (133)	29 (148)	27 (150)	21 (155)	15 (161)	13 (162)	10 (165)	5 (170)	4 (171)	1 (173)
Placebo	206 (0)	163 (33)	137 (57)	119 (69)	97 (89)	83 (103)	73 (113)	65 (120)	56 (128)	47 (137)	40 (144)	37 (147)	29 (155)	27 (157)	22 (161)	20 (163)	17 (166)	9 (174)	5 (178)	5 (178)	2 (181)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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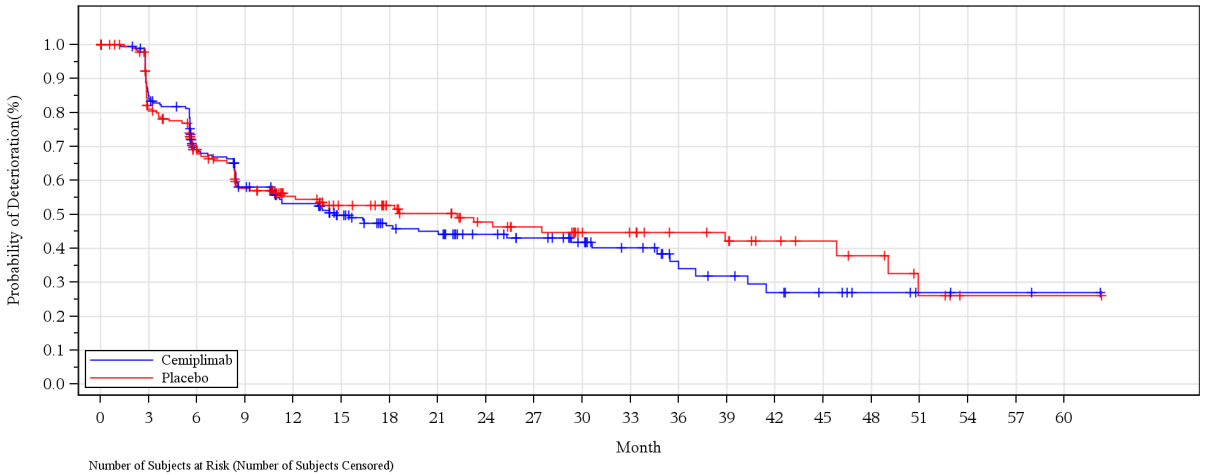
Figure 14.2.8.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	159 (22)	121 (30)	98 (35)	83 (42)	69 (51)	56 (60)	53 (61)	43 (70)	38 (74)	31 (80)	24 (86)	16 (91)	14 (92)	11 (93)	8 (96)	5 (99)	3 (101)	2 (102)	2 (102)	1 (103)
Placebo	206 (0)	142 (30)	106 (46)	84 (51)	64 (68)	54 (75)	46 (83)	41 (86)	34 (91)	30 (94)	23 (100)	22 (101)	18 (105)	16 (106)	12 (110)	10 (112)	8 (113)	4 (115)	1 (118)	1 (118)	1 (118)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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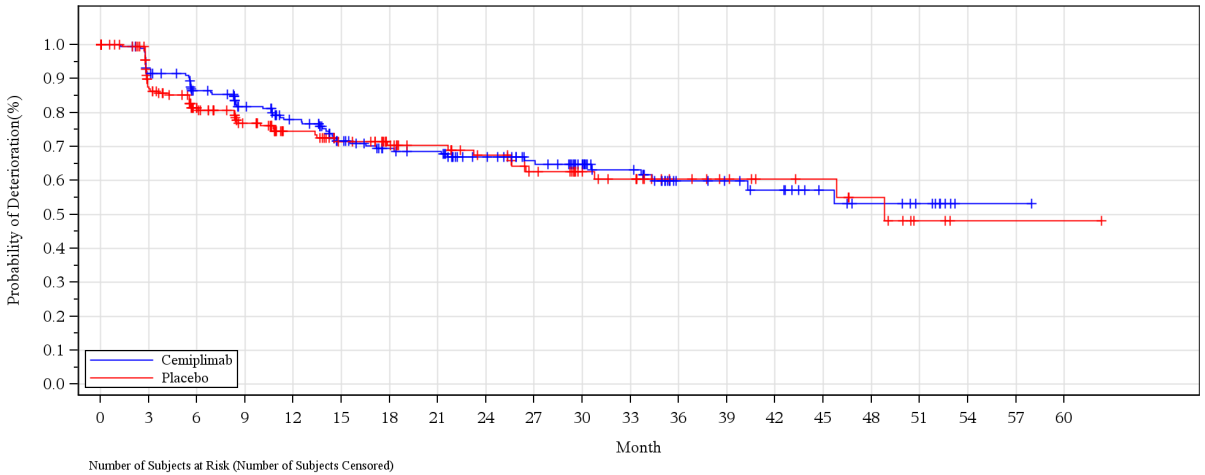
Figure 14.2.8.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	170 (23)	152 (32)	133 (43)	118 (52)	98 (63)	86 (72)	83 (74)	70 (85)	60 (94)	49 (104)	41 (111)	25 (125)	23 (127)	20 (129)	14 (135)	11 (137)	8 (140)	1 (147)	1 (147)	0 (148)
Placebo	206 (0)	150 (34)	120 (54)	98 (70)	79 (86)	68 (94)	57 (104)	51 (110)	44 (115)	37 (119)	29 (127)	26 (129)	18 (137)	15 (140)	12 (143)	11 (144)	8 (146)	3 (150)	1 (152)	1 (152)	1 (152)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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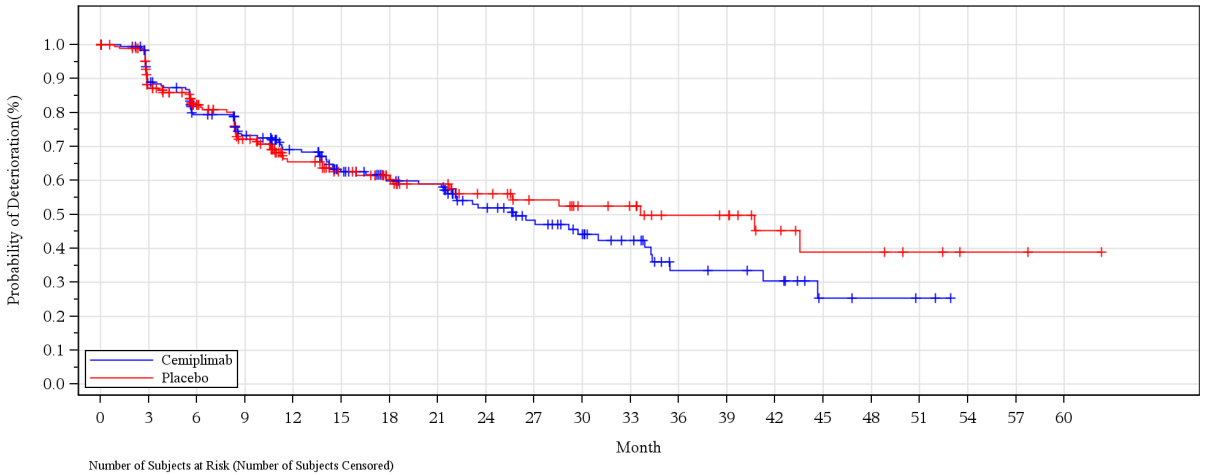
Figure 14.2.8.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	161 (28)	136 (36)	116 (46)	99 (57)	79 (68)	67 (77)	64 (79)	48 (88)	38 (95)	29 (101)	23 (106)	13 (112)	12 (113)	10 (114)	4 (119)	3 (120)	2 (121)	0 (123)	0 (123)	0 (123)
Placebo	206 (0)	152 (31)	123 (52)	96 (65)	71 (82)	60 (90)	49 (99)	42 (105)	35 (110)	29 (115)	24 (119)	22 (121)	16 (126)	15 (127)	9 (132)	6 (134)	6 (134)	4 (136)	2 (138)	2 (138)	1 (139)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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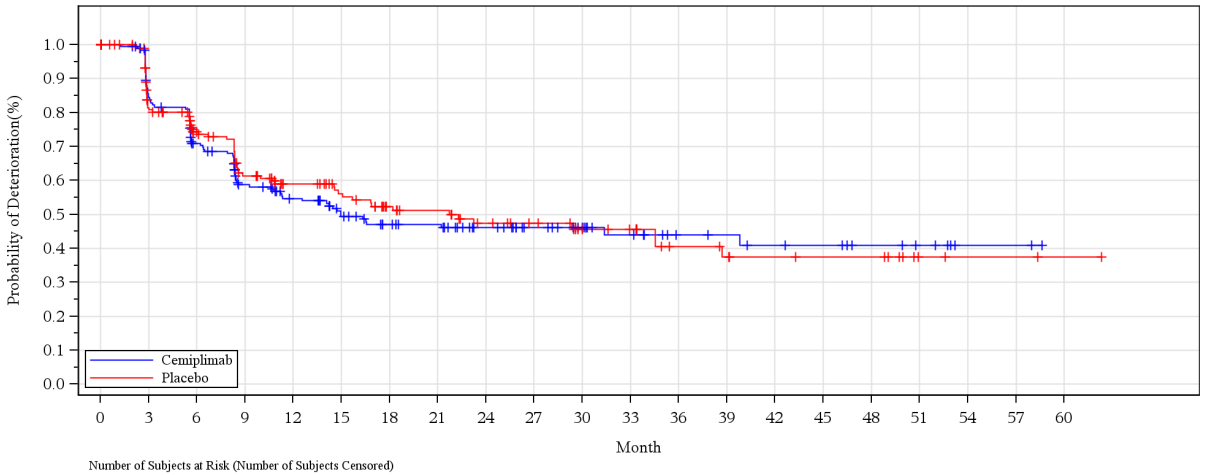
Figure 14.2.8.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	151 (30)	121 (36)	91 (46)	78 (53)	64 (60)	54 (67)	51 (70)	41 (79)	33 (87)	26 (94)	21 (98)	15 (104)	14 (105)	12 (106)	11 (107)	8 (110)	6 (112)	2 (116)	2 (116)	0 (118)
Placebo	206 (0)	136 (38)	107 (56)	83 (62)	68 (74)	59 (80)	46 (89)	42 (92)	34 (97)	30 (101)	23 (107)	21 (109)	14 (114)	12 (115)	10 (117)	9 (118)	9 (118)	3 (124)	2 (125)	2 (125)	1 (126)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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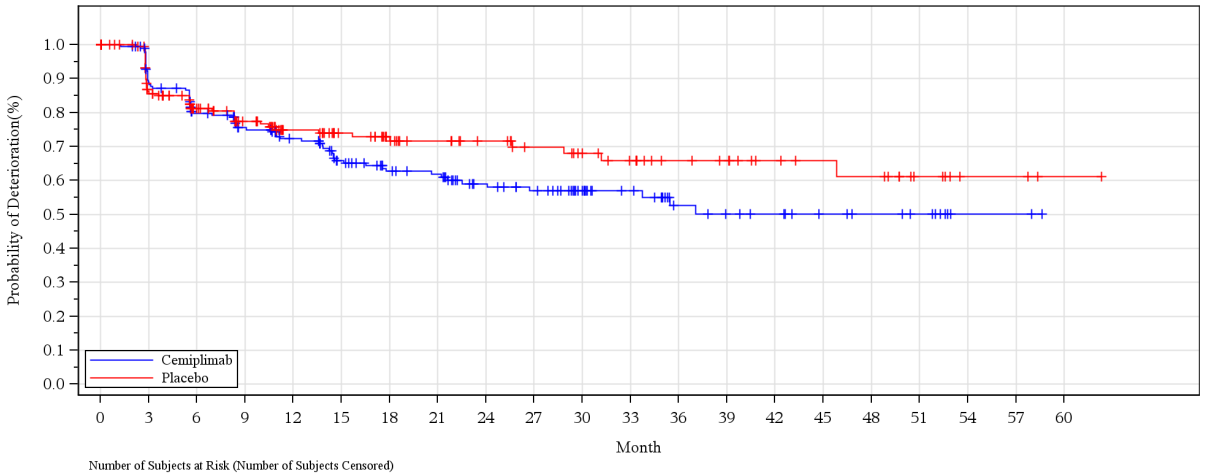
Figure 14.2.8.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	159 (30)	136 (37)	121 (45)	107 (54)	88 (64)	75 (73)	71 (76)	57 (87)	51 (91)	39 (103)	32 (110)	21 (119)	18 (121)	16 (123)	12 (127)	10 (129)	8 (131)	2 (137)	2 (137)	0 (139)
Placebo	206 (0)	146 (36)	116 (58)	98 (71)	77 (89)	66 (99)	56 (108)	49 (114)	44 (119)	38 (124)	33 (128)	29 (131)	23 (137)	21 (139)	16 (144)	14 (146)	13 (146)	7 (152)	3 (156)	3 (156)	1 (158)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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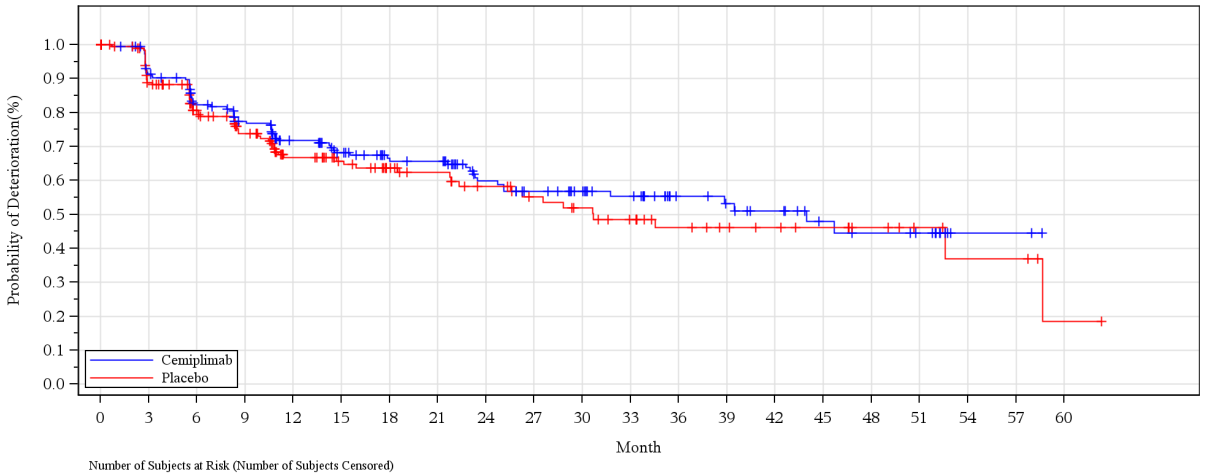
Figure 14.2.8.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale
(Full Analysis Set)



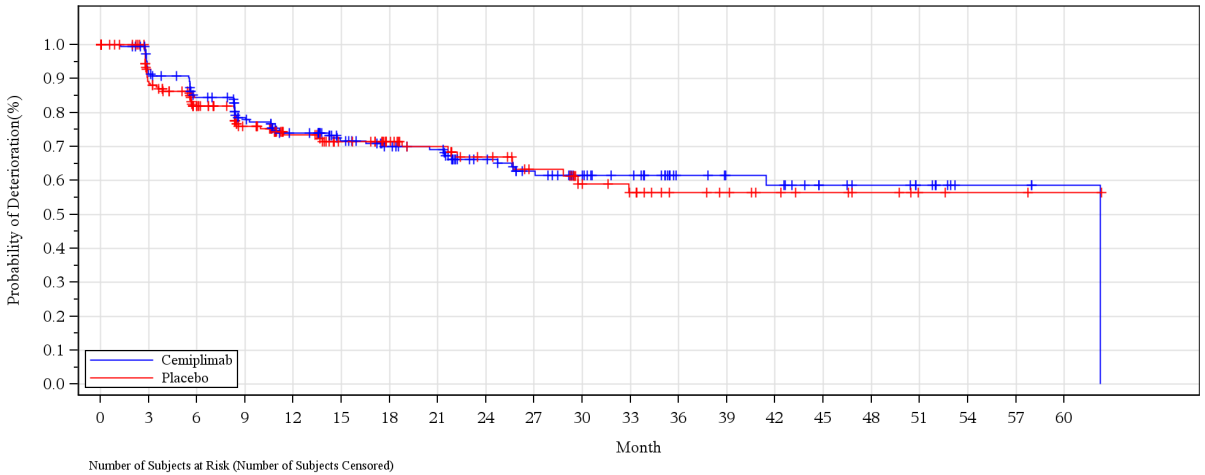
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	166 (27)	142 (35)	125 (44)	105 (55)	91 (64)	79 (74)	77 (75)	59 (87)	52 (91)	46 (97)	40 (102)	27 (115)	24 (117)	20 (120)	14 (125)	12 (126)	10 (128)	2 (136)	2 (136)	0 (138)
Placebo	206 (0)	155 (31)	123 (50)	102 (61)	75 (79)	64 (89)	53 (98)	47 (103)	40 (107)	34 (111)	30 (113)	25 (116)	19 (121)	16 (124)	14 (126)	12 (128)	9 (131)	6 (134)	4 (135)	4 (135)	1 (137)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km2.sas' (wenju.shi 10DEC2025 12:03 SAS Linux 9.4)

Figure 14.2.8.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	167 (26)	147 (34)	126 (45)	107 (57)	90 (71)	80 (79)	75 (83)	60 (95)	51 (101)	42 (109)	37 (114)	24 (127)	21 (130)	20 (130)	14 (136)	12 (138)	9 (141)	3 (147)	3 (147)	1 (149)
Placebo	206 (0)	155 (32)	122 (53)	96 (71)	77 (87)	64 (98)	54 (108)	47 (114)	40 (119)	33 (124)	24 (131)	21 (133)	15 (139)	13 (141)	10 (144)	8 (146)	6 (148)	3 (151)	2 (152)	2 (152)	1 (153)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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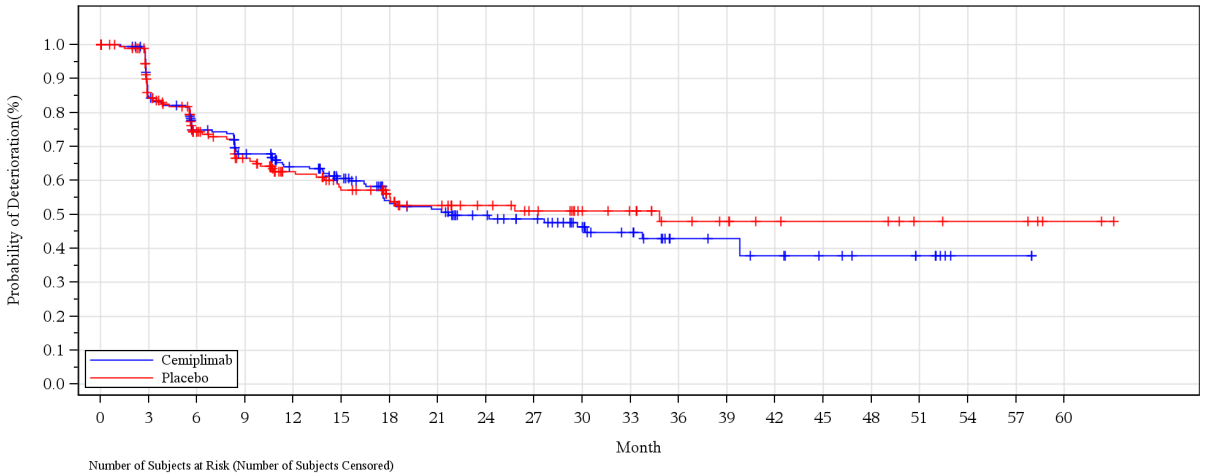
Figure 14.2.8.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	156 (25)	132 (31)	113 (38)	97 (48)	82 (58)	64 (68)	60 (69)	50 (77)	44 (82)	33 (91)	27 (96)	18 (104)	17 (105)	14 (106)	11 (109)	9 (111)	7 (113)	2 (118)	2 (118)	0 (120)
Placebo	206 (0)	146 (32)	110 (52)	90 (61)	71 (75)	60 (80)	49 (90)	41 (95)	35 (101)	30 (105)	23 (112)	21 (114)	15 (119)	13 (121)	10 (124)	9 (125)	9 (125)	6 (128)	5 (129)	5 (129)	2 (132)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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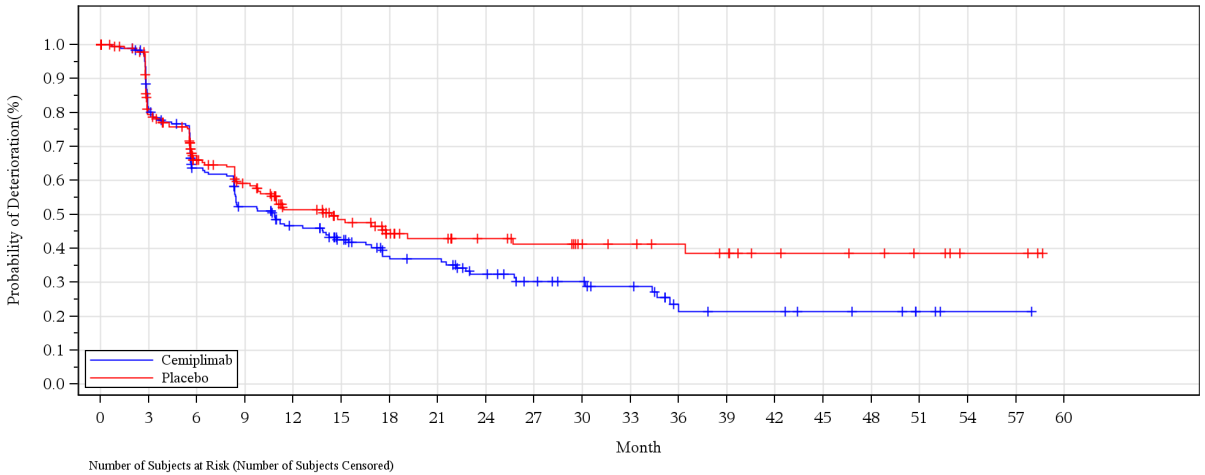
Figure 14.2.8.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	146 (29)	108 (36)	86 (39)	71 (45)	58 (52)	45 (59)	43 (60)	33 (65)	26 (70)	23 (73)	19 (76)	10 (81)	9 (82)	9 (82)	7 (84)	6 (85)	3 (88)	1 (90)	1 (90)	0 (91)
Placebo	206 (0)	139 (30)	99 (48)	82 (55)	60 (67)	49 (75)	37 (83)	32 (87)	27 (92)	24 (94)	19 (99)	18 (100)	16 (102)	14 (103)	10 (107)	9 (108)	8 (109)	6 (111)	3 (114)	3 (114)	0 (117)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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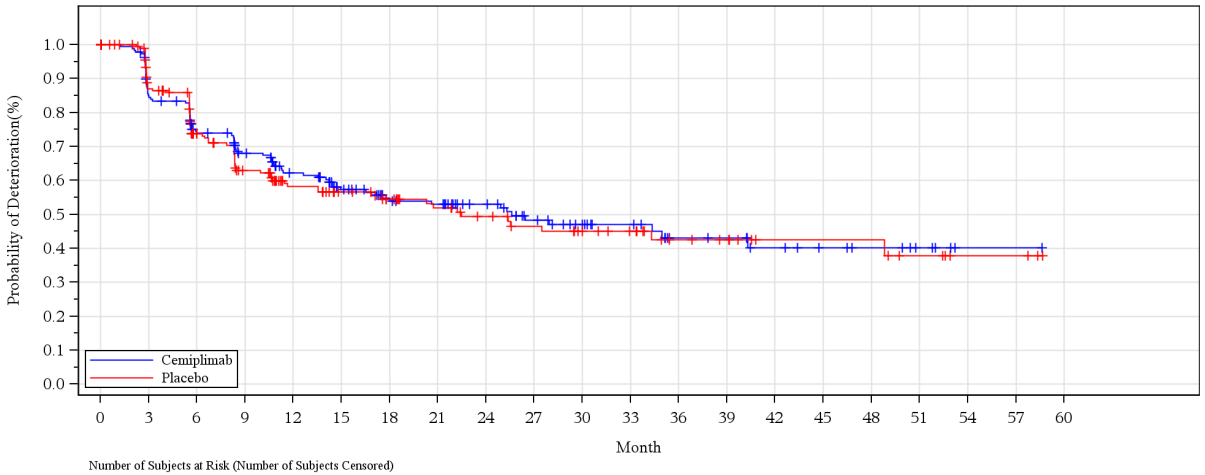
Figure 14.2.8.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	157 (24)	129 (32)	111 (40)	93 (49)	76 (59)	63 (69)	59 (71)	49 (81)	38 (88)	30 (95)	26 (99)	18 (105)	17 (106)	13 (109)	10 (112)	8 (114)	5 (117)	1 (121)	1 (121)	0 (122)
Placebo	206 (0)	152 (31)	112 (49)	88 (57)	68 (71)	58 (79)	49 (86)	42 (91)	36 (95)	31 (98)	26 (102)	23 (105)	16 (111)	14 (113)	9 (118)	9 (118)	9 (118)	6 (120)	3 (123)	3 (123)	0 (126)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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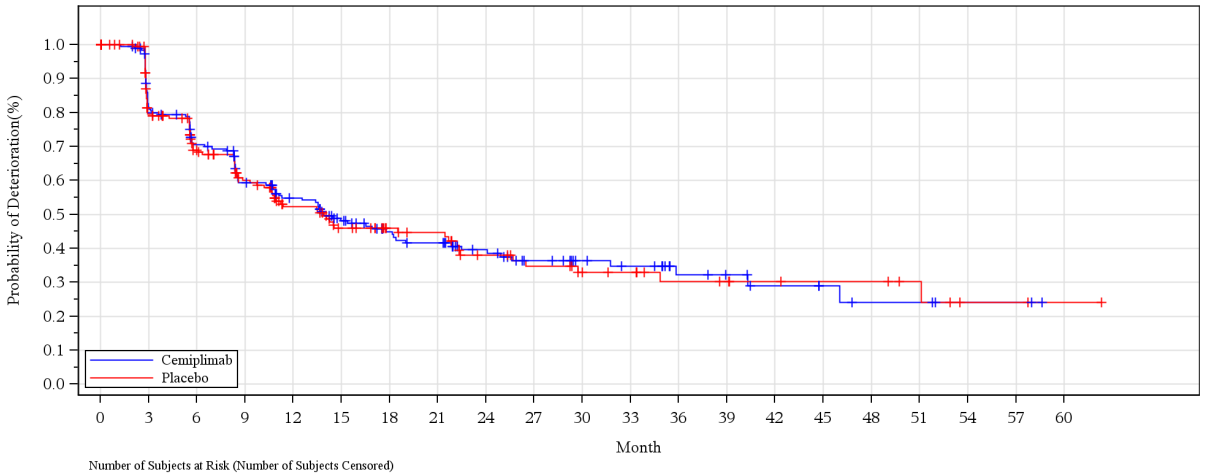
Figure 14.2.8.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	150 (25)	124 (31)	99 (37)	84 (45)	66 (53)	53 (62)	48 (63)	38 (71)	29 (77)	23 (83)	20 (85)	13 (91)	11 (93)	8 (95)	6 (97)	4 (98)	4 (98)	2 (100)	2 (100)	0 (102)
Placebo	206 (0)	137 (33)	106 (47)	83 (57)	61 (69)	48 (75)	38 (85)	35 (87)	25 (92)	21 (94)	16 (98)	15 (99)	11 (102)	10 (103)	8 (105)	7 (106)	7 (106)	5 (108)	2 (110)	2 (110)	1 (111)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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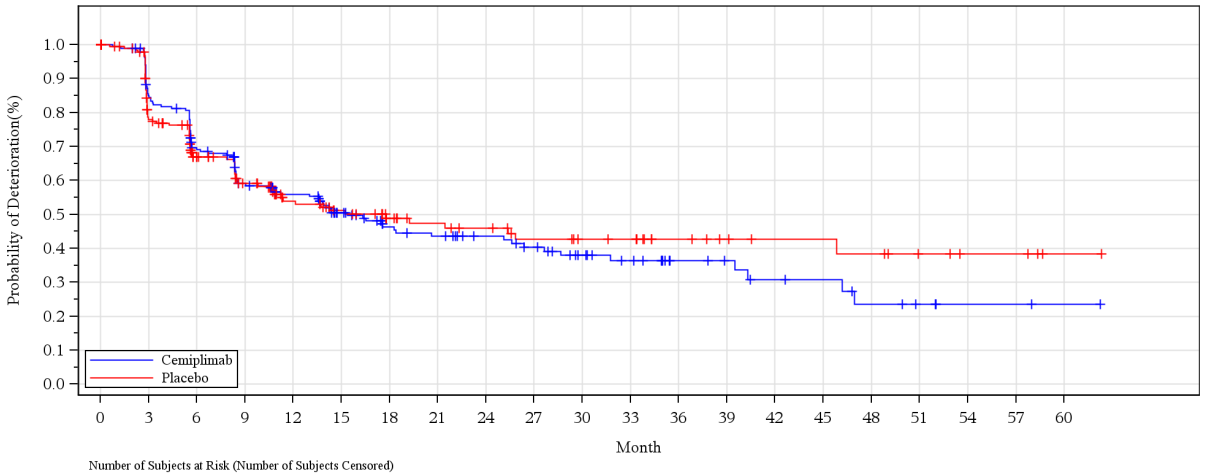
Figure 14.2.8.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	157 (24)	123 (29)	98 (37)	86 (44)	66 (56)	51 (66)	47 (67)	41 (73)	36 (75)	28 (81)	23 (85)	15 (93)	13 (95)	10 (96)	9 (97)	6 (98)	4 (100)	2 (102)	2 (102)	1 (103)
Placebo	206 (0)	135 (32)	99 (50)	79 (59)	58 (74)	49 (80)	38 (89)	33 (93)	30 (95)	25 (98)	22 (101)	21 (102)	15 (108)	12 (111)	10 (113)	10 (113)	9 (113)	6 (116)	4 (118)	4 (118)	1 (121)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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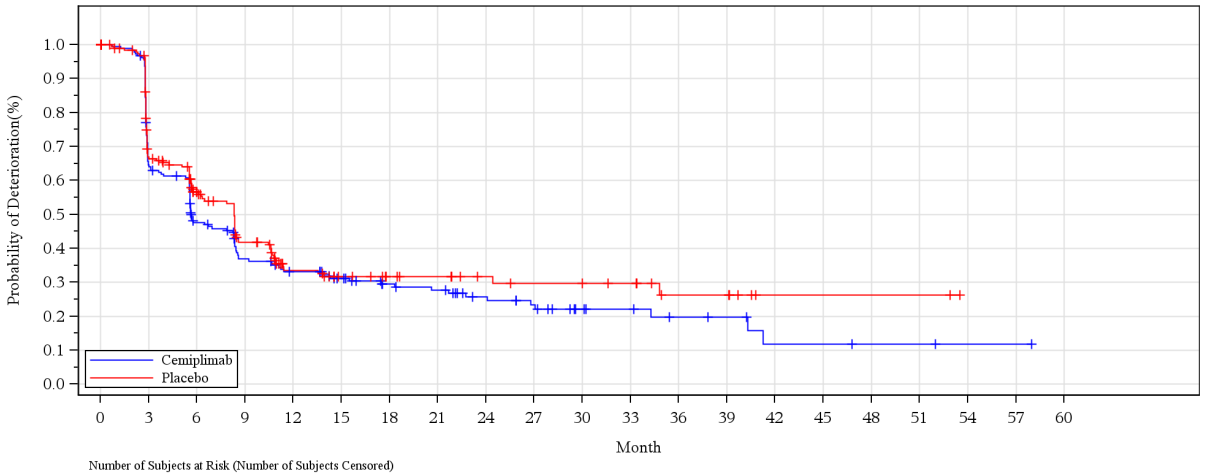
Figure 14.2.8.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	120 (23)	83 (29)	61 (33)	52 (36)	43 (42)	34 (49)	31 (50)	23 (56)	19 (58)	12 (64)	10 (66)	7 (68)	6 (69)	3 (70)	3 (70)	2 (71)	2 (71)	1 (72)	1 (72)	0 (73)
Placebo	206 (0)	117 (30)	85 (45)	57 (52)	35 (64)	27 (70)	22 (75)	20 (77)	16 (81)	14 (82)	13 (83)	12 (84)	7 (88)	7 (88)	2 (93)	2 (93)	2 (93)	2 (93)	0 (95)	0 (95)	0 (95)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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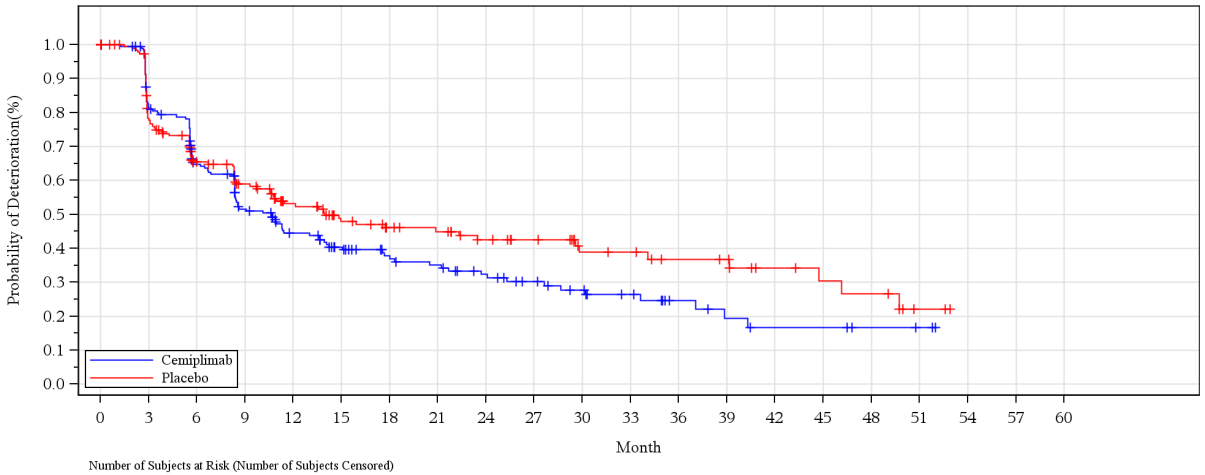
Figure 14.2.8.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	149 (26)	112 (33)	84 (39)	66 (46)	53 (53)	43 (60)	39 (61)	32 (65)	26 (69)	21 (72)	16 (76)	10 (81)	7 (82)	5 (83)	5 (83)	3 (85)	2 (86)	0 (88)	0 (88)	0 (88)
Placebo	206 (0)	139 (28)	103 (42)	87 (48)	66 (61)	52 (69)	43 (76)	40 (78)	33 (83)	29 (87)	21 (93)	20 (94)	16 (97)	15 (98)	10 (102)	8 (103)	7 (103)	2 (107)	0 (109)	0 (109)	0 (109)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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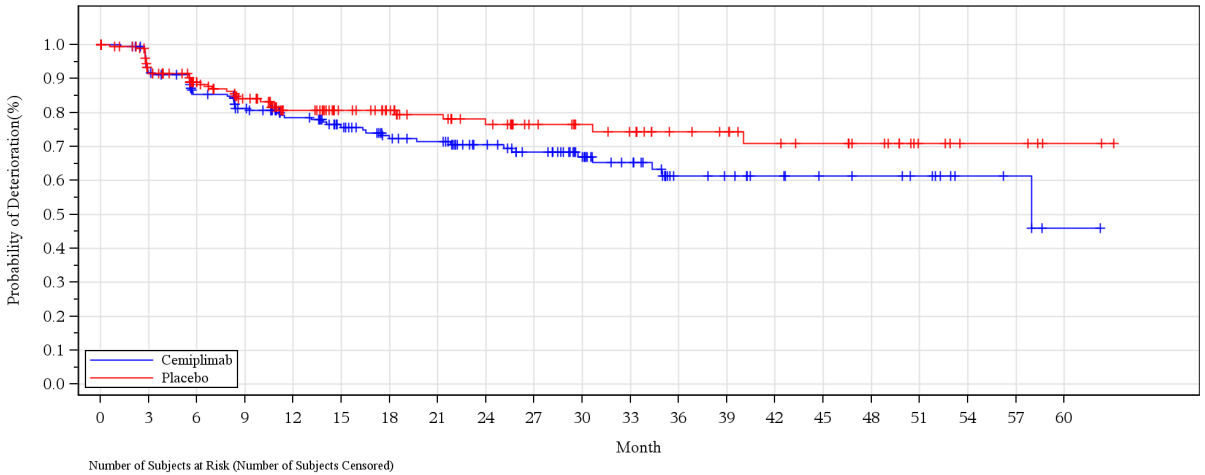
Figure 14.2.8.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	165 (29)	147 (36)	131 (45)	115 (57)	99 (69)	85 (79)	81 (82)	68 (94)	59 (101)	46 (113)	37 (121)	22 (134)	20 (136)	16 (140)	13 (143)	12 (144)	10 (146)	5 (151)	4 (152)	1 (154)
Placebo	206 (0)	158 (33)	130 (57)	111 (69)	87 (89)	74 (102)	65 (111)	57 (118)	50 (123)	41 (132)	36 (137)	33 (139)	26 (146)	24 (148)	20 (151)	18 (153)	15 (156)	8 (163)	5 (166)	5 (166)	2 (169)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

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1.2 EQ 5D 3L VAS

1.2.1 1. Datenschnitt

Table 2.2.2: Completion rate at scale level-EQ-5D-3L VAS scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	185 (88.9%)	185 (88.5%)
Cycle 2 - Day 1	175	150 (85.7%)	150 (71.8%)
Cycle 3 - Day 1	155	131 (84.5%)	131 (62.7%)
Cycle 4 - Day 1	138	119 (86.2%)	119 (56.9%)
Placebo (N=206)			
Baseline	203	185 (91.1%)	185 (89.8%)
Cycle 2 - Day 1	179	145 (81.0%)	145 (70.4%)
Cycle 3 - Day 1	146	121 (82.9%)	121 (58.7%)
Cycle 4 - Day 1	123	109 (88.6%)	109 (52.9%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as the VAS score to be non missing.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; VAS: Visual Analogue Scale.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 4 April 2025 at 20:40:35.

Table A2.2.2: Completion rate at scale level-EQ-5D-3L VAS scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	172	136 (79.1%)	136 (65.1%)
FOLLOW-UP VISIT 1	143	109 (76.2%)	109 (52.2%)
FOLLOW-UP VISIT 2	131	105 (80.2%)	105 (50.2%)
FOLLOW-UP VISIT 3	117	80 (68.4%)	80 (38.3%)
FOLLOW-UP VISIT 4	97	67 (69.1%)	67 (32.1%)
FOLLOW-UP VISIT 5	79	50 (63.3%)	50 (23.9%)
FOLLOW-UP VISIT 6	57	37 (64.9%)	37 (17.7%)
FOLLOW-UP VISIT 7	40	25 (62.5%)	25 (12.0%)
FOLLOW-UP VISIT 8	30	21 (70.0%)	21 (10.0%)
FOLLOW-UP VISIT 9	14	7 (50.0%)	7 (3.3%)
FOLLOW-UP VISIT 10	3	3 (100.0%)	3 (1.4%)
FOLLOW-UP VISIT 11	1	1 (100.0%)	1 (0.5%)
Placebo (N=206)			
END OF TREATMENT	172	134 (77.9%)	134 (65.0%)
FOLLOW-UP VISIT 1	139	79 (56.8%)	79 (38.3%)
FOLLOW-UP VISIT 2	124	69 (55.6%)	69 (33.5%)
FOLLOW-UP VISIT 3	103	58 (56.3%)	58 (28.2%)
FOLLOW-UP VISIT 4	86	42 (48.8%)	42 (20.4%)
FOLLOW-UP VISIT 5	70	31 (44.3%)	31 (15.0%)
FOLLOW-UP VISIT 6	56	29 (51.8%)	29 (14.1%)
FOLLOW-UP VISIT 7	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 8	27	16 (59.3%)	16 (7.8%)
FOLLOW-UP VISIT 9	13	10 (76.9%)	10 (4.9%)
FOLLOW-UP VISIT 10	3	2 (66.7%)	2 (1.0%)
FOLLOW-UP VISIT 11	1	0	0

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as the VAS score to be non missing.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; VAS: Visual Analogue Scale.
Source: ADSL,AXDS,ADQS. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 10 July 2025 at 10:33:52.

Table 6.2.1.2: Time to confirmed deterioration in EQ-5D-3L VAS scale (excluding death)
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
EQ-5D-3L VAS Score (Deterioration threshold = 7)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	72 (34.4 %)	60 (29.1 %)
Number of censored cases	n (%)	137 (65.6 %)	146 (70.9 %)
No baseline score	n (%)	24 (11.5 %)	21 (10.2 %)
No post-baseline score	n (%)	11 (5.3 %)	10 (4.9 %)
No deterioration possible	n (%)	0	1 (0.5 %)
No confirmed deterioration	n (%)	102 (48.8 %)	114 (55.3 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.38 [5.62, 10.91]	6.41 [5.55, 10.81]
	Median [95% CI]	25.59 [18.56, NC]	NYR [17.77, NC]
	Q3 [95% CI]	NYR [50.76, NC]	NYR [NC, NC]
	p-value[b]		0.629
	HR [95 % CI][c]		1.09 [0.77, 1.54]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
Source: AXTTD. Extract date: 04Oct2024.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T06.sas] Generated: 4 April 2025 at 20:40:35.

Table 14.2.11.5 Time to confirmed deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range)
(Full Analysis Set)

EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	49 (23.4%)	38 (18.4%)
Number of censored cases	n (%)	160 (76.6%)	168 (81.6%)
No baseline score	n (%)	24 (11.5%)	21 (10.2%)
No post-baseline score	n (%)	11 (5.3%)	10 (4.9%)
No deterioration possible	n (%)	0	1 (0.5%)
No confirmed deterioration	n (%)	125 (59.8%)	136 (66.0%)
Time to confirmed deterioration (months)	Q1 [95% CI]	17.77 [10.68, 24.74]	13.54 [8.38, NC]
	Median [95% CI]	50.76 [35.29, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.506
	HR [95 % CI][c]		1.16 [0.75, 1.77]

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, Stratified by high-risk tumor (HN vs non-HN) and geographical region (North America vs Australia/New Zealand vs ROW) per EDC.
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by high-risk tumor (HN vs non-HN) and geographical region (North America vs Australia/New Zealand vs ROW) per EDC.
CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments).

Table A4.1.2.1: Mixed model repeated measures: Change from Baseline - EQ-5D-3L VAS scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value
Overall	-1.69 (0.96), [-3.58, 0.20]	-0.60 (1.03), [-2.63, 1.43]	-1.09 [-3.43, 1.25], 0.360
Month 3	-1.41 (1.03), [-3.43, 0.61]	-0.73 (1.07), [-2.84, 1.38]	-0.68 [-3.19, 1.83], 0.597
Month 6	-1.49 (0.98), [-3.42, 0.44]	-0.70 (1.03), [-2.71, 1.32]	-0.79 [-3.15, 1.57], 0.510
Month 9	-1.57 (0.96), [-3.45, 0.31]	-0.66 (1.01), [-2.64, 1.32]	-0.91 [-3.19, 1.38], 0.436
Month 12	-1.64 (0.95), [-3.52, 0.23]	-0.62 (1.01), [-2.62, 1.37]	-1.02 [-3.32, 1.27], 0.382
Month 15	-1.72 (0.97), [-3.63, 0.18]	-0.59 (1.05), [-2.65, 1.48]	-1.14 [-3.52, 1.25], 0.349
Month 18	-1.80 (1.01), [-3.78, 0.18]	-0.55 (1.11), [-2.74, 1.64]	-1.25 [-3.80, 1.30], 0.335
Month 21	-1.88 (1.06), [-3.97, 0.21]	-0.51 (1.19), [-2.86, 1.84]	-1.37 [-4.15, 1.41], 0.333
Month 24	-1.96 (1.14), [-4.20, 0.28]	-0.48 (1.29), [-3.02, 2.07]	-1.48 [-4.54, 1.57], 0.339
Month 27	-2.04 (1.22), [-4.44, 0.37]	-0.44 (1.41), [-3.21, 2.33]	-1.60 [-4.96, 1.76], 0.350
Month 30	-2.11 (1.32), [-4.71, 0.48]	-0.40 (1.53), [-3.42, 2.61]	-1.71 [-5.41, 1.99], 0.362
Month 33	-2.19 (1.42), [-5.00, 0.61]	-0.37 (1.66), [-3.64, 2.91]	-1.83 [-5.88, 2.23], 0.375
Month 36	-2.27 (1.53), [-5.29, 0.75]	-0.33 (1.80), [-3.88, 3.22]	-1.94 [-6.37, 2.48], 0.387
Month 39	-2.35 (1.65), [-5.60, 0.90]	-0.29 (1.94), [-4.12, 3.54]	-2.06 [-6.87, 2.75], 0.399

Note(s): A positive change from baseline value indicates improvement of symptoms. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.

[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.

CI: Confidence interval; EQ-5D-3L: EuroQoL 5 Dimensions 3; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; VAS: Visual Analogue Scale.

The model assumed an unstructured covariance among the random intercept and random coefficient.

Source: ADQS. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 10 July 2025 at 10:00:32.

Table 4.2.1: Mixed model repeated measures analysis: change from Baseline in the EQ-5D-3L VAS scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	155	80.38 (13.73)	80.28 (12.95)	0.16 (1.03), [-1.86, 2.18]	155	78.83 (14.88)	79.38 (14.48)	0.61 (1.07), [-1.51, 2.72]	-0.65	-0.45 [-2.85, 1.94], 0.710	-0.04 [-0.26, 0.18]
Cycle 2 - Day 1	138	80.83 (13.45)	80.49 (13.96)	0.20 (1.18), [-2.12, 2.52]	135	78.41 (15.36)	78.73 (16.10)	0.05 (1.21), [-2.33, 2.43]	-0.67	0.15 [-2.70, 2.99], 0.918	0.01 [-0.22, 0.25]
Cycle 3 - Day 1	123	81.28 (13.00)	80.04 (13.48)	-0.37 (1.20), [-2.74, 2.00]	108	80.30 (13.29)	80.55 (13.81)	0.44 (1.28), [-2.09, 2.96]	-1.49	-0.81 [-3.85, 2.23], 0.600	-0.07 [-0.33, 0.19]
Cycle 4 - Day 1	115	81.17 (13.20)	80.70 (13.58)	0.64 (1.21), [-1.75, 3.03]	99	80.59 (14.50)	81.60 (13.59)	1.34 (1.30), [-1.21, 3.89]	-1.47	-0.70 [-3.78, 2.38], 0.656	-0.06 [-0.33, 0.21]

Note(s): A positive change from baseline value indicates improvement of symptoms. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual Analogue Scale.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 04Oct2024.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 4 April 2025 at 20:40:35.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	138	135
Deterioration	37 (26.8%)	34 (25.2%)
Odds ratio (95% CI)	1.105 (0.641, 1.903)	
P-value for Odds Ratio	0.7196	
Relative Risk (95% CI)	1.08 (0.72, 1.61)	
P-value for Relative Risk	0.7097	
Risk difference (95% CI)	1.68 (-8.71, 12.06)	
P-value for Risk Difference	0.7517	
Improvement	31 (22.5%)	33 (24.4%)
Odds ratio (95% CI)	0.917 (0.520, 1.616)	
P-value for Odds Ratio	0.7640	
Relative Risk (95% CI)	0.94 (0.62, 1.44)	
P-value for Relative Risk	0.7776	
Risk difference (95% CI)	-1.55 (-11.37, 8.28)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7580	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	123	108
Deterioration	33 (26.8%)	28 (25.9%)
Odds ratio (95% CI)	1.060 (0.587, 1.915)	
P-value for Odds Ratio	0.8469	
Relative Risk (95% CI)	1.04 (0.67, 1.60)	
P-value for Relative Risk	0.8713	
Risk difference (95% CI)	1.46 (-9.92, 12.84)	
P-value for Risk Difference	0.8011	
Improvement	25 (20.3%)	28 (25.9%)
Odds ratio (95% CI)	0.724 (0.389, 1.347)	
P-value for Odds Ratio	0.3074	
Relative Risk (95% CI)	0.81 (0.50, 1.30)	
P-value for Relative Risk	0.3787	
Risk difference (95% CI)	-7.15 (-18.10, 3.79)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2001	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	115	99
Deterioration	32 (27.8%)	19 (19.2%)
Odds ratio (95% CI)	1.775 (0.920, 3.425)	
P-value for Odds Ratio	0.0872	
Relative Risk (95% CI)	1.55 (0.94, 2.55)	
P-value for Relative Risk	0.0835	
Risk difference (95% CI)	8.69 (-2.69, 20.06)	
P-value for Risk Difference	0.1345	
Improvement	27 (23.5%)	28 (28.3%)
Odds ratio (95% CI)	0.805 (0.432, 1.501)	
P-value for Odds Ratio	0.4953	
Relative Risk (95% CI)	0.84 (0.54, 1.33)	
P-value for Relative Risk	0.4589	
Risk difference (95% CI)	-3.34 (-15.37, 8.69)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5863	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	125	125
Deterioration	38 (30.4%)	38 (30.4%)
Odds ratio (95% CI)	1.008 (0.581, 1.746)	
P-value for Odds Ratio	0.9785	
Relative Risk (95% CI)	1.00 (0.68, 1.46)	
P-value for Relative Risk	0.9901	
Risk difference (95% CI)	0.03 (-11.31, 11.37)	
P-value for Risk Difference	0.9959	
Improvement	23 (18.4%)	38 (30.4%)
Odds ratio (95% CI)	0.541 (0.297, 0.986)	
P-value for Odds Ratio	0.0448	
Relative Risk (95% CI)	0.63 (0.40, 1.00)	
P-value for Relative Risk	0.0481	
Risk difference (95% CI)	-10.87 (-21.49, -0.25)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0448	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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(pingping.xu 11AUG2025 12:01 SAS Linux 9.4)

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	100	71
Deterioration	30 (30.0%)	21 (29.6%)
Odds ratio (95% CI)	1.184 (0.593, 2.362)	
P-value for Odds Ratio	0.6322	
Relative Risk (95% CI)	1.10 (0.70, 1.74)	
P-value for Relative Risk	0.6860	
Risk difference (95% CI)	4.76 (-10.19, 19.71)	
P-value for Risk Difference	0.5328	
Improvement	25 (25.0%)	22 (31.0%)
Odds ratio (95% CI)	0.680 (0.339, 1.365)	
P-value for Odds Ratio	0.2783	
Relative Risk (95% CI)	0.77 (0.47, 1.25)	
P-value for Relative Risk	0.2871	
Risk difference (95% CI)	-7.43 (-21.08, 6.21)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.2858	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	95	61
Deterioration	30 (31.6%)	11 (18.0%)
Odds ratio (95% CI)	2.385 (1.066, 5.336)	
P-value for Odds Ratio	0.0343	
Relative Risk (95% CI)	1.85 (1.02, 3.37)	
P-value for Relative Risk	0.0441	
Risk difference (95% CI)	16.09 (1.96, 30.21)	
P-value for Risk Difference	0.0256	
Improvement	26 (27.4%)	19 (31.1%)
Odds ratio (95% CI)	0.779 (0.379, 1.602)	
P-value for Odds Ratio	0.4973	
Relative Risk (95% CI)	0.83 (0.51, 1.37)	
P-value for Relative Risk	0.4717	
Risk difference (95% CI)	-5.27 (-19.97, 9.42)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4818	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	75	54
Deterioration	21 (28.0%)	16 (29.6%)
Odds ratio (95% CI)	0.973 (0.443, 2.139)	
P-value for Odds Ratio	0.9460	
Relative Risk (95% CI)	0.99 (0.58, 1.69)	
P-value for Relative Risk	0.9604	
Risk difference (95% CI)	0.86 (-15.78, 17.49)	
P-value for Risk Difference	0.9195	
Improvement	19 (25.3%)	14 (25.9%)
Odds ratio (95% CI)	0.912 (0.400, 2.076)	
P-value for Odds Ratio	0.8258	
Relative Risk (95% CI)	0.90 (0.50, 1.62)	
P-value for Relative Risk	0.7191	
Risk difference (95% CI)	0.33 (-14.66, 15.32)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9652	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	63	39
Deterioration	21 (33.3%)	10 (25.6%)
Odds ratio (95% CI)	1.549 (0.615, 3.899)	
P-value for Odds Ratio	0.3527	
Relative Risk (95% CI)	1.33 (0.71, 2.50)	
P-value for Relative Risk	0.3744	
Risk difference (95% CI)	8.90 (-8.38, 26.17)	
P-value for Risk Difference	0.3127	
Improvement	14 (22.2%)	9 (23.1%)
Odds ratio (95% CI)	0.820 (0.304, 2.214)	
P-value for Odds Ratio	0.6955	
Relative Risk (95% CI)	0.85 (0.40, 1.83)	
P-value for Relative Risk	0.6858	
Risk difference (95% CI)	-2.95 (-19.44, 13.53)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7254	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	47	30
Deterioration	16 (34.0%)	10 (33.3%)
Odds ratio (95% CI)	1.126 (0.416, 3.046)	
P-value for Odds Ratio	0.8157	
Relative Risk (95% CI)	1.14 (0.60, 2.16)	
P-value for Relative Risk	0.6858	
Risk difference (95% CI)	2.45 (-20.54, 25.44)	
P-value for Risk Difference	0.8346	
Improvement	10 (21.3%)	7 (23.3%)
Odds ratio (95% CI)	0.812 (0.263, 2.505)	
P-value for Odds Ratio	0.7173	
Relative Risk (95% CI)	0.95 (0.41, 2.23)	
P-value for Relative Risk	0.9144	
Risk difference (95% CI)	-5.43 (-23.86, 13.01)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.5640	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	36	29
Deterioration	10 (27.8%)	7 (24.1%)
Odds ratio (95% CI)	1.150 (0.368, 3.593)	
P-value for Odds Ratio	0.8093	
Relative Risk (95% CI)	1.06 (0.46, 2.44)	
P-value for Relative Risk	0.8978	
Risk difference (95% CI)	4.52 (-17.04, 26.07)	
P-value for Risk Difference	0.6812	
Improvement	3 (8.3%)	6 (20.7%)
Odds ratio (95% CI)	0.356 (0.078, 1.614)	
P-value for Odds Ratio	0.1803	
Relative Risk (95% CI)	0.77 (0.77, 0.77)*	
Risk difference (95% CI)	-10.97 (-32.67, 10.74)	
P-value for Risk Difference	0.3221	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	25	21
Deterioration	7 (28.0%)	3 (14.3%)
Odds ratio (95% CI)	2.540 (0.525, 12.294)	
P-value for Odds Ratio	0.2467	
Relative Risk (95% CI)	1.78 (0.53, 5.96)	
P-value for Relative Risk	0.3507	
Risk difference (95% CI)	17.26 (17.26, 17.26)*	
Improvement	5 (20.0%)	3 (14.3%)
Odds ratio (95% CI)	1.543 (0.308, 7.734)	
P-value for Odds Ratio	0.5976	
Relative Risk (95% CI)	1.42 (0.39, 5.15)	
P-value for Relative Risk	0.5892	
Risk difference (95% CI)	7.18 (7.18, 7.18)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	15
Deterioration	2 (10.0%)	2 (13.3%)
Odds ratio (95% CI)	0.490 (0.032, 7.577)	
P-value for Odds Ratio	0.6099	
Relative Risk (95% CI)	0.19 (0.19, 0.19)*	
Risk difference (95% CI)	-8.98 (-8.98, -8.98)*	
Improvement	5 (25.0%)	4 (26.7%)
Odds ratio (95% CI)	0.670 (0.112, 4.012)	
P-value for Odds Ratio	0.6608	
Relative Risk (95% CI)	0.77 (0.21, 2.88)	
P-value for Relative Risk	0.6982	
Risk difference (95% CI)	-9.41 (-43.18, 24.35)	
P-value for Risk Difference	0.5847	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	6	10
Deterioration	2 (33.3%)	3 (30.0%)
Odds ratio (95% CI)	0.618 (0.039, 9.865)	
P-value for Odds Ratio	0.7335	
Relative Risk (95% CI)	0.28 (0.28, 0.28)*	
Risk difference (95% CI)	-18.27 (-93.60, 57.06)	
P-value for Risk Difference	0.6346	
Improvement	1 (16.7%)	1 (10.0%)
Odds ratio (95% CI)	2.000 (0.078, 51.592)	
P-value for Odds Ratio	0.6760	
Relative Risk (95% CI)	1.67 (0.16, 17.89)	
P-value for Relative Risk	0.6732	
Risk difference (95% CI)	5.04 (-55.24, 65.32)	
P-value for Risk Difference	0.8698	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	1 (50.0%)	1 (50.0%)
Odds ratio (95% CI)	31738.10 (0.000, 1.43E156)	
P-value for Odds Ratio	0.9536	
Relative Risk (95% CI)	1.63 (0.00, 29878.71)	
P-value for Relative Risk	0.9225	
Risk difference (95% CI)	50.00 (50.00, 50.00)*	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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(pingping.xu 11AUG2025 12:01 SAS Linux 9.4)

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	138	135
Deterioration	19 (13.8%)	20 (14.8%)
Odds ratio (95% CI)	0.939 (0.472, 1.868)	
P-value for Odds Ratio	0.8577	
Relative Risk (95% CI)	0.95 (0.54, 1.69)	
P-value for Relative Risk	0.8607	
Risk difference (95% CI)	-0.69 (-11.94, 10.55)	
P-value for Risk Difference	0.9038	
Improvement	20 (14.5%)	22 (16.3%)
Odds ratio (95% CI)	0.897 (0.460, 1.749)	
P-value for Odds Ratio	0.7495	
Relative Risk (95% CI)	0.92 (0.53, 1.59)	
P-value for Relative Risk	0.7659	
Risk difference (95% CI)	-1.37 (-9.68, 6.94)	
P-value for Risk Difference	0.7465	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	123	108
Deterioration	19 (15.4%)	16 (14.8%)
Odds ratio (95% CI)	1.105 (0.532, 2.297)	
P-value for Odds Ratio	0.7883	
Relative Risk (95% CI)	1.07 (0.58, 1.97)	
P-value for Relative Risk	0.8207	
Risk difference (95% CI)	1.63 (-7.17, 10.44)	
P-value for Risk Difference	0.7163	
Improvement	13 (10.6%)	17 (15.7%)
Odds ratio (95% CI)	0.626 (0.287, 1.364)	
P-value for Odds Ratio	0.2387	
Relative Risk (95% CI)	0.67 (0.34, 1.32)	
P-value for Relative Risk	0.2476	
Risk difference (95% CI)	-5.89 (-14.66, 2.87)	
P-value for Risk Difference	0.1875	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	115	99
Deterioration	18 (15.7%)	13 (13.1%)
Odds ratio (95% CI)	1.309 (0.599, 2.862)	
P-value for Odds Ratio	0.4997	
Relative Risk (95% CI)	1.28 (0.67, 2.48)	
P-value for Relative Risk	0.4561	
Risk difference (95% CI)	-0.56 (-11.25, 10.14)	
P-value for Risk Difference	0.9186	
Improvement	16 (13.9%)	14 (14.1%)
Odds ratio (95% CI)	0.956 (0.434, 2.109)	
P-value for Odds Ratio	0.9120	
Relative Risk (95% CI)	0.97 (0.50, 1.88)	
P-value for Relative Risk	0.9202	
Risk difference (95% CI)	-1.01 (-10.71, 8.70)	
P-value for Risk Difference	0.8391	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	125	124
Deterioration	27 (21.6%)	26 (21.0%)
Odds ratio (95% CI)	1.104 (0.595, 2.049)	
P-value for Odds Ratio	0.7533	
Relative Risk (95% CI)	1.06 (0.66, 1.71)	
P-value for Relative Risk	0.7984	
Risk difference (95% CI)	2.05 (-8.22, 12.33)	
P-value for Risk Difference	0.6954	
Improvement	12 (9.6%)	23 (18.5%)
Odds ratio (95% CI)	0.482 (0.225, 1.030)	
P-value for Odds Ratio	0.0595	
Relative Risk (95% CI)	0.53 (0.28, 1.03)	
P-value for Relative Risk	0.0618	
Risk difference (95% CI)	-8.16 (-16.68, 0.35)	
P-value for Risk Difference	0.0603	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	100	71
Deterioration	18 (18.0%)	14 (19.7%)
Odds ratio (95% CI)	1.067 (0.477, 2.386)	
P-value for Odds Ratio	0.8743	
Relative Risk (95% CI)	1.05 (0.57, 1.93)	
P-value for Relative Risk	0.8778	
Risk difference (95% CI)	0.46 (-13.12, 14.04)	
P-value for Risk Difference	0.9474	
Improvement	19 (19.0%)	17 (23.9%)
Odds ratio (95% CI)	0.676 (0.315, 1.452)	
P-value for Odds Ratio	0.3154	
Relative Risk (95% CI)	0.71 (0.40, 1.28)	
P-value for Relative Risk	0.2582	
Risk difference (95% CI)	-4.72 (-17.36, 7.92)	
P-value for Risk Difference	0.4640	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	95	61
Deterioration	19 (20.0%)	7 (11.5%)
Odds ratio (95% CI)	2.329 (0.879, 6.172)	
P-value for Odds Ratio	0.0890	
Relative Risk (95% CI)	1.87 (0.86, 4.08)	
P-value for Relative Risk	0.1133	
Risk difference (95% CI)	9.21 (-5.39, 23.82)	
P-value for Risk Difference	0.2164	
Improvement	11 (11.6%)	12 (19.7%)
Odds ratio (95% CI)	0.533 (0.213, 1.331)	
P-value for Odds Ratio	0.1776	
Relative Risk (95% CI)	0.61 (0.29, 1.28)	
P-value for Relative Risk	0.1922	
Risk difference (95% CI)	-8.51 (-20.41, 3.40)	
P-value for Risk Difference	0.1614	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	75	54
Deterioration	14 (18.7%)	8 (14.8%)
Odds ratio (95% CI)	1.387 (0.518, 3.716)	
P-value for Odds Ratio	0.5149	
Relative Risk (95% CI)	1.26 (0.59, 2.71)	
P-value for Relative Risk	0.5562	
Risk difference (95% CI)	6.68 (-6.05, 19.41)	
P-value for Risk Difference	0.3035	
Improvement	12 (16.0%)	8 (14.8%)
Odds ratio (95% CI)	0.990 (0.358, 2.740)	
P-value for Odds Ratio	0.9844	
Relative Risk (95% CI)	0.97 (0.43, 2.17)	
P-value for Relative Risk	0.9399	
Risk difference (95% CI)	1.72 (-8.35, 11.80)	
P-value for Risk Difference	0.7373	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	63	39
Deterioration	13 (20.6%)	8 (20.5%)
Odds ratio (95% CI)	1.204 (0.422, 3.433)	
P-value for Odds Ratio	0.7281	
Relative Risk (95% CI)	1.08 (0.52, 2.27)	
P-value for Relative Risk	0.8291	
Risk difference (95% CI)	2.50 (-16.37, 21.36)	
P-value for Risk Difference	0.7954	
Improvement	10 (15.9%)	5 (12.8%)
Odds ratio (95% CI)	1.022 (0.304, 3.437)	
P-value for Odds Ratio	0.9723	
Relative Risk (95% CI)	0.97 (0.34, 2.76)	
P-value for Relative Risk	0.9494	
Risk difference (95% CI)	3.45 (-10.39, 17.30)	
P-value for Risk Difference	0.6249	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	47	30
Deterioration	7 (14.9%)	6 (20.0%)
Odds ratio (95% CI)	0.703 (0.200, 2.471)	
P-value for Odds Ratio	0.5822	
Relative Risk (95% CI)	0.74 (0.29, 1.93)	
P-value for Relative Risk	0.5428	
Risk difference (95% CI)	-3.14 (-22.99, 16.71)	
P-value for Risk Difference	0.7564	
Improvement	7 (14.9%)	2 (6.7%)
Odds ratio (95% CI)	2.249 (0.414, 12.226)	
P-value for Odds Ratio	0.3481	
Relative Risk (95% CI)	1.41 (1.41, 1.41)*	
Risk difference (95% CI)	7.86 (-16.39, 32.10)	
P-value for Risk Difference	0.5253	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

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Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	36	29
Deterioration	6 (16.7%)	4 (13.8%)
Odds ratio (95% CI)	1.194 (0.294, 4.851)	
P-value for Odds Ratio	0.8040	
Relative Risk (95% CI)	1.11 (0.35, 3.52)	
P-value for Relative Risk	0.8622	
Risk difference (95% CI)	3.76 (-12.86, 20.38)	
P-value for Risk Difference	0.6578	
Improvement	2 (5.6%)	4 (13.8%)
Odds ratio (95% CI)	0.386 (0.064, 2.326)	
P-value for Odds Ratio	0.2992	
Relative Risk (95% CI)	0.44 (0.09, 2.21)	
P-value for Relative Risk	0.3178	
Risk difference (95% CI)	-6.91 (-27.13, 13.31)	
P-value for Risk Difference	0.5030	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	25	21
Deterioration	4 (16.0%)	3 (14.3%)
Odds ratio (95% CI)	1.228 (0.216, 7.000)	
P-value for Odds Ratio	0.8168	
Relative Risk (95% CI)	0.99 (0.28, 3.57)	
P-value for Relative Risk	0.9929	
Risk difference (95% CI)	6.74 (-27.95, 41.43)	
P-value for Risk Difference	0.7032	
Improvement	3 (12.0%)	1 (4.8%)
Odds ratio (95% CI)	2.358 (0.216, 25.771)	
P-value for Odds Ratio	0.4821	
Relative Risk (95% CI)	2.13 (0.23, 19.59)	
P-value for Relative Risk	0.5036	
Risk difference (95% CI)	6.93 (-19.86, 33.72)	
P-value for Risk Difference	0.6121	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	20	15
Deterioration	0	1 (6.7%)
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.31 (0.01, 6.74)	
P-value for Relative Risk	0.4310	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	3 (15.0%)	1 (6.7%)
Odds ratio (95% CI)	0.900 (0.049, 16.594)	
P-value for Odds Ratio	0.9435	
Relative Risk (95% CI)	0.31 (0.01, 6.74)	
P-value for Relative Risk	0.4310	
Risk difference (95% CI)	-0.41 (-31.98, 31.16)	
P-value for Risk Difference	0.9796	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	6	10
Deterioration	1 (16.7%)	2 (20.0%)
Odds ratio (95% CI)	0.366 (0.012, 11.043)	
P-value for Odds Ratio	0.5627	
Relative Risk (95% CI)	0.21 (0.21, 0.21)*	
Risk difference (95% CI)	-18.57 (-108.60, 71.46)	
P-value for Risk Difference	0.6860	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

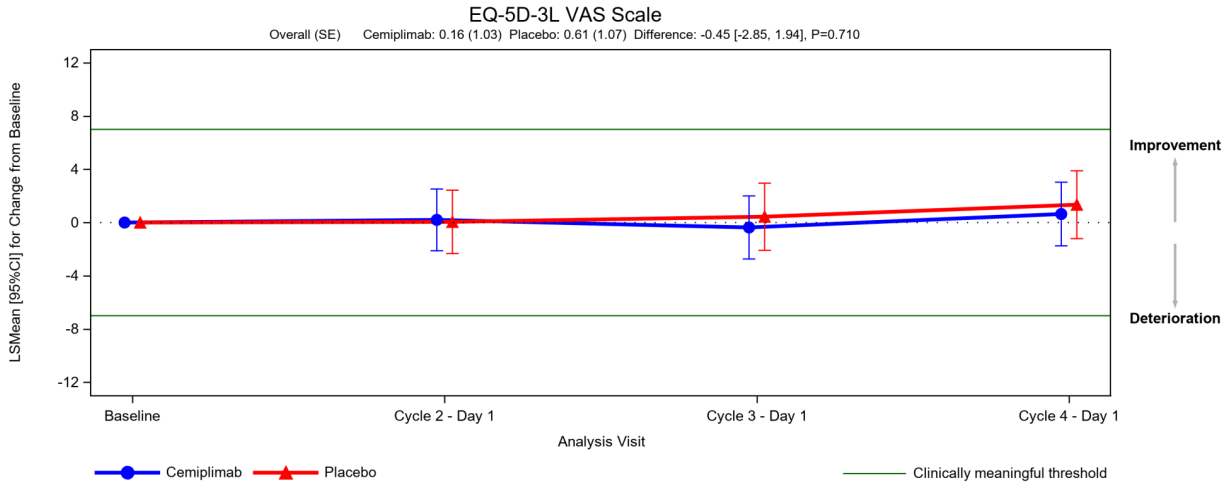
Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	1	0
Deterioration	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	(NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	(NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024.CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW); *The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Figure 4.2.1: Mixed Model Repeated Measures: Change from Baseline - EQ-5D-3L VAS scale
FAS (N=415)

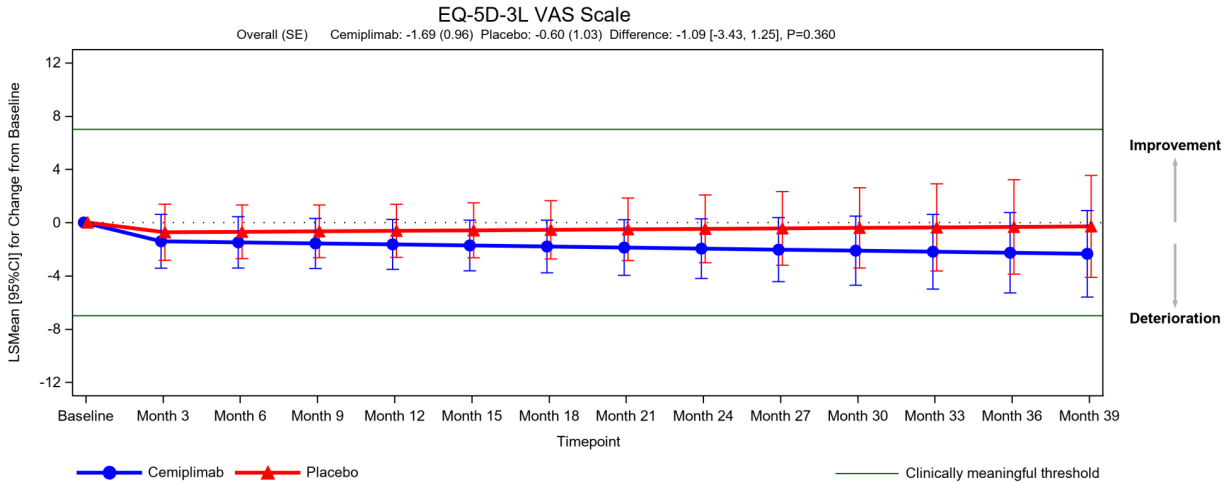


Number of patients

Cemiplimab	138	123	115
Placebo	135	108	99

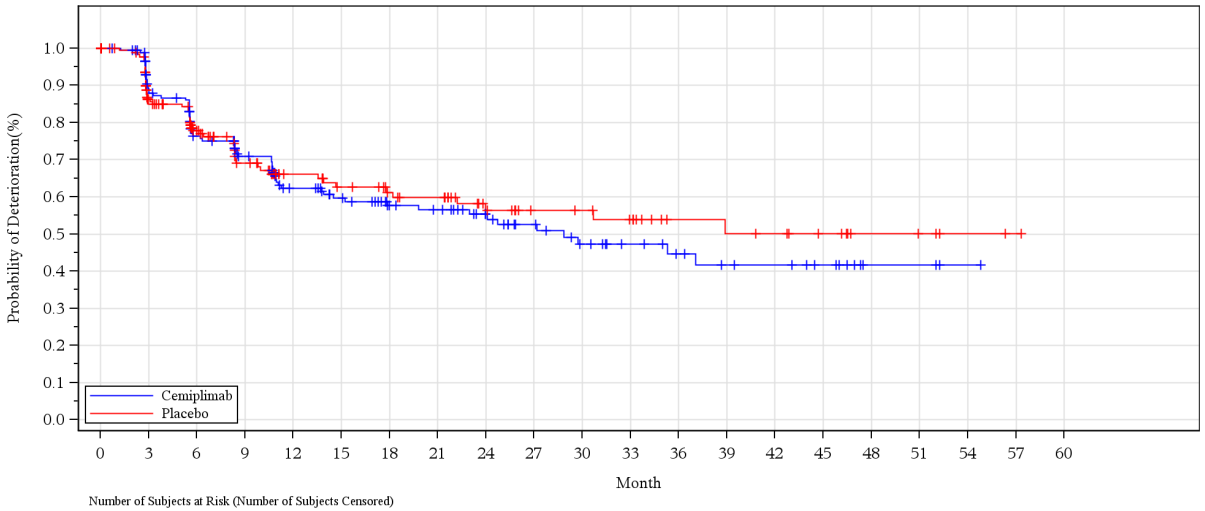
Note(s): EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; FAS: Full Analysis Set; VAS: Visual Analogue Scale.
Source: AXPRO. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 4 April 2025 at 20:54:23.

Figure A3.2.1: Mixed model repeated measures: Change from Baseline - EQ-5D-3L VAS scale
FAS (N=415)



Note(s): EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; FAS: Full Analysis Set; VAS: Visual Analogue Scale.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 04Oct2024.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 10 July 2025 at 17:48:17.

Figure 14.2.10.3 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range)
(Full Analysis Set)

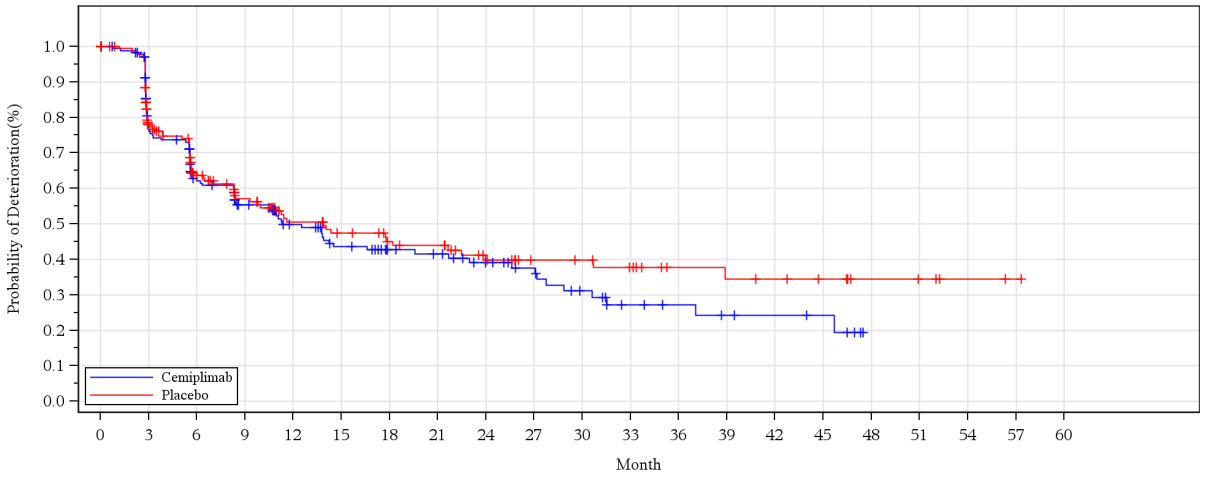


Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	144 (47)	115 (56)	97 (66)	74 (78)	65 (84)	53 (94)	50 (96)	40 (105)	32 (111)	25 (115)	20 (120)	16 (123)	13 (125)	12 (126)	9 (129)	3 (135)	3 (135)	1 (137)	0 (138)	0 (138)
Placebo	206 (0)	132 (51)	99 (72)	75 (86)	58 (100)	51 (104)	45 (109)	42 (111)	31 (120)	25 (126)	24 (127)	21 (129)	14 (136)	13 (136)	12 (137)	9 (140)	5 (144)	4 (145)	2 (147)	1 (148)	0 (149)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.

Figure 14.2.10.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points)
(Full Analysis Set)



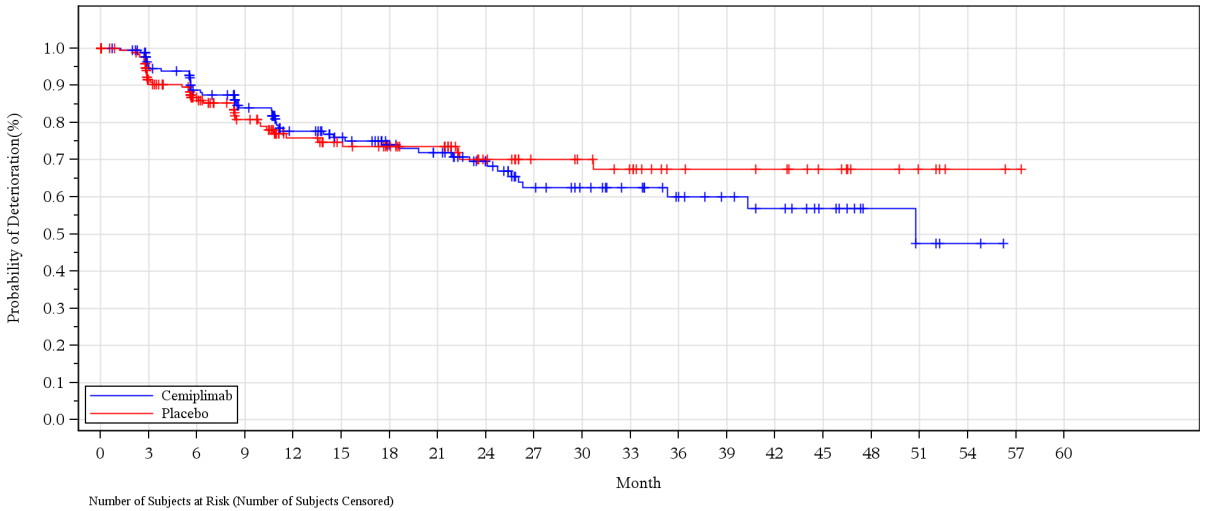
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	126 (45)	94 (53)	76 (61)	59 (71)	48 (75)	39 (83)	36 (85)	29 (90)	24 (94)	17 (97)	11 (101)	9 (103)	7 (104)	6 (105)	5 (106)	0 (110)	0 (110)	0 (110)	0 (110)
Placebo	206 (0)	121 (48)	85 (63)	67 (73)	50 (83)	44 (86)	38 (90)	36 (91)	27 (97)	21 (103)	20 (104)	17 (106)	12 (111)	11 (111)	10 (112)	8 (114)	5 (117)	4 (118)	2 (120)	1 (121)	0 (122)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km1.sas' (wenju.shi 04DEC2025 7:12 SAS Linux 9.4)

Figure 14.2.10.5 Time to Confirmed Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range)
(Full Analysis Set)

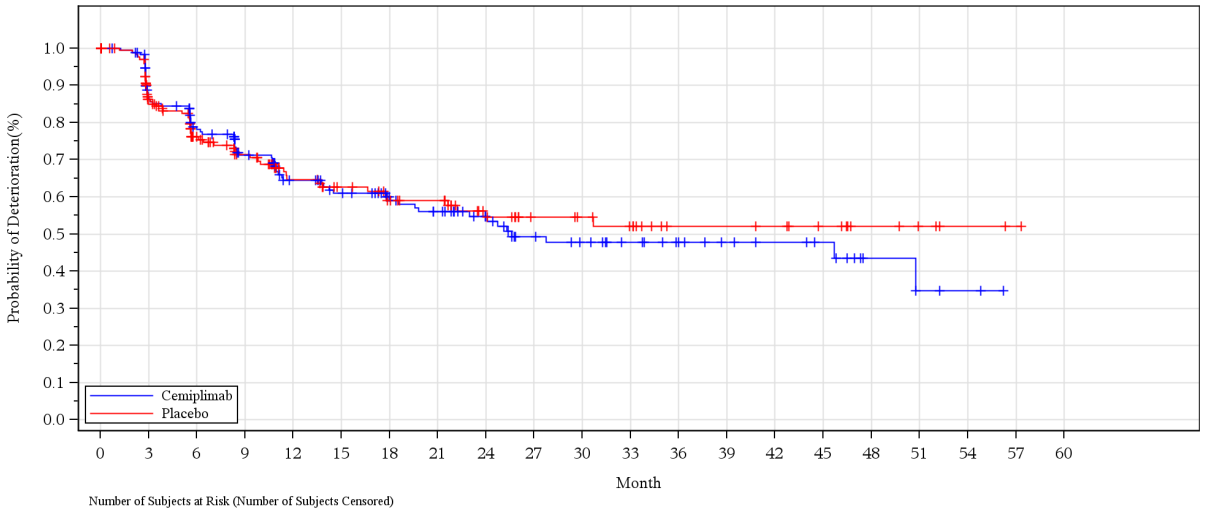


Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	154 (47)	135 (56)	116 (68)	93 (83)	84 (90)	71 (101)	66 (104)	53 (115)	41 (122)	36 (127)	31 (132)	23 (139)	20 (142)	17 (144)	12 (149)	6 (155)	4 (156)	2 (158)	0 (160)	0 (160)
Placebo	206 (0)	141 (51)	113 (72)	89 (89)	68 (105)	60 (112)	54 (117)	50 (121)	37 (132)	30 (139)	28 (141)	24 (144)	17 (151)	16 (152)	15 (153)	11 (157)	7 (161)	5 (163)	2 (166)	1 (167)	0 (168)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.

Figure 14.2.10.7 Time to Confirmed Deterioration (Excluding Death) - EQ-5D-3L VAS scale (7 points)
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	142 (45)	120 (53)	100 (63)	79 (75)	71 (79)	60 (89)	53 (92)	42 (102)	32 (108)	28 (111)	23 (116)	18 (121)	15 (124)	13 (126)	11 (128)	5 (133)	3 (134)	2 (135)	0 (137)	0 (137)
Placebo	206 (0)	135 (48)	102 (66)	82 (80)	63 (92)	55 (98)	48 (102)	45 (105)	33 (114)	26 (121)	24 (123)	21 (125)	14 (132)	14 (132)	13 (133)	10 (136)	6 (140)	4 (142)	2 (144)	1 (145)	0 (146)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event

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Table 2.2.2: Completion rate at scale level-EQ-5D-3L VAS scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
Baseline	208	185 (88.9%)	185 (88.5%)
Cycle 2 - Day 1	182	157 (86.3%)	157 (75.1%)
Cycle 3 - Day 1	173	149 (86.1%)	149 (71.3%)
Cycle 4 - Day 1	158	139 (88.0%)	139 (66.5%)
Placebo (N=206)			
Baseline	203	186 (91.6%)	186 (90.3%)
Cycle 2 - Day 1	185	152 (82.2%)	152 (73.8%)
Cycle 3 - Day 1	162	135 (83.3%)	135 (65.5%)
Cycle 4 - Day 1	142	125 (88.0%)	125 (60.7%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as the VAS score to be non missing.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; VAS: Visual Analogue Scale.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T02.sas] Generated: 8 September 2025 at 11:00:26.

Table A2.2.2: Completion rate at scale level-EQ-5D-3L VAS scale
Full Analysis Set

Treatment/Timepoint	PRO assessment expected	Completion rate[a] (minimum requirements for scoring)	Unadjusted Completion rate[b] (minimum requirements for scoring)
Cemiplimab (N=209)			
END OF TREATMENT	193	159 (82.4%)	159 (76.1%)
FOLLOW-UP VISIT 1	170	135 (79.4%)	135 (64.6%)
FOLLOW-UP VISIT 2	151	119 (78.8%)	119 (56.9%)
FOLLOW-UP VISIT 3	134	96 (71.6%)	96 (45.9%)
FOLLOW-UP VISIT 4	116	84 (72.4%)	84 (40.2%)
FOLLOW-UP VISIT 5	107	72 (67.3%)	72 (34.4%)
FOLLOW-UP VISIT 6	86	56 (65.1%)	56 (26.8%)
FOLLOW-UP VISIT 7	54	35 (64.8%)	35 (16.7%)
FOLLOW-UP VISIT 8	41	28 (68.3%)	28 (13.4%)
FOLLOW-UP VISIT 9	30	19 (63.3%)	19 (9.1%)
FOLLOW-UP VISIT 10	14	6 (42.9%)	6 (2.9%)
FOLLOW-UP VISIT 11	2	2 (100.0%)	2 (1.0%)
Placebo (N=206)			
END OF TREATMENT	194	150 (77.3%)	150 (72.8%)
FOLLOW-UP VISIT 1	170	103 (60.6%)	103 (50.0%)
FOLLOW-UP VISIT 2	147	86 (58.5%)	86 (41.7%)
FOLLOW-UP VISIT 3	122	67 (54.9%)	67 (32.5%)
FOLLOW-UP VISIT 4	108	54 (50.0%)	54 (26.2%)
FOLLOW-UP VISIT 5	94	45 (47.9%)	45 (21.8%)
FOLLOW-UP VISIT 6	79	39 (49.4%)	39 (18.9%)
FOLLOW-UP VISIT 7	55	30 (54.5%)	30 (14.6%)
FOLLOW-UP VISIT 8	39	22 (56.4%)	22 (10.7%)
FOLLOW-UP VISIT 9	24	16 (66.7%)	16 (7.8%)
FOLLOW-UP VISIT 10	10	7 (70.0%)	7 (3.4%)
FOLLOW-UP VISIT 11	3	2 (66.7%)	2 (1.0%)

Note(s): [a]: Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients with a PRO assessments expected. Minimum requirements for scoring is defined as the VAS score to be non missing.
[b] Completion rate is calculated as the number of patients with minimum requirements for scoring divided by the number of patients in the FAS population.
EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; VAS: Visual Analogue Scale.

Source: ADSL,AXDS,ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA02.sas] Generated: 12 September 2025 at 10:26:14.

Table 6.2.1.2: Time to confirmed deterioration in EQ-5D-3L VAS scale (excluding death)
Full Analysis Set

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
EQ-5D-3L VAS Score (Deterioration threshold = 7)			
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	87 (41.6 %)	59 (28.6 %)
Number of censored cases	n (%)	122 (58.4 %)	147 (71.4 %)
No baseline score	n (%)	24 (11.5 %)	20 (9.7 %)
No post-baseline score	n (%)	4 (1.9 %)	5 (2.4 %)
No deterioration possible	n (%)	0	1 (0.5 %)
No confirmed deterioration	n (%)	94 (45.0 %)	121 (58.7 %)
Time to confirmed deterioration (months)	Q1 [95% CI]	8.38 [5.62, 10.87]	8.38 [5.62, 16.62]
	Median [95% CI]	28.81 [19.81, 45.70]	53.52 [30.69, NC]
	Q3 [95% CI]	62.26 [50.76, NC]	NYR [53.52, NC]
	p-value[b]		0.080
	HR [95 % CI][c]		1.34 [0.96, 1.88]

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck and geographic region (North America vs Australia/New Zealand vs Rest of World).
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by anatomic region of resected high-risk tumor (head and neck vs non-head and neck) and geographic region (North America vs Australia/New Zealand vs Rest of World) with treatment covariate.
CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments)
Source: AXTTD. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T06.sas] Generated: 8 September 2025 at 11:00:26.

Table 14.2.11.5 Time to confirmed deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range)
(Full Analysis Set)

EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=209)	Placebo (N=206)
Total number of patients[a]	n	209	206
Number of patients with events	n (%)	61 (29.2%)	42 (20.4%)
Number of censored cases	n (%)	148 (70.8%)	164 (79.6%)
No baseline score	n (%)	24 (11.5%)	20 (9.7%)
No post-baseline score	n (%)	4 (1.9%)	5 (2.4%)
No deterioration possible	n (%)	0	1 (0.5%)
No confirmed deterioration	n (%)	120 (57.4%)	138 (67.0%)
Time to confirmed deterioration (months)	Q1 [95% CI]	17.77 [10.68, 24.74]	21.65 [9.82, 33.35]
	Median [95% CI]	40.21 [34.96, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b]		0.212
	HR [95 % CI][c]		1.29 [0.86, 1.92]

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature.
[b] Stratified log-rank test, Stratified by high-risk tumor (HN vs non-HN) and geographical region (North America vs Australia/New Zealand vs ROW) per EDC.
[c] Hazard ratio (HR) is based on a stratified Cox regression model stratified by high-risk tumor (HN vs non-HN) and geographical region (North America vs Australia/New Zealand vs ROW) per EDC.
CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments).

Table 14.2.9.5 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EQ-5D-3L VAS scale (excluding death) (7 points)
(Full Analysis Set)

EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	87 (41.6%)	59 (28.6%)
Number of censored participants, n (%)	122 (58.4%)	147 (71.4%)
Proportionality Test p-value[a][b]	0.0318	
Hazard ratio(interaction)	0.648 (0.436, 0.963)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table 14.2.9.7 Test of Proportional Hazards Assumption for Time to confirmed deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range)
(Full Analysis Set)

EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=209)	Placebo (N=206)
Number of events, n (%)	61 (29.2%)	42 (20.4%)
Number of censored participants, n (%)	148 (70.8%)	164 (79.6%)
Proportionality Test p-value[a][b]	0.0294	
Hazard ratio(interaction)	0.585 (0.361, 0.948)	

Data cut-off as of April 07, 2025.
[a] Based on high-risk tumor (HN vs. non-HN) and geographical region (North America vs. Australia/New Zealand vs. Rest of World) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)

Table A4.1.2.1: Mixed model repeated measures: Change from Baseline - EQ-5D-3L VAS scale
Full Analysis Set

	Cemiplimab (N=209)	Placebo (N=206)	Cemiplimab vs Placebo	
Timepoint[a]	Change from Baseline: LSMean (SE), [95% CI][b]	Change from Baseline: LSMean (SE), [95% CI][b]	Diff. in Mean Change [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	-1.89 (0.92), [-3.71, -0.07]	-0.48 (1.00), [-2.45, 1.49]	-1.41 [-3.68, 0.86], 0.224	-0.09 [-0.30, 0.11]
Month 3	-1.46 (0.97), [-3.37, 0.45]	-0.08 (1.03), [-2.10, 1.94]	-1.38 [-3.77, 1.01], 0.256	-0.09 [-0.29, 0.11]
Month 6	-1.58 (0.93), [-3.42, 0.26]	-0.19 (0.99), [-2.13, 1.76]	-1.39 [-3.65, 0.88], 0.229	-0.09 [-0.29, 0.11]
Month 9	-1.69 (0.92), [-3.49, 0.11]	-0.30 (0.97), [-2.21, 1.62]	-1.39 [-3.60, 0.81], 0.215	-0.09 [-0.29, 0.11]
Month 12	-1.80 (0.91), [-3.60, -0.01]	-0.40 (0.98), [-2.33, 1.52]	-1.40 [-3.61, 0.81], 0.214	-0.09 [-0.30, 0.11]
Month 15	-1.92 (0.93), [-3.74, -0.09]	-0.51 (1.01), [-2.49, 1.47]	-1.41 [-3.70, 0.88], 0.227	-0.09 [-0.30, 0.11]
Month 18	-2.03 (0.96), [-3.92, -0.14]	-0.62 (1.06), [-2.70, 1.47]	-1.41 [-3.84, 1.01], 0.252	-0.09 [-0.30, 0.11]
Month 21	-2.14 (1.01), [-4.13, -0.16]	-0.72 (1.13), [-2.94, 1.49]	-1.42 [-4.03, 1.19], 0.285	-0.09 [-0.30, 0.11]
Month 24	-2.26 (1.07), [-4.36, -0.15]	-0.83 (1.21), [-3.21, 1.55]	-1.43 [-4.27, 1.41], 0.323	-0.09 [-0.30, 0.11]
Month 27	-2.37 (1.14), [-4.62, -0.12]	-0.94 (1.30), [-3.50, 1.63]	-1.43 [-4.53, 1.67], 0.363	-0.09 [-0.30, 0.11]
Month 30	-2.48 (1.22), [-4.89, -0.07]	-1.04 (1.41), [-3.82, 1.73]	-1.44 [-4.83, 1.95], 0.403	-0.09 [-0.30, 0.11]
Month 33	-2.60 (1.31), [-5.18, -0.01]	-1.15 (1.52), [-4.15, 1.85]	-1.45 [-5.14, 2.25], 0.441	-0.09 [-0.30, 0.11]
Month 36	-2.71 (1.41), [-5.48, 0.06]	-1.26 (1.64), [-4.49, 1.98]	-1.45 [-5.46, 2.56], 0.476	-0.10 [-0.30, 0.11]
Month 39	-2.82 (1.50), [-5.79, 0.15]	-1.36 (1.76), [-4.84, 2.12]	-1.46 [-5.80, 2.88], 0.508	-0.10 [-0.30, 0.11]

Note(s): A positive change from baseline value indicates improvement of symptoms. A positive difference in mean change from baseline favors Cemiplimab over Placebo.
Only patients with a baseline and at least one post-baseline score are included in the analysis. All assessments are included in this linear mixed model, up to the earliest timepoint where at least 10 patients per treatment arm had available data within the corresponding 3-month interval. All the subsequent assessments after the earliest timepoint where less than 10 patients per treatment arm had available data were excluded from the model.

[a] The overall treatment effect is presented, rather than at specific timepoints.
[b] Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
CI: Confidence interval; EQ-5D-3L: EuroQoL 5 Dimensions 3; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SE: Standard error; SMD: Standardized mean difference; VAS: Visual Analogue Scale.
The model assumed an unstructured covariance among the random intercept and random coefficient.
The Hedges' g is based on the pooled standard deviation at Baseline.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\TA04_01.sas] Generated: 12 September 2025 at 10:26:14.

Table 4.2.1: Mixed model repeated measures analysis: change from Baseline in the EQ-5D-3L VAS scale
Full Analysis Set

	Cemiplimab (N=209)				Placebo (N=206)				Cemiplimab vs Placebo		
Timepoint	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	N [1]	Baseline Value: Mean (SD)	Score Value: Mean (SD)	Change from Baseline: LSMean (SE), [95% CI]	Observed diff in Mean change	Diff. in Mean Change [2] [95% CI], nominal p-value	SMD as Hedges' g [95% CI]
Overall	162	79.91 (14.51)	79.75 (13.22)	0.11 (0.97), [-1.80, 2.02]	161	78.94 (14.65)	79.60 (14.28)	1.11 (1.03), [-0.92, 3.14]	-0.82	-1.00 [-3.29, 1.30], 0.393	-0.09 [-0.31, 0.12]
Cycle 2 - Day 1	145	80.28 (14.36)	80.17 (14.15)	0.46 (1.12), [-1.74, 2.66]	140	78.51 (15.14)	78.96 (15.96)	0.43 (1.17), [-1.86, 2.73]	-0.55	0.03 [-2.73, 2.78], 0.985	0.00 [-0.23, 0.23]
Cycle 3 - Day 1	138	80.41 (14.38)	79.41 (14.56)	-0.36 (1.13), [-2.59, 1.86]	121	80.60 (12.90)	81.25 (13.41)	1.14 (1.22), [-1.26, 3.54]	-1.64	-1.51 [-4.39, 1.38], 0.305	-0.13 [-0.37, 0.12]
Cycle 4 - Day 1	132	80.27 (14.61)	80.00 (14.66)	0.23 (1.16), [-2.06, 2.52]	115	80.39 (14.39)	81.80 (13.42)	1.75 (1.25), [-0.72, 4.21]	-1.67	-1.51 [-4.49, 1.46], 0.318	-0.13 [-0.38, 0.12]

Note(s): A positive change from baseline value indicates improvement of symptoms. A positive difference in mean change from baseline favors Cemiplimab over Placebo.

[1] N is the number of subjects with a baseline and a post-baseline score at corresponding timepoint. For Overall, N is the number of subjects with a baseline and at least one post-baseline score.

[2] Estimates are based on a mixed model repeated measures treating time categorical: Change=Treatment arm + Time + Baseline PRO Value + Anatomic region of resected high-risk tumor + Geographic Region Geographical region+ Time*Baseline PRO Value +Timepoint*Treatment arm.

The model assumed an unstructured covariance among the within subject repeated measurement.

CI: Confidence interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; FAS: Full analysis set; LS: Least-squares; QoL: Quality of Life; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual Analogue Scale.

This analysis will include only regular cycle visits.

Baseline value for the first row is based on subjects who had an assessment at Baseline and at least one post-baseline assessment; Baseline value for the second-fourth row is based on those subjects who had an assessment at Baseline and Cycle X - Day 1.

Source: ADPRO. Extract date: 07Apr2025.

Program: [\03. Biostatistics\02.Analysis\02.Production\Tables\T04.sas] Generated: 8 September 2025 at 11:00:26.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	145	140
Deterioration	39 (26.9%)	35 (25.0%)
Odds ratio (95% CI)	1.126 (0.661, 1.918)	
P-value for Odds Ratio	0.6619	
Relative Risk (95% CI)	1.10 (0.74, 1.63)	
P-value for Relative Risk	0.6420	
Risk difference (95% CI)	1.85 (-8.35, 12.05)	
P-value for Risk Difference	0.7225	
Improvement	33 (22.8%)	35 (25.0%)
Odds ratio (95% CI)	0.909 (0.523, 1.581)	
P-value for Odds Ratio	0.7353	
Relative Risk (95% CI)	0.94 (0.62, 1.41)	
P-value for Relative Risk	0.7648	
Risk difference (95% CI)	-1.94 (-11.56, 7.68)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.6929	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	138	121
Deterioration	39 (28.3%)	28 (23.1%)
Odds ratio (95% CI)	1.309 (0.743, 2.306)	
P-value for Odds Ratio	0.3510	
Relative Risk (95% CI)	1.22 (0.80, 1.86)	
P-value for Relative Risk	0.3606	
Risk difference (95% CI)	5.21 (-5.45, 15.87)	
P-value for Risk Difference	0.3384	
Improvement	29 (21.0%)	33 (27.3%)
Odds ratio (95% CI)	0.698 (0.391, 1.248)	
P-value for Odds Ratio	0.2256	
Relative Risk (95% CI)	0.79 (0.51, 1.22)	
P-value for Relative Risk	0.2849	
Risk difference (95% CI)	-7.81 (-18.22, 2.60)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1413	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	132	115
Deterioration	38 (28.8%)	22 (19.1%)
Odds ratio (95% CI)	1.813 (0.990, 3.322)	
P-value for Odds Ratio	0.0541	
Relative Risk (95% CI)	1.58 (1.00, 2.51)	
P-value for Relative Risk	0.0500	
Risk difference (95% CI)	9.04 (-1.60, 19.68)	
P-value for Risk Difference	0.0959	
Improvement	32 (24.2%)	34 (29.6%)
Odds ratio (95% CI)	0.786 (0.444, 1.394)	
P-value for Odds Ratio	0.4103	
Relative Risk (95% CI)	0.83 (0.55, 1.25)	
P-value for Relative Risk	0.3763	
Risk difference (95% CI)	-4.18 (-15.45, 7.09)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4676	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	145	141
Deterioration	45 (31.0%)	42 (29.8%)
Odds ratio (95% CI)	1.071 (0.642, 1.785)	
P-value for Odds Ratio	0.7933	
Relative Risk (95% CI)	1.04 (0.73, 1.48)	
P-value for Relative Risk	0.8204	
Risk difference (95% CI)	1.34 (-9.26, 11.95)	
P-value for Risk Difference	0.8039	
Improvement	27 (18.6%)	45 (31.9%)
Odds ratio (95% CI)	0.509 (0.293, 0.884)	
P-value for Odds Ratio	0.0165	
Relative Risk (95% CI)	0.60 (0.40, 0.92)	
P-value for Relative Risk	0.0178	
Risk difference (95% CI)	-12.17 (-22.20, -2.13)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0175	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	124	93
Deterioration	36 (29.0%)	26 (28.0%)
Odds ratio (95% CI)	1.193 (0.647, 2.202)	
P-value for Odds Ratio	0.5715	
Relative Risk (95% CI)	1.12 (0.73, 1.71)	
P-value for Relative Risk	0.6083	
Risk difference (95% CI)	5.89 (-7.03, 18.81)	
P-value for Risk Difference	0.3718	
Improvement	31 (25.0%)	32 (34.4%)
Odds ratio (95% CI)	0.600 (0.327, 1.102)	
P-value for Odds Ratio	0.0998	
Relative Risk (95% CI)	0.72 (0.47, 1.09)	
P-value for Relative Risk	0.1186	
Risk difference (95% CI)	-10.37 (-22.54, 1.79)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.0947	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	108	77
Deterioration	35 (32.4%)	17 (22.1%)
Odds ratio (95% CI)	2.001 (0.996, 4.020)	
P-value for Odds Ratio	0.0512	
Relative Risk (95% CI)	1.60 (0.98, 2.61)	
P-value for Relative Risk	0.0596	
Risk difference (95% CI)	14.13 (0.53, 27.72)	
P-value for Risk Difference	0.0416	
Improvement	29 (26.9%)	24 (31.2%)
Odds ratio (95% CI)	0.801 (0.416, 1.544)	
P-value for Odds Ratio	0.5079	
Relative Risk (95% CI)	0.86 (0.55, 1.35)	
P-value for Relative Risk	0.5110	
Risk difference (95% CI)	-4.79 (-18.26, 8.69)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.4863	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	88	62
Deterioration	24 (27.3%)	20 (32.3%)
Odds ratio (95% CI)	0.870 (0.419, 1.808)	
P-value for Odds Ratio	0.7095	
Relative Risk (95% CI)	0.90 (0.55, 1.45)	
P-value for Relative Risk	0.6582	
Risk difference (95% CI)	-1.12 (-16.91, 14.67)	
P-value for Risk Difference	0.8890	
Improvement	20 (22.7%)	16 (25.8%)
Odds ratio (95% CI)	0.816 (0.375, 1.778)	
P-value for Odds Ratio	0.6093	
Relative Risk (95% CI)	0.81 (0.46, 1.44)	
P-value for Relative Risk	0.4788	
Risk difference (95% CI)	-1.34 (-15.17, 12.49)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.8490	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	78	50
Deterioration	24 (30.8%)	15 (30.0%)
Odds ratio (95% CI)	1.121 (0.504, 2.497)	
P-value for Odds Ratio	0.7792	
Relative Risk (95% CI)	1.07 (0.63, 1.79)	
P-value for Relative Risk	0.8059	
Risk difference (95% CI)	2.72 (-12.99, 18.43)	
P-value for Risk Difference	0.7341	
Improvement	16 (20.5%)	11 (22.0%)
Odds ratio (95% CI)	0.826 (0.340, 2.007)	
P-value for Odds Ratio	0.6725	
Relative Risk (95% CI)	0.85 (0.43, 1.67)	
P-value for Relative Risk	0.6324	
Risk difference (95% CI)	-2.23 (-16.54, 12.07)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.7596	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	68	40
Deterioration	22 (32.4%)	10 (25.0%)
Odds ratio (95% CI)	1.548 (0.636, 3.766)	
P-value for Odds Ratio	0.3357	
Relative Risk (95% CI)	1.37 (0.72, 2.61)	
P-value for Relative Risk	0.3344	
Risk difference (95% CI)	11.13 (-7.67, 29.94)	
P-value for Risk Difference	0.2457	
Improvement	17 (25.0%)	13 (32.5%)
Odds ratio (95% CI)	0.648 (0.265, 1.584)	
P-value for Odds Ratio	0.3413	
Relative Risk (95% CI)	0.79 (0.43, 1.45)	
P-value for Relative Risk	0.4425	
Risk difference (95% CI)	-8.47 (-25.52, 8.59)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.3305	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	53	38
Deterioration	18 (34.0%)	10 (26.3%)
Odds ratio (95% CI)	1.489 (0.581, 3.814)	
P-value for Odds Ratio	0.4072	
Relative Risk (95% CI)	1.25 (0.65, 2.40)	
P-value for Relative Risk	0.5010	
Risk difference (95% CI)	10.34 (-9.12, 29.81)	
P-value for Risk Difference	0.2977	
Improvement	5 (9.4%)	8 (21.1%)
Odds ratio (95% CI)	0.312 (0.084, 1.164)	
P-value for Odds Ratio	0.0829	
Relative Risk (95% CI)	0.69 (0.69, 0.69)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-13.27 (-31.35, 4.80)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.1500	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	29
Deterioration	14 (40.0%)	5 (17.2%)
Odds ratio (95% CI)	3.189 (0.943, 10.784)	
P-value for Odds Ratio	0.0621	
Relative Risk (95% CI)	2.17 (0.89, 5.33)	
P-value for Relative Risk	0.0899	
Risk difference (95% CI)	24.51 (24.51, 24.51)*	
P-value for Risk Difference	NE	
Improvement	6 (17.1%)	6 (20.7%)
Odds ratio (95% CI)	0.799 (0.218, 2.923)	
P-value for Odds Ratio	0.7344	
Relative Risk (95% CI)	0.81 (0.30, 2.17)	
P-value for Relative Risk	0.6758	
Risk difference (95% CI)	-0.64 (-0.64, -0.64)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	27	21
Deterioration	5 (18.5%)	4 (19.0%)
Odds ratio (95% CI)	1.191 (0.216, 6.564)	
P-value for Odds Ratio	0.8409	
Relative Risk (95% CI)	1.15 (0.42, 3.14)	
P-value for Relative Risk	0.7918	
Risk difference (95% CI)	-2.27 (-32.97, 28.44)	
P-value for Risk Difference	0.8849	
Improvement	6 (22.2%)	5 (23.8%)
Odds ratio (95% CI)	0.906 (0.227, 3.622)	
P-value for Odds Ratio	0.8890	
Relative Risk (95% CI)	0.91 (0.32, 2.59)	
P-value for Relative Risk	0.8525	
Risk difference (95% CI)	0.37 (-26.97, 27.70)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9791	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	18	16
Deterioration	5 (27.8%)	4 (25.0%)
Odds ratio (95% CI)	1.141 (0.220, 5.922)	
P-value for Odds Ratio	0.8753	
Relative Risk (95% CI)	1.16 (0.35, 3.84)	
P-value for Relative Risk	0.8134	
Risk difference (95% CI)	0.91 (-30.85, 32.68)	
P-value for Risk Difference	0.9550	
Improvement	4 (22.2%)	3 (18.8%)
Odds ratio (95% CI)	0.916 (0.137, 6.111)	
P-value for Odds Ratio	0.9279	
Relative Risk (95% CI)	0.91 (0.21, 3.94)	
P-value for Relative Risk	0.8981	
Risk difference (95% CI)	-0.25 (-38.27, 37.76)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	0.9896	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	1 (20.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.70 (0.00, 7238.63)	
P-value for Relative Risk	0.6794	
Risk difference (95% CI)	18.13 (18.13, 18.13)*	
P-value for Risk Difference	NE	
Improvement	2 (40.0%)	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	33.07 (33.07, 33.07)*	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	1 (50.0%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.50 (0.32, 63.94)	
P-value for Relative Risk	0.2433	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	1 (50.0%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.50 (0.04, 7.10)	
P-value for Relative Risk	0.6171	
Risk difference (95% CI)	NE (NE, NE)	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.1 Response status over time for the EQ-5D-3L VAS scale (threshold of 7 points for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Improvement		
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; GHS: Global Health Status; FAS: Full analysis set; NE: Not Estimable; QoL: Quality of Life.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 7 or more points with respect to Baseline; improvement is defined as an increase of 7 or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 2 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	145	140
Deterioration	19 (13.1%)	20 (14.3%)
Odds ratio (95% CI)	0.948 (0.478, 1.882)	
P-value for Odds Ratio	0.8794	
Relative Risk (95% CI)	0.96 (0.54, 1.70)	
P-value for Relative Risk	0.8844	
Risk difference (95% CI)	-0.59 (-11.62, 10.44)	
P-value for Risk Difference	0.9165	
Improvement	22 (15.2%)	23 (16.4%)
Odds ratio (95% CI)	0.940 (0.492, 1.796)	
P-value for Odds Ratio	0.8519	
Relative Risk (95% CI)	0.97 (0.57, 1.64)	
P-value for Relative Risk	0.8973	
Risk difference (95% CI)	-1.46 (-9.65, 6.73)	
P-value for Risk Difference	0.7271	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 3 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	138	121
Deterioration	22 (15.9%)	16 (13.2%)
Odds ratio (95% CI)	1.288 (0.636, 2.606)	
P-value for Odds Ratio	0.4820	
Relative Risk (95% CI)	1.22 (0.68, 2.21)	
P-value for Relative Risk	0.5059	
Risk difference (95% CI)	3.07 (-5.15, 11.30)	
P-value for Risk Difference	0.4638	
Improvement	16 (11.6%)	18 (14.9%)
Odds ratio (95% CI)	0.742 (0.358, 1.537)	
P-value for Odds Ratio	0.4216	
Relative Risk (95% CI)	0.78 (0.42, 1.47)	
P-value for Relative Risk	0.4441	
Risk difference (95% CI)	-4.44 (-12.83, 3.94)	
P-value for Risk Difference	0.2990	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :CYCLE 4 DAY 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	132	115
Deterioration	22 (16.7%)	14 (12.2%)
Odds ratio (95% CI)	1.502 (0.723, 3.121)	
P-value for Odds Ratio	0.2754	
Relative Risk (95% CI)	1.44 (0.77, 2.67)	
P-value for Relative Risk	0.2515	
Risk difference (95% CI)	2.00 (-7.66, 11.65)	
P-value for Risk Difference	0.6854	
Improvement	20 (15.2%)	18 (15.7%)
Odds ratio (95% CI)	0.962 (0.475, 1.950)	
P-value for Odds Ratio	0.9153	
Relative Risk (95% CI)	0.98 (0.55, 1.74)	
P-value for Relative Risk	0.9371	
Risk difference (95% CI)	-1.49 (-10.82, 7.83)	
P-value for Risk Difference	0.7534	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :END OF TREATMENT

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	145	140
Deterioration	32 (22.1%)	28 (20.0%)
Odds ratio (95% CI)	1.187 (0.666, 2.118)	
P-value for Odds Ratio	0.5606	
Relative Risk (95% CI)	1.13 (0.72, 1.77)	
P-value for Relative Risk	0.5911	
Risk difference (95% CI)	3.00 (-6.49, 12.50)	
P-value for Risk Difference	0.5355	
Improvement	15 (10.3%)	29 (20.7%)
Odds ratio (95% CI)	0.461 (0.234, 0.910)	
P-value for Odds Ratio	0.0256	
Relative Risk (95% CI)	0.52 (0.29, 0.93)	
P-value for Relative Risk	0.0283	
Risk difference (95% CI)	-9.54 (-17.79, -1.29)	
P-value for Risk Difference	0.0235	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 1

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	124	92
Deterioration	23 (18.5%)	16 (17.4%)
Odds ratio (95% CI)	1.233 (0.599, 2.539)	
P-value for Odds Ratio	0.5701	
Relative Risk (95% CI)	1.16 (0.66, 2.06)	
P-value for Relative Risk	0.6039	
Risk difference (95% CI)	4.59 (-6.33, 15.51)	
P-value for Risk Difference	0.4097	
Improvement	22 (17.7%)	23 (25.0%)
Odds ratio (95% CI)	0.620 (0.316, 1.218)	
P-value for Odds Ratio	0.1652	
Relative Risk (95% CI)	0.69 (0.41, 1.16)	
P-value for Relative Risk	0.1562	
Risk difference (95% CI)	-7.39 (-18.47, 3.69)	
P-value for Risk Difference	0.1909	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 2

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	108	77
Deterioration	22 (20.4%)	9 (11.7%)
Odds ratio (95% CI)	2.519 (1.038, 6.111)	
P-value for Odds Ratio	0.0410	
Relative Risk (95% CI)	1.99 (1.00, 3.98)	
P-value for Relative Risk	0.0499	
Risk difference (95% CI)	9.63 (-2.91, 22.17)	
P-value for Risk Difference	0.1322	
Improvement	13 (12.0%)	15 (19.5%)
Odds ratio (95% CI)	0.620 (0.271, 1.419)	
P-value for Odds Ratio	0.2577	
Relative Risk (95% CI)	0.68 (0.35, 1.35)	
P-value for Relative Risk	0.2702	
Risk difference (95% CI)	-7.52 (-18.16, 3.11)	
P-value for Risk Difference	0.1657	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 3

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	88	62
Deterioration	16 (18.2%)	12 (19.4%)
Odds ratio (95% CI)	1.040 (0.440, 2.457)	
P-value for Odds Ratio	0.9296	
Relative Risk (95% CI)	0.98 (0.51, 1.89)	
P-value for Relative Risk	0.9548	
Risk difference (95% CI)	4.29 (-9.05, 17.62)	
P-value for Risk Difference	0.5286	
Improvement	13 (14.8%)	10 (16.1%)
Odds ratio (95% CI)	0.859 (0.339, 2.182)	
P-value for Odds Ratio	0.7499	
Relative Risk (95% CI)	0.87 (0.41, 1.84)	
P-value for Relative Risk	0.7103	
Risk difference (95% CI)	-0.12 (-10.65, 10.41)	
P-value for Risk Difference	0.9824	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 4

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	78	50
Deterioration	15 (19.2%)	11 (22.0%)
Odds ratio (95% CI)	0.977 (0.383, 2.492)	
P-value for Odds Ratio	0.9606	
Relative Risk (95% CI)	0.92 (0.48, 1.74)	
P-value for Relative Risk	0.7937	
Risk difference (95% CI)	0.81 (-15.76, 17.39)	
P-value for Risk Difference	0.9234	
Improvement	10 (12.8%)	7 (14.0%)
Odds ratio (95% CI)	0.758 (0.256, 2.241)	
P-value for Odds Ratio	0.6160	
Relative Risk (95% CI)	0.74 (0.30, 1.85)	
P-value for Relative Risk	0.5202	
Risk difference (95% CI)	-0.34 (-12.54, 11.86)	
P-value for Risk Difference	0.9564	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 5

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	68	40
Deterioration	11 (16.2%)	6 (15.0%)
Odds ratio (95% CI)	1.211 (0.399, 3.672)	
P-value for Odds Ratio	0.7357	
Relative Risk (95% CI)	1.10 (0.45, 2.72)	
P-value for Relative Risk	0.8361	
Risk difference (95% CI)	2.88 (-11.93, 17.70)	
P-value for Risk Difference	0.7031	
Improvement	9 (13.2%)	8 (20.0%)
Odds ratio (95% CI)	0.557 (0.187, 1.662)	
P-value for Odds Ratio	0.2939	
Relative Risk (95% CI)	0.59 (0.25, 1.39)	
P-value for Relative Risk	0.2280	
Risk difference (95% CI)	-1.96 (-16.28, 12.36)	
P-value for Risk Difference	0.7886	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 6

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	53	38
Deterioration	12 (22.6%)	7 (18.4%)
Odds ratio (95% CI)	1.352 (0.461, 3.968)	
P-value for Odds Ratio	0.5828	
Relative Risk (95% CI)	1.16 (0.51, 2.63)	
P-value for Relative Risk	0.7224	
Risk difference (95% CI)	10.02 (-6.26, 26.29)	
P-value for Risk Difference	0.2277	
Improvement	3 (5.7%)	6 (15.8%)
Odds ratio (95% CI)	0.315 (0.071, 1.397)	
P-value for Odds Ratio	0.1285	
Relative Risk (95% CI)	0.71 (0.71, 0.71)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-10.13 (-27.18, 6.92)	
P-value for Risk Difference	0.2442	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 7

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	35	29
Deterioration	11 (31.4%)	5 (17.2%)
Odds ratio (95% CI)	2.303 (0.648, 8.182)	
P-value for Odds Ratio	0.1971	
Relative Risk (95% CI)	1.69 (0.67, 4.28)	
P-value for Relative Risk	0.2642	
Risk difference (95% CI)	16.36 (16.36, 16.36)*	
P-value for Risk Difference	NE	
Improvement	3 (8.6%)	3 (10.3%)
Odds ratio (95% CI)	0.761 (0.139, 4.185)	
P-value for Odds Ratio	0.7538	
Relative Risk (95% CI)	0.77 (0.17, 3.56)	
P-value for Relative Risk	0.7413	
Risk difference (95% CI)	-2.04 (-2.04, -2.04)*	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 8

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	27	21
Deterioration	1 (3.7%)	3 (14.3%)
Odds ratio (95% CI)	0.239 (0.021, 2.762)	
P-value for Odds Ratio	0.2517	
Relative Risk (95% CI)	0.34 (0.34, 0.34)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-8.56 (-43.53, 26.42)	
P-value for Risk Difference	0.6315	
Improvement	4 (14.8%)	2 (9.5%)
Odds ratio (95% CI)	1.478 (0.228, 9.559)	
P-value for Odds Ratio	0.6819	
Relative Risk (95% CI)	1.37 (0.27, 6.93)	
P-value for Relative Risk	0.7001	
Risk difference (95% CI)	5.96 (-20.75, 32.68)	
P-value for Risk Difference	0.6619	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 9

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	18	16
Deterioration	2 (11.1%)	2 (12.5%)
Odds ratio (95% CI)	0.794 (0.074, 8.503)	
P-value for Odds Ratio	0.8488	
Relative Risk (95% CI)	0.75 (0.75, 0.75)*	
P-value for Relative Risk	NE	
Risk difference (95% CI)	-7.46 (-47.15, 32.23)	
P-value for Risk Difference	0.7126	
Improvement	0	1 (6.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.37 (0.02, 8.01)	
P-value for Relative Risk	0.5111	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 10

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	5	7
Deterioration	0	1 (14.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.67 (0.08, 5.54)	
P-value for Relative Risk	0.7237	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

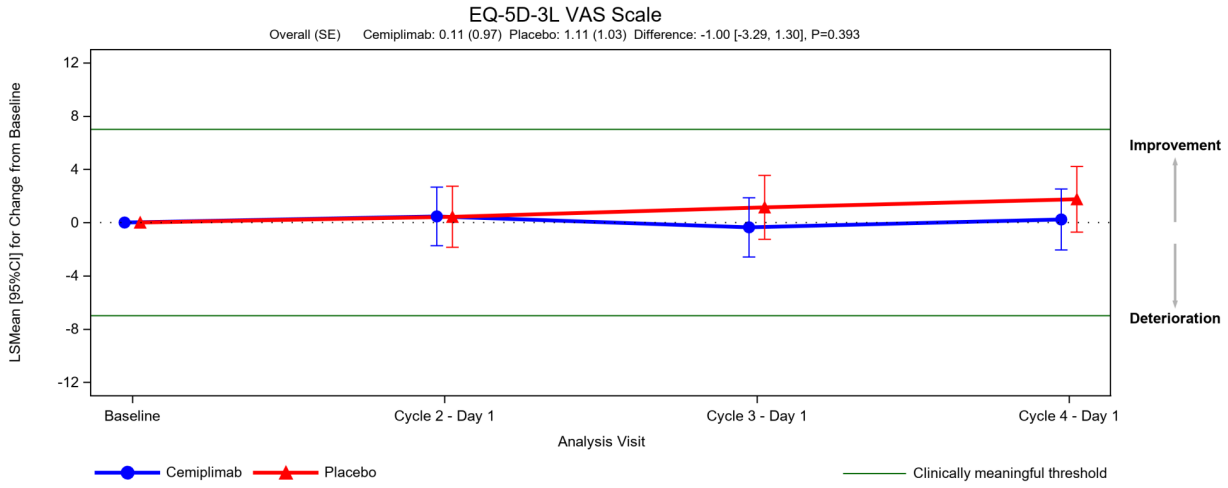
Table 14.2.7.2 Response status over time for the EQ-5D-3L VAS scale (threshold of 15% of the scale range for a meaningful change)
(Full Analysis Set)

EQ5D01-EQ VAS Score :FOLLOW-UP VISIT 11

Timepoint/Category	Cemiplimab (N=209)	Placebo (N=206)
Total non-missing	2	2
Deterioration	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Improvement	0	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; NE: Not Estimable; VAS: Visual Analogue Scale.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and (geographical region North America vs Australia/New Zealand vs ROW);*The estimate is either invalid or at a limit of its range for some observations.
Note(s): For VAS the following was used: deterioration is defined as a decrease of 15% or more points with respect to Baseline; improvement is defined as an increase of 15% or more points with respect to Baseline.
Analysis includes only patients with a baseline and at least one post-baseline assessment. Percentages are calculated using the number of patients in FAS expected to complete the patient-reported outcome assessment at the specific visit.

Figure 4.2.1: Mixed Model Repeated Measures: Change from Baseline - EQ-5D-3L VAS scale
FAS (N=415)

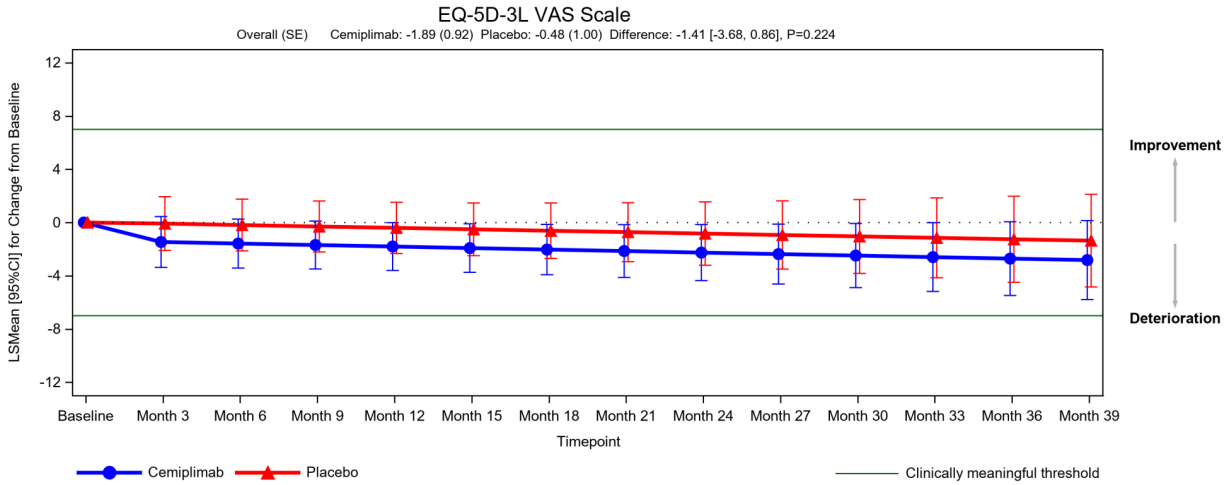


Number of patients

Cemiplimab	145	138	132
Placebo	140	121	115

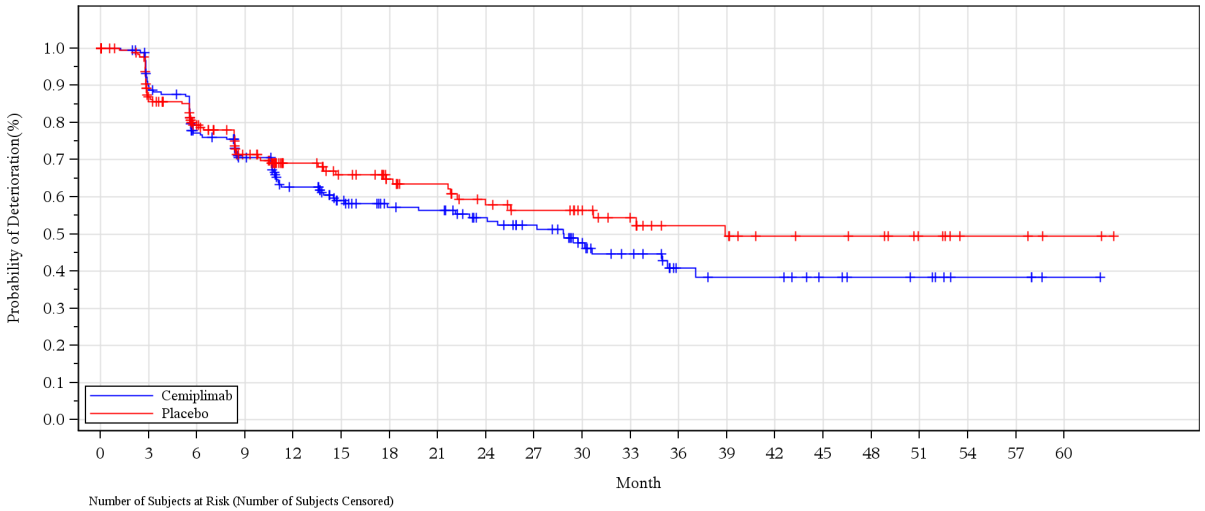
Note(s): EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; FAS: Full Analysis Set; VAS: Visual Analogue Scale.
Source: AXPRO. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\F_4.sas] Generated: 8 September 2025 at 11:25:44.

Figure A3.2.1: Mixed model repeated measures: Change from Baseline - EQ-5D-3L VAS scale
FAS (N=415)



Note(s): EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; FAS: Full Analysis Set; VAS: Visual Analogue Scale.
Estimates are based on a mixed model repeated measures treating time as continuous: Change=random intercept + random coefficient *Time (in months) +Baseline PRO score + Time*Baseline PRO score + treatment arm +treatment*time+ Anatomic region of resected high-risk tumor + Geographic Region.
Source: ADQS. Extract date: 07Apr2025.
Program: [\03.Biostatistics\02.Analysis\02.Production\Figures\FA_3.sas] Generated: 9 September 2025 at 12:14:06.

Figure 14.2.10.3 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range)
(Full Analysis Set)

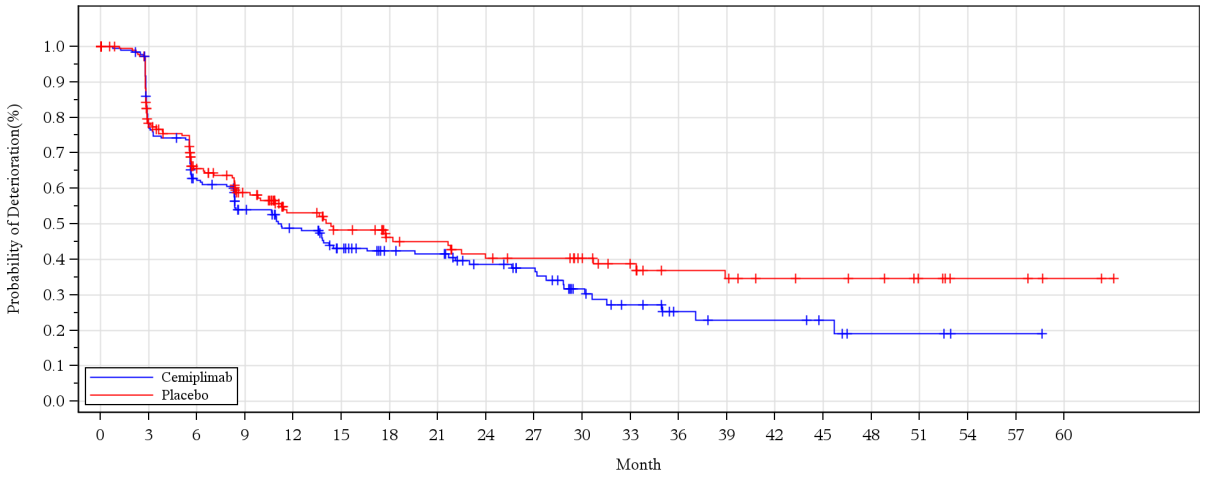


Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	159 (32)	130 (39)	111 (47)	91 (55)	76 (65)	65 (74)	63 (75)	53 (83)	46 (88)	34 (96)	27 (101)	17 (109)	15 (110)	15 (110)	11 (114)	9 (116)	8 (117)	4 (121)	4 (121)	1 (124)
Placebo	206 (0)	147 (36)	118 (53)	93 (67)	71 (86)	62 (92)	52 (101)	47 (105)	39 (109)	35 (112)	30 (117)	25 (121)	19 (126)	18 (126)	14 (130)	13 (131)	12 (132)	8 (136)	4 (140)	4 (140)	2 (142)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.

Figure 14.2.10.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points)
(Full Analysis Set)



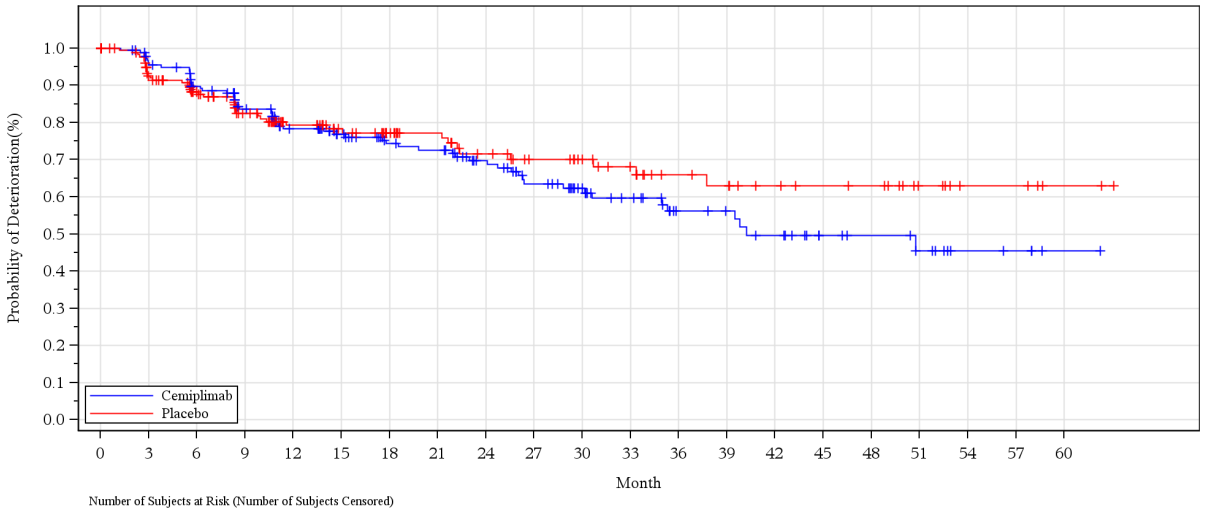
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	139 (31)	107 (35)	86 (42)	73 (47)	59 (53)	49 (62)	47 (63)	38 (69)	33 (73)	22 (79)	16 (82)	10 (87)	8 (88)	8 (88)	6 (90)	3 (92)	3 (92)	1 (94)	1 (94)	0 (95)
Placebo	206 (0)	134 (34)	101 (46)	80 (57)	59 (71)	50 (75)	41 (82)	39 (83)	33 (85)	31 (87)	26 (92)	21 (96)	16 (100)	15 (100)	12 (103)	11 (104)	10 (105)	7 (108)	4 (111)	4 (111)	2 (113)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.

'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km1.sas' (wenju.shi 04DEC2025 7:20 SAS Linux 9.4)

Figure 14.2.10.5 Time to Confirmed Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range)
(Full Analysis Set)

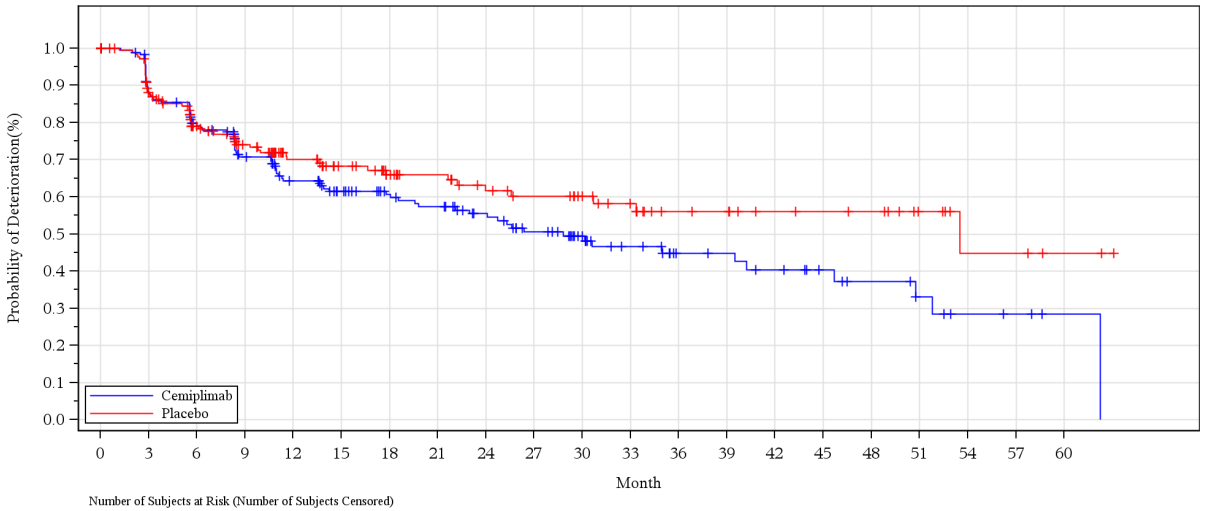


Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	170 (32)	152 (39)	132 (49)	114 (59)	99 (72)	86 (82)	83 (83)	70 (93)	58 (99)	47 (109)	39 (115)	28 (124)	26 (126)	22 (127)	15 (134)	13 (136)	10 (138)	5 (143)	4 (144)	1 (147)
Placebo	206 (0)	157 (36)	132 (54)	109 (69)	86 (88)	75 (98)	64 (108)	57 (115)	48 (120)	41 (126)	36 (131)	31 (135)	24 (141)	22 (142)	18 (146)	16 (148)	15 (149)	9 (155)	5 (159)	5 (159)	2 (162)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.

Figure 14.2.10.7 Time to Confirmed Deterioration (Excluding Death) - EQ-5D-3L VAS scale (7 points)
(Full Analysis Set)



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	209 (0)	157 (31)	137 (35)	114 (44)	96 (52)	83 (61)	73 (70)	68 (71)	58 (79)	48 (84)	37 (94)	29 (100)	21 (107)	20 (108)	17 (109)	13 (113)	10 (115)	7 (117)	4 (119)	3 (120)	1 (122)
Placebo	206 (0)	151 (34)	120 (50)	100 (63)	78 (80)	66 (90)	55 (99)	49 (105)	41 (110)	37 (113)	32 (118)	27 (122)	20 (128)	19 (129)	15 (133)	14 (134)	13 (135)	8 (140)	4 (143)	4 (143)	2 (145)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event

1.3 Verträglichkeit

1.3.1 1. Datenschnitt

Table 14.3.1.1 Overview of Treatment-Emergent Adverse Events (Part 1)
(Safety Analysis Set)

Participant with at least one	Cemiplimab (N=205)	Placebo (N=204)
TEAE	187 (91.2%)	182 (89.2%)
Odds ratio (95% CI)	1.252 (0.635, 2.470)	
P-value for Odds Ratio	0.5151	
Relative Risk (95% CI)	1.02 (0.97, 1.07)	
P-value for Relative Risk	0.4524	
Risk difference (95% CI)	1.75 (-2.93, 6.43)	
P-value for Risk Difference	0.4626	
TEAE with any NCI grade 3/4/5	49 (23.9%)	29 (14.2%)
Odds ratio (95% CI)	1.864 (1.116, 3.115)	
P-value for Odds Ratio	0.0175	
Relative Risk (95% CI)	1.62 (1.07, 2.46)	
P-value for Relative Risk	0.0236	
Risk difference (95% CI)	9.93 (2.48, 17.37)	
P-value for Risk Difference	0.0091	
TE-SAE	36 (17.6%)	19 (9.3%)
Odds ratio (95% CI)	2.042 (1.121, 3.718)	
P-value for Odds Ratio	0.0197	
Relative Risk (95% CI)	1.84 (1.09, 3.11)	
P-value for Relative Risk	0.0222	
Risk difference (95% CI)	7.92 (1.37, 14.46)	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW/ #0041

Table 14.3.1.1 Overview of Treatment-Emergent Adverse Events (Part 1)
(Safety Analysis Set)

Participant with at least one	Cemiplimab (N=205)	Placebo (N=204)
TE-SAE		
P-value for Risk Difference	0.0179	
TEAE leading to study treatment discontinuation	20 (9.8%)	3 (1.5%)
Odds ratio (95% CI)	7.248 (2.106, 24.945)	
P-value for Odds Ratio	0.0018	
Relative Risk (95% CI)	6.63 (1.99, 22.10)	
P-value for Relative Risk	0.0021	
Risk difference (95% CI)	8.73 (2.66, 14.80)	
P-value for Risk Difference	0.0049	
TEAE leading to death	2 (1.0%)	2 (1.0%)
Odds ratio (95% CI)	1.113 (0.154, 8.068)	
P-value for Odds Ratio	0.9154	
Relative Risk (95% CI)	1.11 (0.16, 7.83)	
P-value for Relative Risk	0.9153	
Risk difference (95% CI)	0.11 (-2.64, 2.86)	
P-value for Risk Difference	0.9369	
TEAE leading to study treatment interruption/delay	46 (22.4%)	26 (12.7%)
Odds ratio (95% CI)	1.915 (1.125, 3.261)	
P-value for Odds Ratio	0.0169	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW/ #0041

Table 14.3.1.1 Overview of Treatment-Emergent Adverse Events (Part 1)
(Safety Analysis Set)

Participant with at least one	Cemiplimab (N=205)	Placebo (N=204)
TEAE leading to study treatment interruption/delay		
Relative Risk (95% CI)	1.70 (1.09, 2.64)	
P-value for Relative Risk	0.0188	
Risk difference (95% CI)	9.07 (1.82, 16.33)	
P-value for Risk Difference	0.0143	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW/ #0041

Table 14.3.2.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1)
(Safety Analysis Set)

Participant with at least one	Cemiplimab (N=205)	Placebo (N=204)
TE-SAE	36 (17.6%)	19 (9.3%)
Odds ratio (95% CI)	2.042 (1.121, 3.718)	
P-value for Odds Ratio	0.0197	
Relative Risk (95% CI)	1.84 (1.09, 3.11)	
P-value for Relative Risk	0.0222	
Risk difference (95% CI)	7.92 (1.37, 14.46)	
P-value for Risk Difference	0.0179	
TE-SAE with any NCI grade 3/4/5	31 (15.1%)	14 (6.9%)
Odds ratio (95% CI)	2.390 (1.221, 4.679)	
P-value for Odds Ratio	0.0111	
Relative Risk (95% CI)	2.14 (1.17, 3.91)	
P-value for Relative Risk	0.0135	
Risk difference (95% CI)	8.09 (2.19, 13.98)	
P-value for Risk Difference	0.0073	
Treatment-related TE-SAE	12 (5.9%)	1 (0.5%)
Odds ratio (95% CI)	13.102 (1.671, 102.732)	
P-value for Odds Ratio	0.0145	
Relative Risk (95% CI)	12.16 (1.59, 93.26)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0. NCI grades were coded using CTCAE Version 5.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW/ #0041

Table 14.3.2.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1)
(Safety Analysis Set)

Participant with at least one	Cemiplimab (N=205)	Placebo (N=204)
Treatment-related TE-SAE		
P-value for Relative Risk	0.0163	
Risk difference (95% CI)	6.53 (-4.87, 17.93)	
P-value for Risk Difference	0.2609	
TE-SAE leading to study treatment discontinuation	12 (5.9%)	3 (1.5%)
Odds ratio (95% CI)	4.155 (1.142, 15.121)	
P-value for Odds Ratio	0.0308	
Relative Risk (95% CI)	3.91 (1.11, 13.72)	
P-value for Relative Risk	0.0333	
Risk difference (95% CI)	4.80 (-0.77, 10.37)	
P-value for Risk Difference	0.0913	
TE-SAE leading to death	2 (1.0%)	2 (1.0%)
Odds ratio (95% CI)	1.113 (0.154, 8.068)	
P-value for Odds Ratio	0.9154	
Relative Risk (95% CI)	1.11 (0.16, 7.83)	
P-value for Relative Risk	0.9153	
Risk difference (95% CI)	0.11 (-2.64, 2.86)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0. NCI grades were coded using CTCAE Version 5.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW/ #0041

Table 14.3.2.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1)
(Safety Analysis Set)

Participant with at least one	Cemiplimab (N=205)	Placebo (N=204)
TE-SAE leading to death		
P-value for Risk Difference	0.9369	
TE-SAE leading to study treatment interruption/delay	5 (2.4%)	5 (2.5%)
Odds ratio (95% CI)	1.010 (0.282, 3.622)	
P-value for Odds Ratio	0.9875	
Relative Risk (95% CI)	1.00 (0.30, 3.39)	
P-value for Relative Risk	0.9940	
Risk difference (95% CI)	1.16 (-5.86, 8.19)	
P-value for Risk Difference	0.7451	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0. NCI grades were coded using CTCAE Version 5.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW/ #0041

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Number of participants with at least one such TEAE	187 (91.2%)	182 (89.2%)
Odds ratio (95% CI)	1.252 (0.635, 2.470)	
P-value for Odds Ratio	0.5151	
Relative Risk (95% CI)	1.02 (0.97, 1.07)	
P-value for Relative Risk	0.4524	
Risk difference (95% CI)	1.75 (-2.93, 6.43)	
P-value for Risk Difference	0.4626	
Skin and subcutaneous tissue disorders	111 (54.1%)	85 (41.7%)
Odds ratio (95% CI)	1.702 (1.141, 2.539)	
P-value for Odds Ratio	0.0092	
Relative Risk (95% CI)	1.31 (1.07, 1.60)	
P-value for Relative Risk	0.0089	
Risk difference (95% CI)	12.82 (3.27, 22.37)	
P-value for Risk Difference	0.0086	
Pruritus	33 (16.1%)	25 (12.3%)
Odds ratio (95% CI)	1.440 (0.817, 2.539)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Pruritus		
P-value for Odds Ratio	0.2065	
Relative Risk (95% CI)	1.37 (0.85, 2.22)	
P-value for Relative Risk	0.1987	
Risk difference (95% CI)	4.20 (-2.39, 10.78)	
P-value for Risk Difference	0.2109	
Rash	33 (16.1%)	18 (8.8%)
Odds ratio (95% CI)	1.943 (1.044, 3.617)	
P-value for Odds Ratio	0.0361	
Relative Risk (95% CI)	1.76 (1.03, 3.01)	
P-value for Relative Risk	0.0398	
Risk difference (95% CI)	6.26 (0.18, 12.35)	
P-value for Risk Difference	0.0436	
Rash maculo-papular	23 (11.2%)	12 (5.9%)
Odds ratio (95% CI)	2.081 (0.987, 4.389)	
P-value for Odds Ratio	0.0542	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Rash maculo-papular		
Relative Risk (95% CI)	1.87 (0.97, 3.63)	
P-value for Relative Risk	0.0626	
Risk difference (95% CI)	5.84 (-2.49, 14.16)	
P-value for Risk Difference	0.1687	
Actinic keratosis	20 (9.8%)	16 (7.8%)
Odds ratio (95% CI)	1.299 (0.650, 2.598)	
P-value for Odds Ratio	0.4581	
Relative Risk (95% CI)	1.27 (0.68, 2.39)	
P-value for Relative Risk	0.4570	
Risk difference (95% CI)	1.95 (-3.56, 7.45)	
P-value for Risk Difference	0.4875	
Dry skin	9 (4.4%)	5 (2.5%)
Odds ratio (95% CI)	1.880 (0.607, 5.827)	
P-value for Odds Ratio	0.2731	
Relative Risk (95% CI)	1.83 (0.63, 5.31)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Dry skin		
P-value for Relative Risk	0.2683	
Risk difference (95% CI)	1.61 (-5.30, 8.52)	
P-value for Risk Difference	0.6470	
Infections and infestations	87 (42.4%)	78 (38.2%)
Odds ratio (95% CI)	1.167 (0.780, 1.746)	
P-value for Odds Ratio	0.4511	
Relative Risk (95% CI)	1.11 (0.88, 1.39)	
P-value for Relative Risk	0.3964	
Risk difference (95% CI)	3.24 (-6.23, 12.71)	
P-value for Risk Difference	0.5013	
COVID-19	15 (7.3%)	18 (8.8%)
Odds ratio (95% CI)	0.773 (0.374, 1.598)	
P-value for Odds Ratio	0.4864	
Relative Risk (95% CI)	0.79 (0.41, 1.53)	
P-value for Relative Risk	0.4876	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
COVID-19		
Risk difference (95% CI)	-1.58 (-6.59, 3.42)	
P-value for Risk Difference	0.5339	
Oral candidiasis	8 (3.9%)	5 (2.5%)
Odds ratio (95% CI)	1.756 (0.549, 5.613)	
P-value for Odds Ratio	0.3417	
Relative Risk (95% CI)	1.67 (0.57, 4.94)	
P-value for Relative Risk	0.3492	
Risk difference (95% CI)	2.24 (-5.62, 10.09)	
P-value for Risk Difference	0.5757	
Urinary tract infection	8 (3.9%)	4 (2.0%)
Odds ratio (95% CI)	2.001 (0.588, 6.814)	
P-value for Odds Ratio	0.2662	
Relative Risk (95% CI)	1.96 (0.60, 6.45)	
P-value for Relative Risk	0.2679	
Risk difference (95% CI)	2.24 (-1.70, 6.19)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Urinary tract infection		
P-value for Risk Difference	0.2641	
Skin infection	6 (2.9%)	11 (5.4%)
Odds ratio (95% CI)	0.527 (0.187, 1.484)	
P-value for Odds Ratio	0.2246	
Relative Risk (95% CI)	0.54 (0.21, 1.43)	
P-value for Relative Risk	0.2174	
Risk difference (95% CI)	-0.69 (-4.83, 3.44)	
P-value for Risk Difference	0.7415	
Upper respiratory tract infection	3 (1.5%)	7 (3.4%)
Odds ratio (95% CI)	0.426 (0.107, 1.691)	
P-value for Odds Ratio	0.2244	
Relative Risk (95% CI)	0.44 (0.11, 1.67)	
P-value for Relative Risk	0.2248	
Risk difference (95% CI)	-2.11 (-7.56, 3.34)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Upper respiratory tract infection		
P-value for Risk Difference	0.4472	
General disorders and administration site conditions	75 (36.6%)	73 (35.8%)
Odds ratio (95% CI)	1.022 (0.680, 1.536)	
P-value for Odds Ratio	0.9149	
Relative Risk (95% CI)	1.01 (0.78, 1.31)	
P-value for Relative Risk	0.9122	
Risk difference (95% CI)	0.53 (-8.82, 9.89)	
P-value for Risk Difference	0.9111	
Fatigue	45 (22.0%)	44 (21.6%)
Odds ratio (95% CI)	0.987 (0.610, 1.596)	
P-value for Odds Ratio	0.9570	
Relative Risk (95% CI)	1.00 (0.70, 1.44)	
P-value for Relative Risk	0.9806	
Risk difference (95% CI)	-0.53 (-8.19, 7.13)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Fatigue		
P-value for Risk Difference	0.8913	
Oedema peripheral	11 (5.4%)	5 (2.5%)
Odds ratio (95% CI)	2.019 (0.676, 6.033)	
P-value for Odds Ratio	0.2075	
Relative Risk (95% CI)	1.98 (0.70, 5.58)	
P-value for Relative Risk	0.1970	
Risk difference (95% CI)	1.80 (-1.87, 5.47)	
P-value for Risk Difference	0.3349	
Asthenia	10 (4.9%)	7 (3.4%)
Odds ratio (95% CI)	1.570 (0.563, 4.379)	
P-value for Odds Ratio	0.3879	
Relative Risk (95% CI)	1.50 (0.60, 3.79)	
P-value for Relative Risk	0.3858	
Risk difference (95% CI)	1.73 (-7.65, 11.11)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Asthenia		
P-value for Risk Difference	0.7170	
Gastrointestinal disorders	73 (35.6%)	72 (35.3%)
Odds ratio (95% CI)	0.990 (0.654, 1.498)	
P-value for Odds Ratio	0.9618	
Relative Risk (95% CI)	1.00 (0.78, 1.30)	
P-value for Relative Risk	0.9785	
Risk difference (95% CI)	-0.44 (-9.57, 8.69)	
P-value for Risk Difference	0.9247	
Diarrhoea	32 (15.6%)	38 (18.6%)
Odds ratio (95% CI)	0.795 (0.470, 1.344)	
P-value for Odds Ratio	0.3902	
Relative Risk (95% CI)	0.82 (0.54, 1.26)	
P-value for Relative Risk	0.3665	
Risk difference (95% CI)	-2.27 (-9.34, 4.80)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Diarrhoea		
P-value for Risk Difference	0.5289	
Nausea	15 (7.3%)	13 (6.4%)
Odds ratio (95% CI)	1.022 (0.464, 2.250)	
P-value for Odds Ratio	0.9563	
Relative Risk (95% CI)	1.09 (0.54, 2.20)	
P-value for Relative Risk	0.8197	
Risk difference (95% CI)	-1.90 (-6.28, 2.48)	
P-value for Risk Difference	0.3935	
Constipation	12 (5.9%)	17 (8.3%)
Odds ratio (95% CI)	0.667 (0.307, 1.450)	
P-value for Odds Ratio	0.3062	
Relative Risk (95% CI)	0.68 (0.34, 1.40)	
P-value for Relative Risk	0.2963	
Risk difference (95% CI)	-1.98 (-6.84, 2.88)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Constipation		
P-value for Risk Difference	0.4246	
Dry mouth	11 (5.4%)	8 (3.9%)
Odds ratio (95% CI)	1.365 (0.533, 3.495)	
P-value for Odds Ratio	0.5161	
Relative Risk (95% CI)	1.34 (0.55, 3.29)	
P-value for Relative Risk	0.5154	
Risk difference (95% CI)	1.21 (-2.84, 5.27)	
P-value for Risk Difference	0.5562	
Vomiting	7 (3.4%)	6 (2.9%)
Odds ratio (95% CI)	1.147 (0.375, 3.508)	
P-value for Odds Ratio	0.8100	
Relative Risk (95% CI)	1.15 (0.39, 3.39)	
P-value for Relative Risk	0.7940	
Risk difference (95% CI)	-1.81 (-8.02, 4.39)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Vomiting		
P-value for Risk Difference	0.5657	
Abdominal pain	4 (2.0%)	6 (2.9%)
Odds ratio (95% CI)	0.630 (0.173, 2.296)	
P-value for Odds Ratio	0.4824	
Relative Risk (95% CI)	0.64 (0.18, 2.25)	
P-value for Relative Risk	0.4877	
Risk difference (95% CI)	-1.54 (-6.61, 3.54)	
P-value for Risk Difference	0.5521	
Musculoskeletal and connective tissue disorders	61 (29.8%)	53 (26.0%)
Odds ratio (95% CI)	1.215 (0.780, 1.892)	
P-value for Odds Ratio	0.3891	
Relative Risk (95% CI)	1.13 (0.83, 1.53)	
P-value for Relative Risk	0.4508	
Risk difference (95% CI)	4.28 (-4.39, 12.96)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Musculoskeletal and connective tissue disorders		
P-value for Risk Difference	0.3325	
Arthralgia	26 (12.7%)	25 (12.3%)
Odds ratio (95% CI)	1.050 (0.571, 1.931)	
P-value for Odds Ratio	0.8738	
Relative Risk (95% CI)	1.03 (0.62, 1.69)	
P-value for Relative Risk	0.9195	
Risk difference (95% CI)	1.36 (-3.93, 6.65)	
P-value for Risk Difference	0.6139	
Back pain	11 (5.4%)	8 (3.9%)
Odds ratio (95% CI)	1.400 (0.548, 3.579)	
P-value for Odds Ratio	0.4812	
Relative Risk (95% CI)	1.38 (0.56, 3.37)	
P-value for Relative Risk	0.4833	
Risk difference (95% CI)	1.99 (-2.78, 6.76)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Back pain		
P-value for Risk Difference	0.4134	
Pain in extremity	7 (3.4%)	4 (2.0%)
Odds ratio (95% CI)	1.514 (0.425, 5.387)	
P-value for Odds Ratio	0.5211	
Relative Risk (95% CI)	1.45 (0.43, 4.89)	
P-value for Relative Risk	0.5493	
Risk difference (95% CI)	1.41 (-2.62, 5.45)	
P-value for Risk Difference	0.4915	
Myalgia	5 (2.4%)	8 (3.9%)
Odds ratio (95% CI)	0.605 (0.193, 1.899)	
P-value for Odds Ratio	0.3885	
Relative Risk (95% CI)	0.61 (0.20, 1.86)	
P-value for Relative Risk	0.3878	
Risk difference (95% CI)	-1.41 (-4.80, 1.99)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Myalgia		
P-value for Risk Difference	0.4168	
Nervous system disorders	46 (22.4%)	45 (22.1%)
Odds ratio (95% CI)	1.040 (0.649, 1.668)	
P-value for Odds Ratio	0.8689	
Relative Risk (95% CI)	1.03 (0.72, 1.48)	
P-value for Relative Risk	0.8669	
Risk difference (95% CI)	0.70 (-7.31, 8.71)	
P-value for Risk Difference	0.8629	
Headache	14 (6.8%)	18 (8.8%)
Odds ratio (95% CI)	0.738 (0.354, 1.538)	
P-value for Odds Ratio	0.4165	
Relative Risk (95% CI)	0.76 (0.39, 1.50)	
P-value for Relative Risk	0.4321	
Risk difference (95% CI)	-2.77 (-8.06, 2.52)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Headache		
P-value for Risk Difference	0.3042	
Dysgeusia	10 (4.9%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	5.40 (1.29, 22.57)	
P-value for Relative Risk	0.0089	
Risk difference (95% CI)	11.10 (-26.43, 48.64)	
P-value for Risk Difference	0.5612	
Dizziness	8 (3.9%)	7 (3.4%)
Odds ratio (95% CI)	0.961 (0.330, 2.797)	
P-value for Odds Ratio	0.9418	
Relative Risk (95% CI)	1.01 (0.38, 2.69)	
P-value for Relative Risk	0.9796	
Risk difference (95% CI)	-0.92 (-5.07, 3.23)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Dizziness		
P-value for Risk Difference	0.6630	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	44 (21.5%)	51 (25.0%)
Odds ratio (95% CI)	0.829 (0.517, 1.329)	
P-value for Odds Ratio	0.4351	
Relative Risk (95% CI)	0.86 (0.61, 1.21)	
P-value for Relative Risk	0.3839	
Risk difference (95% CI)	-3.53 (-11.32, 4.25)	
P-value for Risk Difference	0.3730	
Bowen's disease	16 (7.8%)	21 (10.3%)
Odds ratio (95% CI)	0.719 (0.356, 1.452)	
P-value for Odds Ratio	0.3566	
Relative Risk (95% CI)	0.74 (0.41, 1.36)	
P-value for Relative Risk	0.3370	
Risk difference (95% CI)	-0.73 (-4.98, 3.53)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Bowen's disease		
P-value for Risk Difference	0.7374	
Squamous cell carcinoma of skin	16 (7.8%)	20 (9.8%)
Odds ratio (95% CI)	0.793 (0.394, 1.597)	
P-value for Odds Ratio	0.5157	
Relative Risk (95% CI)	0.81 (0.44, 1.52)	
P-value for Relative Risk	0.5132	
Risk difference (95% CI)	-1.66 (-7.36, 4.04)	
P-value for Risk Difference	0.5669	
Basal cell carcinoma	14 (6.8%)	16 (7.8%)
Odds ratio (95% CI)	0.903 (0.418, 1.952)	
P-value for Odds Ratio	0.7948	
Relative Risk (95% CI)	0.89 (0.46, 1.75)	
P-value for Relative Risk	0.7408	
Risk difference (95% CI)	1.77 (-4.05, 7.59)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
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Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Basal cell carcinoma		
P-value for Risk Difference	0.5513	
Investigations	39 (19.0%)	23 (11.3%)
Odds ratio (95% CI)	1.855 (1.057, 3.257)	
P-value for Odds Ratio	0.0314	
Relative Risk (95% CI)	1.68 (1.04, 2.72)	
P-value for Relative Risk	0.0329	
Risk difference (95% CI)	7.57 (0.72, 14.41)	
P-value for Risk Difference	0.0303	
Alanine aminotransferase increased	12 (5.9%)	3 (1.5%)
Odds ratio (95% CI)	4.144 (1.140, 15.061)	
P-value for Odds Ratio	0.0309	
Relative Risk (95% CI)	3.91 (1.11, 13.70)	
P-value for Relative Risk	0.0333	
Risk difference (95% CI)	4.50 (0.24, 8.77)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Alanine aminotransferase increased		
P-value for Risk Difference	0.0385	
Aspartate aminotransferase increased	10 (4.9%)	1 (0.5%)
Odds ratio (95% CI)	10.341 (1.299, 82.328)	
P-value for Odds Ratio	0.0274	
Relative Risk (95% CI)	9.83 (1.26, 76.80)	
P-value for Relative Risk	0.0294	
Risk difference (95% CI)	5.02 (-5.19, 15.23)	
P-value for Risk Difference	0.3348	
Weight decreased	6 (2.9%)	5 (2.5%)
Odds ratio (95% CI)	1.334 (0.396, 4.491)	
P-value for Odds Ratio	0.6413	
Relative Risk (95% CI)	1.32 (0.41, 4.25)	
P-value for Relative Risk	0.6409	
Risk difference (95% CI)	0.69 (-3.65, 5.04)	

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Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Weight decreased		
P-value for Risk Difference	0.7540	
Endocrine disorders	33 (16.1%)	7 (3.4%)
Odds ratio (95% CI)	5.375 (2.308, 12.518)	
P-value for Odds Ratio	0.0001	
Relative Risk (95% CI)	4.68 (2.11, 10.38)	
P-value for Relative Risk	0.0002	
Risk difference (95% CI)	12.81 (7.24, 18.39)	
P-value for Risk Difference	<0.0001	
Hypothyroidism	24 (11.7%)	6 (2.9%)
Odds ratio (95% CI)	4.338 (1.722, 10.925)	
P-value for Odds Ratio	0.0019	
Relative Risk (95% CI)	3.90 (1.62, 9.39)	
P-value for Relative Risk	0.0024	
Risk difference (95% CI)	9.06 (3.42, 14.71)	

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Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Hypothyroidism		
P-value for Risk Difference	0.0017	
Hyperthyroidism	12 (5.9%)	1 (0.5%)
Odds ratio (95% CI)	12.318 (1.571, 96.616)	
P-value for Odds Ratio	0.0170	
Relative Risk (95% CI)	11.57 (1.51, 88.85)	
P-value for Relative Risk	0.0187	
Risk difference (95% CI)	5.86 (-1.19, 12.90)	
P-value for Risk Difference	0.1030	
Metabolism and nutrition disorders	30 (14.6%)	17 (8.3%)
Odds ratio (95% CI)	1.945 (1.028, 3.680)	
P-value for Odds Ratio	0.0410	
Relative Risk (95% CI)	1.78 (1.02, 3.12)	
P-value for Relative Risk	0.0438	
Risk difference (95% CI)	6.95 (-0.23, 14.14)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Metabolism and nutrition disorders		
P-value for Risk Difference	0.0578	
Decreased appetite	7 (3.4%)	5 (2.5%)
Odds ratio (95% CI)	1.379 (0.423, 4.491)	
P-value for Odds Ratio	0.5933	
Relative Risk (95% CI)	1.36 (0.44, 4.20)	
P-value for Relative Risk	0.5934	
Risk difference (95% CI)	0.09 (-5.55, 5.73)	
P-value for Risk Difference	0.9739	
Injury, poisoning and procedural complications	29 (14.1%)	25 (12.3%)
Odds ratio (95% CI)	1.178 (0.657, 2.115)	
P-value for Odds Ratio	0.5814	
Relative Risk (95% CI)	1.16 (0.71, 1.90)	
P-value for Relative Risk	0.5569	
Risk difference (95% CI)	0.90 (-5.30, 7.10)	

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Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Injury, poisoning and procedural complications		
P-value for Risk Difference	0.7761	
Fall	9 (4.4%)	5 (2.5%)
Odds ratio (95% CI)	1.818 (0.587, 5.634)	
P-value for Odds Ratio	0.2995	
Relative Risk (95% CI)	1.76 (0.60, 5.14)	
P-value for Relative Risk	0.2981	
Risk difference (95% CI)	1.91 (-4.50, 8.31)	
P-value for Risk Difference	0.5586	
Respiratory, thoracic and mediastinal disorders	29 (14.1%)	26 (12.7%)
Odds ratio (95% CI)	1.114 (0.626, 1.983)	
P-value for Odds Ratio	0.7126	
Relative Risk (95% CI)	1.10 (0.67, 1.81)	
P-value for Relative Risk	0.6945	
Risk difference (95% CI)	0.36 (-6.42, 7.13)	

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A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Respiratory, thoracic and mediastinal disorders		
P-value for Risk Difference	0.9172	
Cough	12 (5.9%)	7 (3.4%)
Odds ratio (95% CI)	1.736 (0.661, 4.560)	
P-value for Odds Ratio	0.2621	
Relative Risk (95% CI)	1.68 (0.67, 4.18)	
P-value for Relative Risk	0.2659	
Risk difference (95% CI)	1.63 (-2.34, 5.60)	
P-value for Risk Difference	0.4208	
Dyspnoea	6 (2.9%)	4 (2.0%)
Odds ratio (95% CI)	1.439 (0.393, 5.270)	
P-value for Odds Ratio	0.5815	
Relative Risk (95% CI)	1.42 (0.41, 4.97)	
P-value for Relative Risk	0.5830	
Risk difference (95% CI)	-0.63 (-7.27, 6.00)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Dyspnoea		
P-value for Risk Difference	0.8512	
Vascular disorders	20 (9.8%)	19 (9.3%)
Odds ratio (95% CI)	0.999 (0.511, 1.952)	
P-value for Odds Ratio	0.9981	
Relative Risk (95% CI)	1.02 (0.56, 1.85)	
P-value for Relative Risk	0.9503	
Risk difference (95% CI)	-1.10 (-6.73, 4.53)	
P-value for Risk Difference	0.7008	
Hypertension	8 (3.9%)	11 (5.4%)
Odds ratio (95% CI)	0.647 (0.249, 1.681)	
P-value for Odds Ratio	0.3700	
Relative Risk (95% CI)	0.69 (0.28, 1.67)	
P-value for Relative Risk	0.4103	
Risk difference (95% CI)	-2.86 (-8.56, 2.84)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Hypertension		
P-value for Risk Difference	0.3250	
Psychiatric disorders	17 (8.3%)	14 (6.9%)
Odds ratio (95% CI)	1.193 (0.565, 2.517)	
P-value for Odds Ratio	0.6429	
Relative Risk (95% CI)	1.19 (0.60, 2.34)	
P-value for Relative Risk	0.6210	
Risk difference (95% CI)	-0.17 (-4.98, 4.63)	
P-value for Risk Difference	0.9437	
Insomnia	11 (5.4%)	5 (2.5%)
Odds ratio (95% CI)	2.136 (0.721, 6.327)	
P-value for Odds Ratio	0.1704	
Relative Risk (95% CI)	2.08 (0.73, 5.90)	
P-value for Relative Risk	0.1698	
Risk difference (95% CI)	2.36 (-1.57, 6.28)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Insomnia		
P-value for Risk Difference	0.2388	
Ear and labyrinth disorders	16 (7.8%)	17 (8.3%)
Odds ratio (95% CI)	0.999 (0.485, 2.056)	
P-value for Odds Ratio	0.9979	
Relative Risk (95% CI)	0.99 (0.52, 1.91)	
P-value for Relative Risk	0.9878	
Risk difference (95% CI)	0.05 (-6.36, 6.46)	
P-value for Risk Difference	0.9880	
Renal and urinary disorders	16 (7.8%)	10 (4.9%)
Odds ratio (95% CI)	1.694 (0.743, 3.859)	
P-value for Odds Ratio	0.2093	
Relative Risk (95% CI)	1.65 (0.77, 3.55)	
P-value for Relative Risk	0.1994	
Risk difference (95% CI)	2.66 (-2.26, 7.59)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Renal and urinary disorders		
P-value for Risk Difference	0.2886	
Eye disorders	14 (6.8%)	10 (4.9%)
Odds ratio (95% CI)	1.382 (0.590, 3.234)	
P-value for Odds Ratio	0.4554	
Relative Risk (95% CI)	1.31 (0.60, 2.88)	
P-value for Relative Risk	0.5001	
Risk difference (95% CI)	2.98 (-1.37, 7.33)	
P-value for Risk Difference	0.1787	
Blood and lymphatic system disorders	12 (5.9%)	11 (5.4%)
Odds ratio (95% CI)	1.026 (0.437, 2.406)	
P-value for Odds Ratio	0.9537	
Relative Risk (95% CI)	1.01 (0.45, 2.25)	
P-value for Relative Risk	0.9765	
Risk difference (95% CI)	0.75 (-3.56, 5.06)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Blood and lymphatic system disorders		
P-value for Risk Difference	0.7322	
Anaemia	4 (2.0%)	6 (2.9%)
Odds ratio (95% CI)	0.528 (0.141, 1.975)	
P-value for Odds Ratio	0.3416	
Relative Risk (95% CI)	0.56 (0.16, 1.93)	
P-value for Relative Risk	0.3571	
Risk difference (95% CI)	-0.71 (-5.99, 4.58)	
P-value for Risk Difference	0.7925	
Cardiac disorders	11 (5.4%)	8 (3.9%)
Odds ratio (95% CI)	1.424 (0.556, 3.647)	
P-value for Odds Ratio	0.4600	
Relative Risk (95% CI)	1.41 (0.58, 3.43)	
P-value for Relative Risk	0.4524	
Risk difference (95% CI)	0.48 (-3.71, 4.67)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Cardiac disorders		
P-value for Risk Difference	0.8227	
Hepatobiliary disorders	10 (4.9%)	2 (1.0%)
Odds ratio (95% CI)	5.452 (1.170, 25.405)	
P-value for Odds Ratio	0.0308	
Relative Risk (95% CI)	5.23 (1.16, 23.72)	
P-value for Relative Risk	0.0319	
Risk difference (95% CI)	4.59 (-2.20, 11.37)	
P-value for Risk Difference	0.1849	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

Table 14.3.5.2 Treatment-Emergent Adverse Events with Grade >=3 by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Number of participants with at least one such TEAE	49 (23.9%)	29 (14.2%)
Odds ratio (95% CI)	1.864 (1.116, 3.115)	
P-value for Odds Ratio	0.0175	
Relative Risk (95% CI)	1.62 (1.07, 2.46)	
P-value for Relative Risk	0.0236	
Risk difference (95% CI)	9.93 (2.48, 17.37)	
P-value for Risk Difference	0.0091	
Infections and infestations	10 (4.9%)	11 (5.4%)
Odds ratio (95% CI)	0.771 (0.310, 1.918)	
P-value for Odds Ratio	0.5758	
Relative Risk (95% CI)	0.79 (0.35, 1.79)	
P-value for Relative Risk	0.5715	
Risk difference (95% CI)	-0.25 (-4.19, 3.70)	
P-value for Risk Difference	0.9017	
Vascular disorders	6 (2.9%)	4 (2.0%)
Odds ratio (95% CI)	1.263 (0.340, 4.685)	
P-value for Odds Ratio	0.7265	
Relative Risk (95% CI)	1.27 (0.37, 4.42)	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0. NCI grades were coded using CTCAE Version 5.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)

Table 14.3.5.2 Treatment-Emergent Adverse Events with Grade >=3 by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Vascular disorders		
P-value for Relative Risk	0.7058	
Risk difference (95% CI)	-0.68 (-5.07, 3.72)	
P-value for Risk Difference	0.7615	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.0%)	8 (3.9%)
Odds ratio (95% CI)	0.264 (0.055, 1.274)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	0.28 (0.06, 1.28)	
P-value for Relative Risk	0.0995	
Risk difference (95% CI)	-3.12 (-7.24, 1.00)	
P-value for Risk Difference	0.1376	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0. NCI grades were coded using CTCAE Version 5.
A patient is counted only once for multiple occurrences within a system organ class/preferred term. For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)

Table 14.3.2.2 Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term (Part 1)
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)
Number of participants with at least one such TEAE	36 (17.6%)	19 (9.3%)
Odds ratio (95% CI)	2.042 (1.121, 3.718)	
P-value for Odds Ratio	0.0197	
Relative Risk (95% CI)	1.84 (1.09, 3.11)	
P-value for Relative Risk	0.0222	
Risk difference (95% CI)	7.92 (1.37, 14.46)	
P-value for Risk Difference	0.0179	
Infections and infestations	10 (4.9%)	9 (4.4%)
Odds ratio (95% CI)	0.988 (0.384, 2.543)	
P-value for Odds Ratio	0.9799	
Relative Risk (95% CI)	0.97 (0.40, 2.32)	
P-value for Relative Risk	0.9401	
Risk difference (95% CI)	0.49 (-3.17, 4.14)	
P-value for Risk Difference	0.7940	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN) and geographical region North America vs Australia/New Zealand vs ROW)
SOCs, and PTs with >=10% in any arm OR number of patients with AE by SOC and PT (any severity) with at least 10 patients with the respective AE and >1% in any arm will be presented.

2 Subgruppenergebnisse

2.1 Gesamtüberleben

2.1.1 1. Datenschnitt

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of deaths, n (%)	11 (5.8%)	12 (6.3%)
Odds ratio (95% CI)	0.821 (0.346, 1.946)	
P-value for Odds Ratio	0.6542	
Relative Risk (95% CI)	0.82 (0.37, 1.83)	
P-value for Relative Risk	0.6243	
Heterogeneity p-value of RR	0.8265	
Risk difference (95% CI)	-0.96 (-5.57, 3.64)	
P-value for Risk Difference	0.6816	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	4 (2.1%)	7 (3.7%)
ADVERSE EVENT	2 (1.1%)	4 (2.1%)
OTHER	5 (2.6%)	1 (0.5%)

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression(GENMOD) with treatment, high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as the fixed factor.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of deaths, n (%)	1 (5.0%)	1 (5.9%)
Odds ratio (95% CI)	3.500 (0.145, 84.693)	
P-value for Odds Ratio	0.4409	
Relative Risk (95% CI)	2.67 (0.23, 30.40)	
P-value for Relative Risk	0.4296	
Heterogeneity p-value of RR	0.8265	
Risk difference (95% CI)	2.04 (-38.38, 42.46)	
P-value for Risk Difference	0.9212	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	0	1 (5.9%)
ADVERSE EVENT	1 (5.0%)	0
OTHER	0	0

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression(GENMOD) with treatment, high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as the fixed factor.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of Deaths, n (%)	11 (5.8%)	12 (6.3%)
Number of censored participants, n (%)	178 (94.2%)	177 (93.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.6853	
HR (95% CI) [c][d]	0.842 (0.365, 1.940)	
Heterogeneity p-value [c][e]	0.7321	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.5 (96.2, 99.9)	100 (100, 100)
6 months	98.8 (95.5, 99.7)	99.4 (96.1, 99.9)
12 months	98.2 (94.6, 99.4)	98.1 (94.3, 99.4)
18 months	96.6 (92.0, 98.6)	92.5 (86.5, 95.9)
24 months	94.8 (89.2, 97.5)	92.5 (86.5, 95.9)
30 months	91.6 (84.6, 95.5)	92.5 (86.5, 95.9)
36 months	89.8 (81.6, 94.4)	92.5 (86.5, 95.9)
42 months	89.8 (81.6, 94.4)	89.7 (80.1, 94.8)
48 months	89.8 (81.6, 94.4)	89.7 (80.1, 94.8)
54 months	89.8 (81.6, 94.4)	83.3 (63.8, 92.9)
60 months	89.8 (81.6, 94.4)	83.3 (63.8, 92.9)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of Deaths, n (%)	1 (5.0%)	1 (5.9%)
Number of censored participants, n (%)	19 (95.0%)	16 (94.1%)
Q1 (95% CI), (months)[a]	NR (0.5, NE)	NR (14.9, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (14.9, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.3022	
HR (95% CI) [c][d]	4.000 (0.236, 67.712)	
Heterogeneity p-value [c][e]	0.7321	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Survival Probability, % (95% CI) [a]		
3 months	94.7 (68.1, 99.2)	100 (100, 100)
6 months	94.7 (68.1, 99.2)	100 (100, 100)
12 months	94.7 (68.1, 99.2)	100 (100, 100)
18 months	94.7 (68.1, 99.2)	88.9 (43.3, 98.4)
24 months	94.7 (68.1, 99.2)	88.9 (43.3, 98.4)
30 months	94.7 (68.1, 99.2)	88.9 (43.3, 98.4)
36 months	94.7 (68.1, 99.2)	88.9 (43.3, 98.4)
42 months	94.7 (68.1, 99.2)	88.9 (43.3, 98.4)
48 months	94.7 (68.1, 99.2)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of Deaths, n (%)	11 (5.8%)	12 (6.3%)
Number of censored participants, n (%)	178 (94.2%)	177 (93.7%)
Proportionality Test p-value[a][b]	0.9851	
Hazard ratio(interaction)	1.010 (0.372, 2.741)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

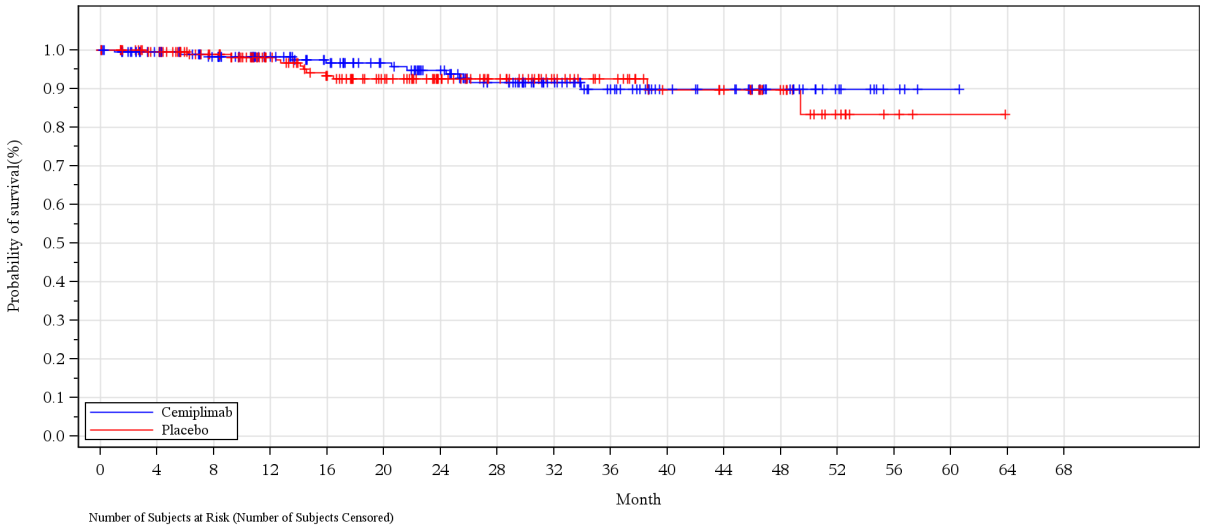
Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of Deaths, n (%)	1 (5.0%)	1 (5.9%)
Number of censored participants, n (%)	19 (95.0%)	16 (94.1%)
Proportionality Test p-value[a][b]	0.9984	
Hazard ratio(interaction)	63442 (0.000, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Race: White



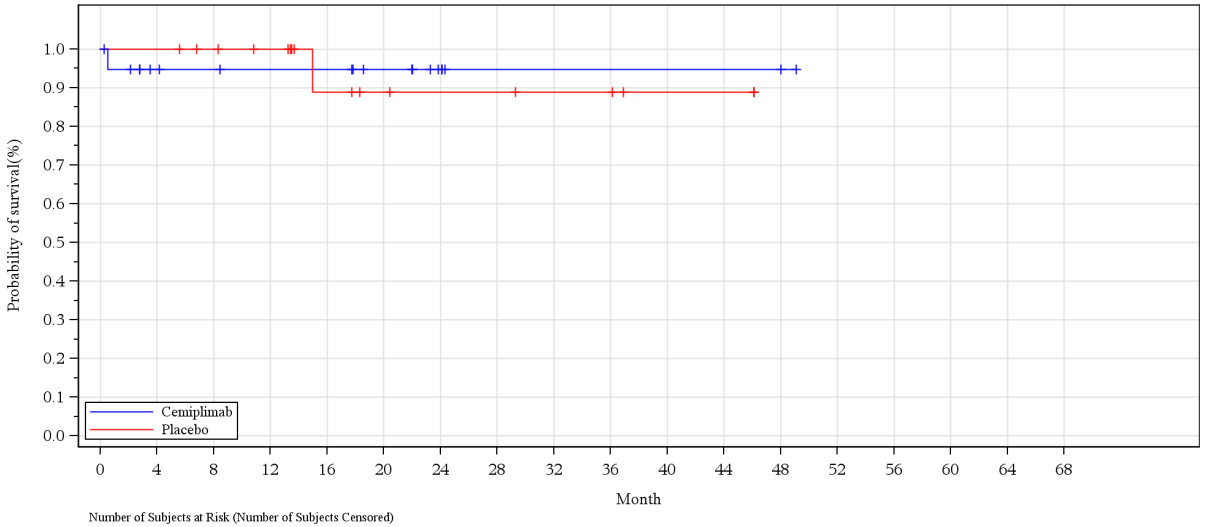
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	171 (17)	153 (33)	132 (54)	119 (65)	106 (78)	95 (87)	77 (102)	59 (120)	45 (133)	32 (146)	29 (149)	19 (159)	10 (168)	4 (174)	1 (177)	0 (178)	0 (178)
Placebo	189 (0)	174 (14)	153 (34)	128 (58)	112 (69)	96 (83)	78 (101)	64 (115)	49 (131)	40 (139)	30 (148)	27 (151)	18 (160)	8 (169)	3 (174)	1 (176)	0 (177)	0 (177)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 11:11 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	14 (5)	13 (6)	12 (7)	12 (7)	9 (10)	5 (14)	2 (17)	2 (17)	2 (17)	2 (17)	2 (17)	2 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	17 (0)	17 (0)	15 (2)	13 (4)	8 (8)	6 (10)	5 (11)	5 (11)	4 (12)	4 (12)	2 (14)	2 (14)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 11:11 SAS Linux 9.4)

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Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of deaths, n (%)	3 (5.4%)	7 (10.8%)
Odds ratio (95% CI)	0.472 (0.114, 1.947)	
P-value for Odds Ratio	0.2990	
Relative Risk (95% CI)	0.50 (0.14, 1.84)	
P-value for Relative Risk	0.2980	
Heterogeneity p-value of RR	0.5808	
Risk difference (95% CI)	-4.77 (-17.85, 8.30)	
P-value for Risk Difference	0.4745	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	1 (1.8%)	7 (10.8%)
ADVERSE EVENT	1 (1.8%)	0
OTHER	1 (1.8%)	0

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of deaths, n (%)	12 (7.8%)	13 (9.2%)
Odds ratio (95% CI)	0.743 (0.319, 1.727)	
P-value for Odds Ratio	0.4897	
Relative Risk (95% CI)	0.76 (0.36, 1.63)	
P-value for Relative Risk	0.4837	
Heterogeneity p-value of RR	0.5808	
Risk difference (95% CI)	-2.97 (-8.73, 2.78)	
P-value for Risk Difference	0.3112	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	5 (3.3%)	5 (3.5%)
ADVERSE EVENT	2 (1.3%)	5 (3.5%)
OTHER	5 (3.3%)	3 (2.1%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of deaths, n (%)	12 (6.9%)	13 (7.5%)
Odds ratio (95% CI)	0.840 (0.367, 1.921)	
P-value for Odds Ratio	0.6798	
Relative Risk (95% CI)	0.83 (0.39, 1.76)	
P-value for Relative Risk	0.6226	
Heterogeneity p-value of RR	0.1962	
Risk difference (95% CI)	0.17 (-5.73, 6.07)	
P-value for Risk Difference	0.9558	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	6 (3.4%)	8 (4.6%)
ADVERSE EVENT	2 (1.1%)	3 (1.7%)
OTHER	4 (2.3%)	2 (1.1%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of deaths, n (%)	3 (8.6%)	7 (21.9%)
Odds ratio (95% CI)	0.324 (0.071, 1.484)	
P-value for Odds Ratio	0.1466	
Relative Risk (95% CI)	0.40 (0.11, 1.46)	
P-value for Relative Risk	0.1656	
Heterogeneity p-value of RR	0.1962	
Risk difference (95% CI)	-12.07 (-36.79, 12.65)	
P-value for Risk Difference	0.3387	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	0	4 (12.5%)
ADVERSE EVENT	1 (2.9%)	2 (6.3%)
OTHER	2 (5.7%)	1 (3.1%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of deaths, n (%)	13 (6.9%)	18 (9.5%)
Odds ratio (95% CI)	0.629 (0.294, 1.346)	
P-value for Odds Ratio	0.2322	
Relative Risk (95% CI)	0.65 (0.32, 1.29)	
P-value for Relative Risk	0.2192	
Heterogeneity p-value of RR	0.6787	
Risk difference (95% CI)	-3.35 (-8.72, 2.02)	
P-value for Risk Difference	0.2213	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	5 (2.6%)	10 (5.3%)
ADVERSE EVENT	2 (1.1%)	5 (2.6%)
OTHER	6 (3.2%)	3 (1.6%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of deaths, n (%)	2 (10.0%)	2 (11.8%)
Odds ratio (95% CI)	1.042 (0.114, 9.523)	
P-value for Odds Ratio	0.9708	
Relative Risk (95% CI)	1.17 (1.17, 1.17)*	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.6787	
Risk difference (95% CI)	2.09 (2.09, 2.09)*	
P-value for Risk Difference	NE	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	1 (5.0%)	2 (11.8%)
ADVERSE EVENT	1 (5.0%)	0
OTHER	0	0

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of deaths, n (%)	11 (6.6%)	14 (7.9%)
Odds ratio (95% CI)	0.821 (0.361, 1.868)	
P-value for Odds Ratio	0.6380	
Relative Risk (95% CI)	0.84 (0.39, 1.80)	
P-value for Relative Risk	0.6534	
Heterogeneity p-value of RR	0.3622	
Risk difference (95% CI)	-2.29 (-7.80, 3.23)	
P-value for Risk Difference	0.4161	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	4 (2.4%)	7 (4.0%)
ADVERSE EVENT	2 (1.2%)	4 (2.3%)
OTHER	5 (3.0%)	3 (1.7%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of deaths, n (%)	4 (9.3%)	6 (20.7%)
Odds ratio (95% CI)	0.352 (0.086, 1.441)	
P-value for Odds Ratio	0.1466	
Relative Risk (95% CI)	0.42 (0.13, 1.32)	
P-value for Relative Risk	0.1382	
Heterogeneity p-value of RR	0.3622	
Risk difference (95% CI)	-11.47 (-28.29, 5.35)	
P-value for Risk Difference	0.1812	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	2 (4.7%)	5 (17.2%)
ADVERSE EVENT	1 (2.3%)	1 (3.4%)
OTHER	1 (2.3%)	0

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of deaths, n (%)	5 (3.8%)	8 (6.1%)
Odds ratio (95% CI)	0.532 (0.166, 1.705)	
P-value for Odds Ratio	0.2884	
Relative Risk (95% CI)	0.55 (0.19, 1.63)	
P-value for Relative Risk	0.2826	
Heterogeneity p-value of RR	0.6708	
Risk difference (95% CI)	-1.00 (-7.99, 5.99)	
P-value for Risk Difference	0.7785	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	2 (1.5%)	6 (4.6%)
ADVERSE EVENT	2 (1.5%)	2 (1.5%)
OTHER	1 (0.8%)	0

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of deaths, n (%)	10 (13.2%)	12 (16.0%)
Odds ratio (95% CI)	0.752 (0.296, 1.910)	
P-value for Odds Ratio	0.5488	
Relative Risk (95% CI)	0.80 (0.37, 1.74)	
P-value for Relative Risk	0.5775	
Heterogeneity p-value of RR	0.6708	
Risk difference (95% CI)	-5.40 (-15.51, 4.71)	
P-value for Risk Difference	0.2954	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	4 (5.3%)	6 (8.0%)
ADVERSE EVENT	1 (1.3%)	3 (4.0%)
OTHER	5 (6.6%)	3 (4.0%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of deaths, n (%)	7 (5.6%)	11 (9.4%)
Odds ratio (95% CI)	0.459 (0.165, 1.279)	
P-value for Odds Ratio	0.1365	
Relative Risk (95% CI)	0.49 (0.20, 1.20)	
P-value for Relative Risk	0.1205	
Heterogeneity p-value of RR	0.4061	
Risk difference (95% CI)	-2.63 (-8.64, 3.37)	
P-value for Risk Difference	0.3896	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	5 (4.0%)	8 (6.8%)
ADVERSE EVENT	1 (0.8%)	2 (1.7%)
OTHER	1 (0.8%)	1 (0.9%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.3.1 Summary of Deaths by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of deaths, n (%)	8 (9.5%)	9 (10.1%)
Odds ratio (95% CI)	0.951 (0.348, 2.604)	
P-value for Odds Ratio	0.9224	
Relative Risk (95% CI)	0.97 (0.39, 2.41)	
P-value for Relative Risk	0.9475	
Heterogeneity p-value of RR	0.4061	
Risk difference (95% CI)	-2.87 (-14.66, 8.91)	
P-value for Risk Difference	0.6328	
Primary cause of death		
PROGRESSION/RECURRENCE OF DISEASE	1 (1.2%)	4 (4.5%)
ADVERSE EVENT	2 (2.4%)	3 (3.4%)
OTHER	5 (6.0%)	2 (2.2%)

Data cut-off as of April 07, 2025.
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
*The estimate is either invalid or at a limit of its range for some observations.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of Deaths, n (%)	3 (5.4%)	7 (10.8%)
Number of censored participants, n (%)	53 (94.6%)	58 (89.2%)
Q1 (95% CI), (months)[a]	NR (33.9, NE)	NR (38.6, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.2777	
HR (95% CI) [c][d]	0.464 (0.113, 1.913)	
Heterogeneity p-value [c][e]	0.6130	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Survival Probability, % (95% CI) [a]		
3 months	98.2 (87.8, 99.7)	100 (100, 100)
6 months	98.2 (87.8, 99.7)	100 (100, 100)
12 months	98.2 (87.8, 99.7)	100 (100, 100)
18 months	96.0 (85.0, 99.0)	88.5 (76.2, 94.7)
24 months	96.0 (85.0, 99.0)	88.5 (76.2, 94.7)
30 months	96.0 (85.0, 99.0)	88.5 (76.2, 94.7)
36 months	91.5 (73.4, 97.5)	88.5 (76.2, 94.7)
42 months	91.5 (73.4, 97.5)	83.6 (66.3, 92.5)
48 months	91.5 (73.4, 97.5)	83.6 (66.3, 92.5)
54 months	91.5 (73.4, 97.5)	83.6 (66.3, 92.5)
60 months	NE (NE, NE)	83.6 (66.3, 92.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of Deaths, n (%)	12 (7.8%)	11 (7.8%)
Number of censored participants, n (%)	141 (92.2%)	130 (92.2%)
Q1 (95% CI), (months)[a]	NR (51.5, NE)	NR (49.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.7193	
HR (95% CI) [c][d]	0.858 (0.371, 1.983)	
Heterogeneity p-value [c][e]	0.6130	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.3 (95.4, 99.9)	100 (100, 100)
6 months	98.7 (94.7, 99.7)	99.3 (94.9, 99.9)
12 months	98.0 (93.9, 99.3)	97.0 (92.2, 98.9)
18 months	96.2 (91.0, 98.4)	92.4 (85.9, 96.0)
24 months	93.1 (86.4, 96.5)	91.3 (84.3, 95.2)
30 months	89.7 (82.0, 94.2)	91.3 (84.3, 95.2)
36 months	89.7 (82.0, 94.2)	91.3 (84.3, 95.2)
42 months	89.7 (82.0, 94.2)	91.3 (84.3, 95.2)
48 months	89.7 (82.0, 94.2)	91.3 (84.3, 95.2)
54 months	85.8 (73.2, 92.8)	86.7 (72.5, 93.9)
60 months	85.8 (73.2, 92.8)	86.7 (72.5, 93.9)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of Deaths, n (%)	12 (6.9%)	12 (6.9%)
Number of censored participants, n (%)	162 (93.1%)	162 (93.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.7568	
HR (95% CI) [c][d]	0.880 (0.392, 1.976)	
Heterogeneity p-value [c][e]	0.5503	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.4 (95.9, 99.9)	100 (100, 100)
6 months	98.8 (95.4, 99.7)	100 (100, 100)
12 months	98.2 (94.6, 99.4)	98.8 (95.2, 99.7)
18 months	96.0 (91.3, 98.2)	93.6 (88.0, 96.6)
24 months	94.3 (88.8, 97.1)	92.5 (86.5, 95.9)
30 months	92.4 (86.2, 95.9)	92.5 (86.5, 95.9)
36 months	91.0 (84.0, 95.0)	92.5 (86.5, 95.9)
42 months	91.0 (84.0, 95.0)	90.4 (82.2, 94.9)
48 months	91.0 (84.0, 95.0)	90.4 (82.2, 94.9)
54 months	87.8 (76.8, 93.8)	86.8 (74.4, 93.4)
60 months	87.8 (76.8, 93.8)	86.8 (74.4, 93.4)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of Deaths, n (%)	3 (8.6%)	6 (18.8%)
Number of censored participants, n (%)	32 (91.4%)	26 (81.3%)
Q1 (95% CI), (months)[a]	NR (20.6, NE)	NR (12.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.3336	
HR (95% CI) [c][d]	0.504 (0.123, 2.071)	
Heterogeneity p-value [c][e]	0.5503	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Survival Probability, % (95% CI) [a]		
3 months	97.1 (80.9, 99.6)	100 (100, 100)
6 months	97.1 (80.9, 99.6)	96.9 (79.8, 99.6)
12 months	97.1 (80.9, 99.6)	93.8 (77.3, 98.4)
18 months	97.1 (80.9, 99.6)	80.4 (61.4, 90.7)
24 months	91.7 (68.9, 98.0)	80.4 (61.4, 90.7)
30 months	85.6 (60.0, 95.3)	80.4 (61.4, 90.7)
36 months	85.6 (60.0, 95.3)	80.4 (61.4, 90.7)
42 months	85.6 (60.0, 95.3)	80.4 (61.4, 90.7)
48 months	85.6 (60.0, 95.3)	80.4 (61.4, 90.7)
54 months	NE (NE, NE)	80.4 (61.4, 90.7)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of Deaths, n (%)	13 (6.9%)	16 (8.5%)
Number of censored participants, n (%)	176 (93.1%)	173 (91.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.4566	
HR (95% CI) [c][d]	0.756 (0.361, 1.584)	
Heterogeneity p-value [c][e]	0.7108	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.5 (96.2, 99.9)	100 (100, 100)
6 months	98.9 (95.7, 99.7)	99.5 (96.2, 99.9)
12 months	98.4 (95.0, 99.5)	98.3 (95.0, 99.5)
18 months	96.3 (91.9, 98.3)	91.7 (86.0, 95.1)
24 months	94.7 (89.6, 97.3)	90.8 (84.8, 94.5)
30 months	92.1 (86.0, 95.6)	90.8 (84.8, 94.5)
36 months	90.8 (84.1, 94.8)	90.8 (84.8, 94.5)
42 months	90.8 (84.1, 94.8)	88.9 (81.5, 93.5)
48 months	90.8 (84.1, 94.8)	88.9 (81.5, 93.5)
54 months	87.6 (76.9, 93.5)	85.7 (74.9, 92.1)
60 months	87.6 (76.9, 93.5)	85.7 (74.9, 92.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of Deaths, n (%)	2 (10.0%)	2 (11.8%)
Number of censored participants, n (%)	18 (90.0%)	15 (88.2%)
Q1 (95% CI), (months)[a]	NR (0.5, NE)	NR (9.0, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.7010	
HR (95% CI) [c][d]	1.543 (0.168, 14.200)	
Heterogeneity p-value [c][e]	0.7108	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Survival Probability, % (95% CI) [a]		
3 months	94.7 (68.1, 99.2)	100 (100, 100)
6 months	94.7 (68.1, 99.2)	100 (100, 100)
12 months	94.7 (68.1, 99.2)	94.1 (65.0, 99.1)
18 months	94.7 (68.1, 99.2)	86.9 (56.5, 96.6)
24 months	86.1 (53.3, 96.5)	86.9 (56.5, 96.6)
30 months	86.1 (53.3, 96.5)	86.9 (56.5, 96.6)
36 months	86.1 (53.3, 96.5)	86.9 (56.5, 96.6)
42 months	86.1 (53.3, 96.5)	86.9 (56.5, 96.6)
48 months	86.1 (53.3, 96.5)	86.9 (56.5, 96.6)
54 months	86.1 (53.3, 96.5)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of Deaths, n (%)	11 (6.6%)	12 (6.8%)
Number of censored participants, n (%)	155 (93.4%)	165 (93.2%)
Q1 (95% CI), (months)[a]	NR (51.5, NE)	NR (NE, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.8609	
HR (95% CI) [c][d]	0.929 (0.409, 2.111)	
Heterogeneity p-value [c][e]	0.3876	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.4 (95.7, 99.9)	100 (100, 100)
6 months	99.4 (95.7, 99.9)	100 (100, 100)
12 months	98.8 (95.2, 99.7)	98.8 (95.3, 99.7)
18 months	97.3 (92.8, 99.0)	93.0 (87.4, 96.2)
24 months	94.5 (88.7, 97.4)	92.0 (86.0, 95.5)
30 months	92.5 (85.9, 96.1)	92.0 (86.0, 95.5)
36 months	90.9 (83.4, 95.2)	92.0 (86.0, 95.5)
42 months	90.9 (83.4, 95.2)	90.0 (82.0, 94.5)
48 months	90.9 (83.4, 95.2)	90.0 (82.0, 94.5)
54 months	87.0 (74.1, 93.7)	90.0 (82.0, 94.5)
60 months	87.0 (74.1, 93.7)	90.0 (82.0, 94.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of Deaths, n (%)	4 (9.3%)	6 (20.7%)
Number of censored participants, n (%)	39 (90.7%)	23 (79.3%)
Q1 (95% CI), (months)[a]	NR (24.4, NE)	49.4 (9.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.3080	
HR (95% CI) [c][d]	0.521 (0.146, 1.864)	
Heterogeneity p-value [c][e]	0.3876	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Survival Probability, % (95% CI) [a]		
3 months	97.6 (84.3, 99.7)	100 (100, 100)
6 months	95.1 (81.6, 98.7)	96.6 (77.9, 99.5)
12 months	95.1 (81.6, 98.7)	93.0 (74.7, 98.2)
18 months	91.4 (75.1, 97.2)	81.5 (61.0, 91.9)
24 months	91.4 (75.1, 97.2)	81.5 (61.0, 91.9)
30 months	87.4 (69.1, 95.2)	81.5 (61.0, 91.9)
36 months	87.4 (69.1, 95.2)	81.5 (61.0, 91.9)
42 months	87.4 (69.1, 95.2)	81.5 (61.0, 91.9)
48 months	87.4 (69.1, 95.2)	81.5 (61.0, 91.9)
54 months	87.4 (69.1, 95.2)	67.9 (33.6, 87.2)
60 months	87.4 (69.1, 95.2)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of Deaths, n (%)	5 (3.8%)	8 (6.1%)
Number of censored participants, n (%)	128 (96.2%)	123 (93.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.3463	
HR (95% CI) [c][d]	0.586 (0.190, 1.804)	
Heterogeneity p-value [c][e]	0.4991	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.2 (94.7, 99.9)	100 (100, 100)
6 months	99.2 (94.7, 99.9)	100 (100, 100)
12 months	98.4 (93.9, 99.6)	99.2 (94.7, 99.9)
18 months	96.3 (90.4, 98.6)	93.4 (86.7, 96.8)
24 months	96.3 (90.4, 98.6)	93.4 (86.7, 96.8)
30 months	95.0 (88.2, 97.9)	93.4 (86.7, 96.8)
36 months	95.0 (88.2, 97.9)	93.4 (86.7, 96.8)
42 months	95.0 (88.2, 97.9)	90.2 (79.0, 95.6)
48 months	95.0 (88.2, 97.9)	90.2 (79.0, 95.6)
54 months	95.0 (88.2, 97.9)	90.2 (79.0, 95.6)
60 months	95.0 (88.2, 97.9)	90.2 (79.0, 95.6)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of Deaths, n (%)	10 (13.2%)	10 (13.3%)
Number of censored participants, n (%)	66 (86.8%)	65 (86.7%)
Q1 (95% CI), (months)[a]	NR (26.0, NE)	NR (24.0, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.9405	
HR (95% CI) [c][d]	0.967 (0.396, 2.359)	
Heterogeneity p-value [c][e]	0.4991	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Survival Probability, % (95% CI) [a]		
3 months	98.7 (90.9, 99.8)	100 (100, 100)
6 months	97.3 (89.6, 99.3)	98.6 (90.4, 99.8)
12 months	97.3 (89.6, 99.3)	95.6 (87.1, 98.6)
18 months	95.7 (87.3, 98.6)	87.2 (76.0, 93.4)
24 months	90.1 (79.1, 95.5)	85.1 (73.1, 92.0)
30 months	86.1 (73.9, 92.9)	85.1 (73.1, 92.0)
36 months	83.3 (69.7, 91.1)	85.1 (73.1, 92.0)
42 months	83.3 (69.7, 91.1)	85.1 (73.1, 92.0)
48 months	83.3 (69.7, 91.1)	85.1 (73.1, 92.0)
54 months	75.7 (53.6, 88.3)	78.0 (57.2, 89.6)
60 months	NE (NE, NE)	78.0 (57.2, 89.6)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of Deaths, n (%)	7 (5.6%)	11 (9.4%)
Number of censored participants, n (%)	118 (94.4%)	106 (90.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.1969	
HR (95% CI) [c][d]	0.539 (0.208, 1.400)	
Heterogeneity p-value [c][e]	0.2629	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Survival Probability, % (95% CI) [a]		
3 months	99.2 (94.4, 99.9)	100 (100, 100)
6 months	98.4 (93.6, 99.6)	100 (100, 100)
12 months	98.4 (93.6, 99.6)	99.1 (93.7, 99.9)
18 months	96.2 (90.0, 98.6)	91.6 (84.0, 95.7)
24 months	94.9 (88.0, 97.9)	90.1 (81.8, 94.8)
30 months	93.5 (85.8, 97.1)	90.1 (81.8, 94.8)
36 months	91.2 (81.5, 95.9)	90.1 (81.8, 94.8)
42 months	91.2 (81.5, 95.9)	87.0 (75.6, 93.3)
48 months	91.2 (81.5, 95.9)	87.0 (75.6, 93.3)
54 months	91.2 (81.5, 95.9)	81.2 (62.9, 91.1)
60 months	91.2 (81.5, 95.9)	81.2 (62.9, 91.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of Deaths, n (%)	8 (9.5%)	7 (7.9%)
Number of censored participants, n (%)	76 (90.5%)	82 (92.1%)
Q1 (95% CI), (months)[a]	NR (51.5, NE)	NR (NE, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.6909	
HR (95% CI) [c][d]	1.230 (0.443, 3.414)	
Heterogeneity p-value [c][e]	0.2629	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.1.1 Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Survival Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	100 (100, 100)
6 months	98.8 (91.7, 99.8)	98.9 (92.1, 99.8)
12 months	97.5 (90.5, 99.4)	96.5 (89.4, 98.8)
18 months	96.1 (88.3, 98.7)	90.7 (81.4, 95.5)
24 months	92.7 (83.0, 96.9)	90.7 (81.4, 95.5)
30 months	88.9 (77.9, 94.6)	90.7 (81.4, 95.5)
36 months	88.9 (77.9, 94.6)	90.7 (81.4, 95.5)
42 months	88.9 (77.9, 94.6)	90.7 (81.4, 95.5)
48 months	88.9 (77.9, 94.6)	90.7 (81.4, 95.5)
54 months	82.1 (61.1, 92.4)	90.7 (81.4, 95.5)
60 months	82.1 (61.1, 92.4)	90.7 (81.4, 95.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value from stratified log-rank test
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors. Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of Deaths, n (%)	3 (5.4%)	7 (10.8%)
Number of censored participants, n (%)	53 (94.6%)	58 (89.2%)
Proportionality Test p-value[a][b]	0.3244	
Hazard ratio(interaction)	2.137 (0.472, 9.680)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of Deaths, n (%)	12 (7.8%)	11 (7.8%)
Number of censored participants, n (%)	141 (92.2%)	130 (92.2%)
Proportionality Test p-value[a][b]	0.7495	
Hazard ratio(interaction)	0.848 (0.309, 2.330)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of Deaths, n (%)	12 (6.9%)	12 (6.9%)
Number of censored participants, n (%)	162 (93.1%)	162 (93.1%)
Proportionality Test p-value[a][b]	0.7682	
Hazard ratio(interaction)	1.162 (0.427, 3.163)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of Deaths, n (%)	3 (8.6%)	6 (18.8%)
Number of censored participants, n (%)	32 (91.4%)	26 (81.3%)
Proportionality Test p-value[a][b]	0.8283	
Hazard ratio(interaction)	1.140 (0.348, 3.739)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of Deaths, n (%)	13 (6.9%)	16 (8.5%)
Number of censored participants, n (%)	176 (93.1%)	173 (91.5%)
Proportionality Test p-value[a][b]	0.7917	
Hazard ratio(interaction)	0.879 (0.339, 2.282)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of Deaths, n (%)	2 (10.0%)	2 (11.8%)
Number of censored participants, n (%)	18 (90.0%)	15 (88.2%)
Proportionality Test p-value[a][b]	0.2793	
Hazard ratio(interaction)	2.689 (0.448, 16.137)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of Deaths, n (%)	11 (6.6%)	12 (6.8%)
Number of censored participants, n (%)	155 (93.4%)	165 (93.2%)
Proportionality Test p-value[a][b]	0.7920	
Hazard ratio(interaction)	0.863 (0.288, 2.584)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of Deaths, n (%)	4 (9.3%)	6 (20.7%)
Number of censored participants, n (%)	39 (90.7%)	23 (79.3%)
Proportionality Test p-value[a][b]	0.4133	
Hazard ratio(interaction)	1.649 (0.498, 5.460)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of Deaths, n (%)	5 (3.8%)	8 (6.1%)
Number of censored participants, n (%)	128 (96.2%)	123 (93.9%)
Proportionality Test p-value[a][b]	0.2676	
Hazard ratio(interaction)	2.568 (0.485, 13.606)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of Deaths, n (%)	10 (13.2%)	10 (13.3%)
Number of censored participants, n (%)	66 (86.8%)	65 (86.7%)
Proportionality Test p-value[a][b]	0.6806	
Hazard ratio(interaction)	0.827 (0.334, 2.047)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of Deaths, n (%)	7 (5.6%)	11 (9.4%)
Number of censored participants, n (%)	118 (94.4%)	106 (90.6%)
Proportionality Test p-value[a][b]	0.3159	
Hazard ratio(interaction)	1.912 (0.539, 6.785)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.1.2.1 Test of Proportional Hazards Assumption for Overall Survival by Subgroup
(Full Analysis Set)

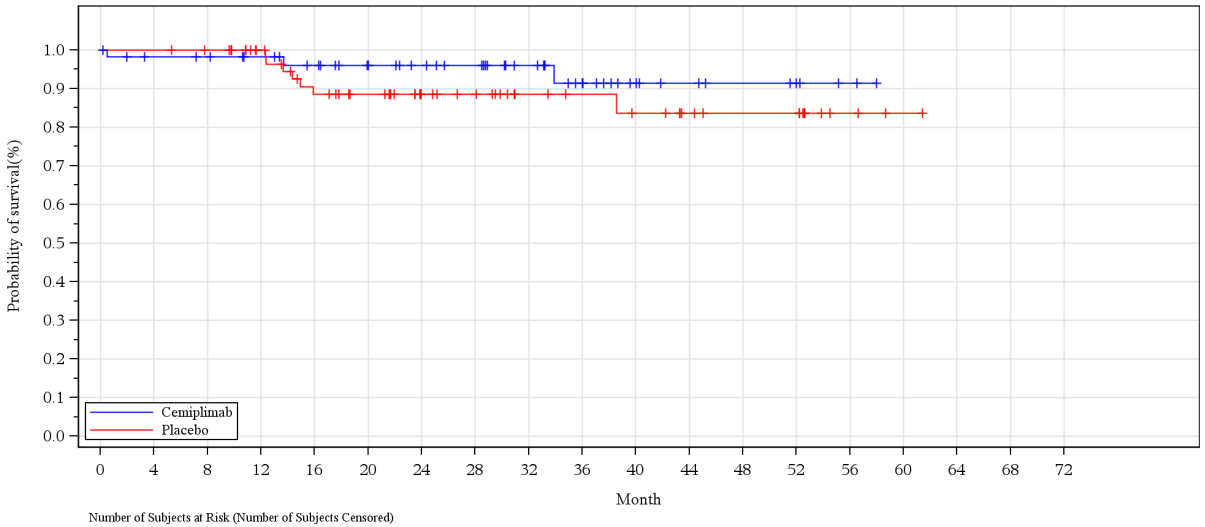
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of Deaths, n (%)	8 (9.5%)	7 (7.9%)
Number of censored participants, n (%)	76 (90.5%)	82 (92.1%)
Proportionality Test p-value[a][b]	0.4609	
Hazard ratio(interaction)	0.681 (0.245, 1.893)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	52 (3)	51 (4)	48 (7)	44 (10)	39 (15)	35 (19)	32 (22)	25 (29)	18 (35)	11 (42)	8 (45)	6 (47)	4 (49)	2 (51)	0 (53)	0 (53)	0 (53)	0 (53)
Placebo	65 (0)	65 (0)	63 (2)	55 (10)	45 (14)	40 (19)	30 (29)	27 (32)	20 (39)	18 (41)	16 (42)	12 (46)	10 (48)	10 (48)	3 (55)	1 (57)	0 (58)	0 (58)	0 (58)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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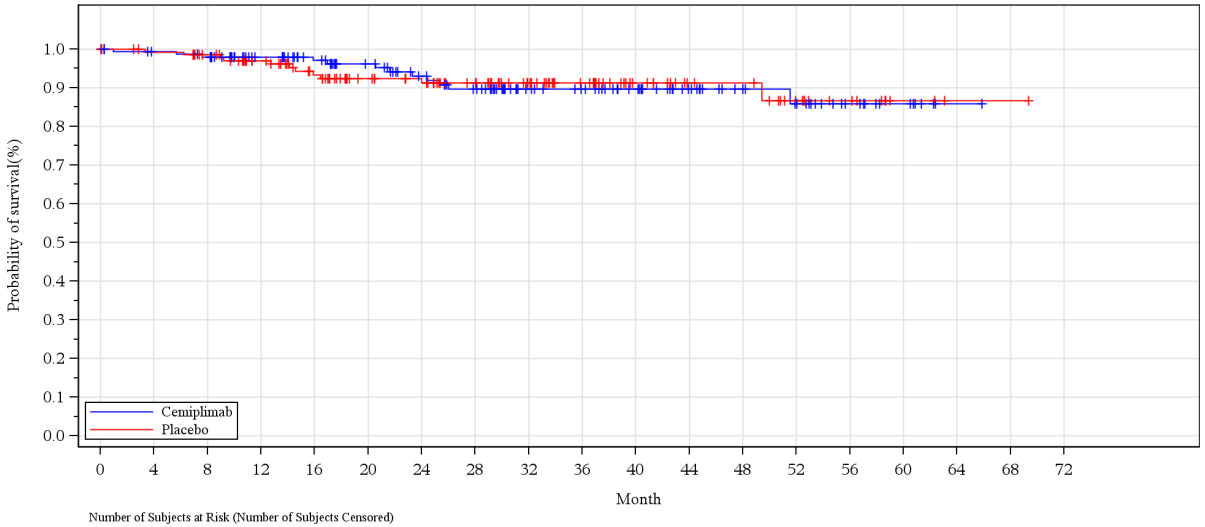
Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	147 (5)	144 (6)	123 (27)	109 (40)	97 (51)	85 (60)	77 (65)	59 (83)	54 (88)	45 (97)	33 (109)	25 (118)	21 (120)	12 (129)	7 (134)	1 (140)	0 (141)	0 (141)
Placebo	141 (0)	136 (4)	129 (10)	115 (22)	100 (33)	84 (48)	78 (53)	68 (63)	55 (76)	44 (87)	30 (101)	22 (109)	21 (110)	14 (116)	9 (121)	3 (127)	1 (129)	1 (129)	0 (130)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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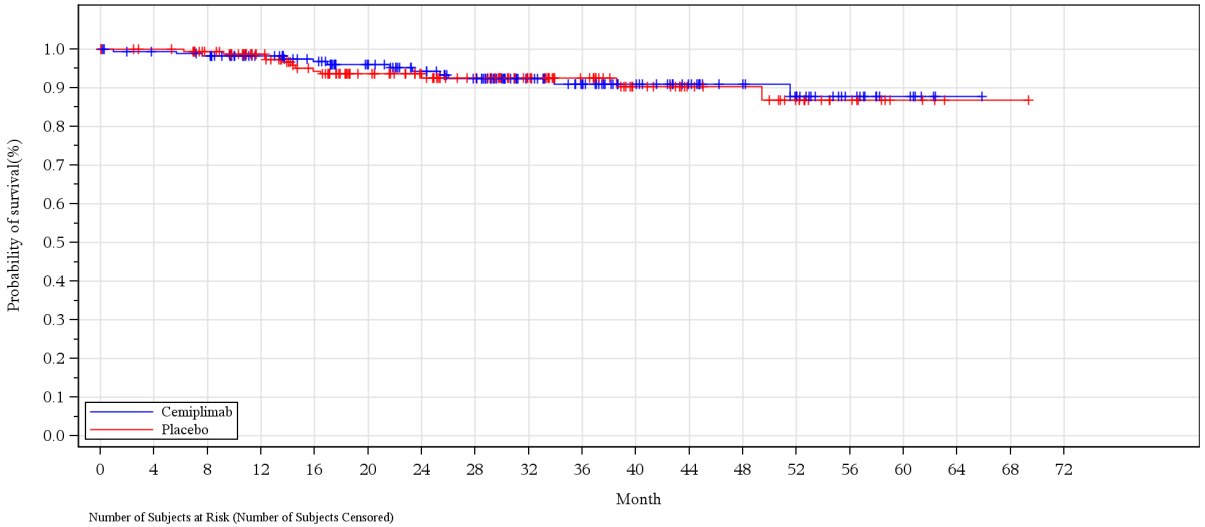
Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	168 (5)	165 (6)	145 (26)	132 (37)	118 (50)	105 (61)	95 (69)	72 (92)	61 (102)	47 (116)	37 (126)	30 (134)	24 (138)	14 (148)	7 (155)	1 (161)	0 (162)	0 (162)
Placebo	174 (0)	170 (4)	161 (12)	140 (32)	122 (44)	103 (62)	90 (74)	79 (85)	62 (102)	51 (113)	36 (127)	27 (136)	25 (138)	19 (143)	10 (152)	4 (158)	1 (161)	1 (161)	0 (162)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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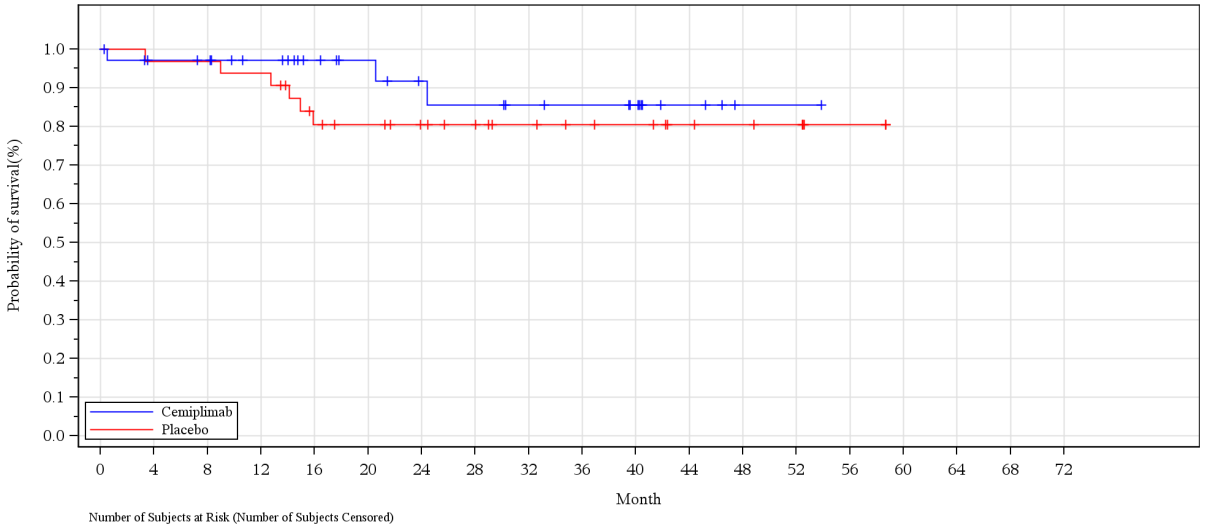
Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Gender group: Female



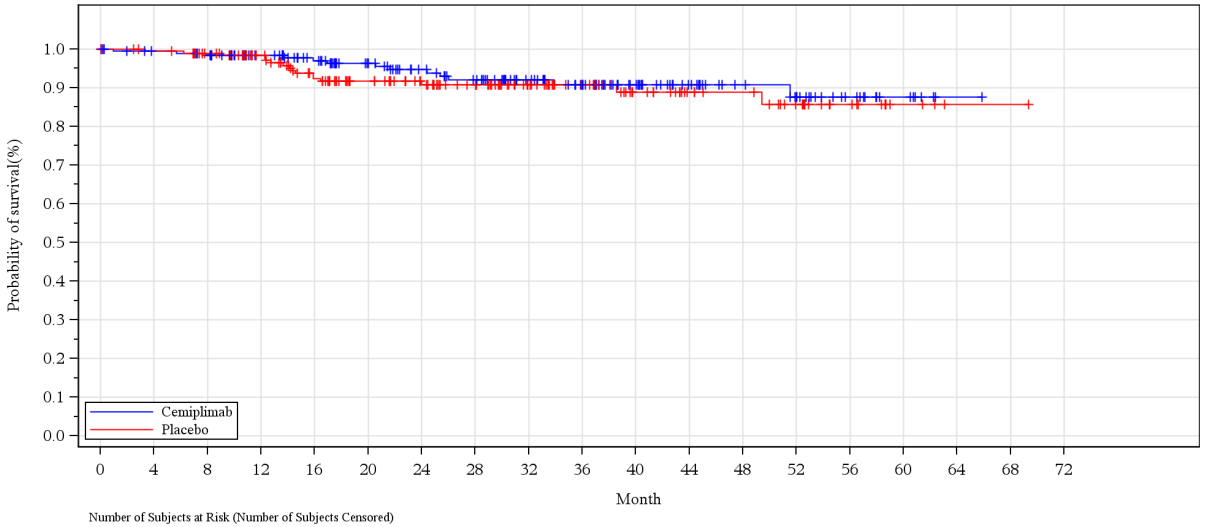
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	31 (3)	30 (4)	26 (8)	21 (13)	18 (16)	15 (18)	14 (18)	12 (20)	11 (21)	9 (23)	4 (28)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	32 (0)	31 (0)	31 (0)	30 (0)	23 (3)	21 (5)	18 (8)	16 (10)	13 (13)	11 (15)	10 (16)	7 (19)	6 (20)	5 (21)	2 (24)	0 (26)	0 (26)	0 (26)	0 (26)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	182 (6)	178 (8)	158 (28)	141 (43)	124 (59)	110 (71)	100 (78)	82 (96)	70 (107)	54 (123)	39 (138)	29 (148)	24 (152)	14 (162)	7 (169)	1 (175)	0 (176)	0 (176)
Placebo	189 (0)	184 (4)	175 (12)	155 (31)	133 (44)	115 (61)	102 (73)	90 (85)	71 (104)	58 (117)	42 (132)	32 (142)	29 (145)	22 (151)	12 (161)	4 (169)	1 (172)	1 (172)	0 (173)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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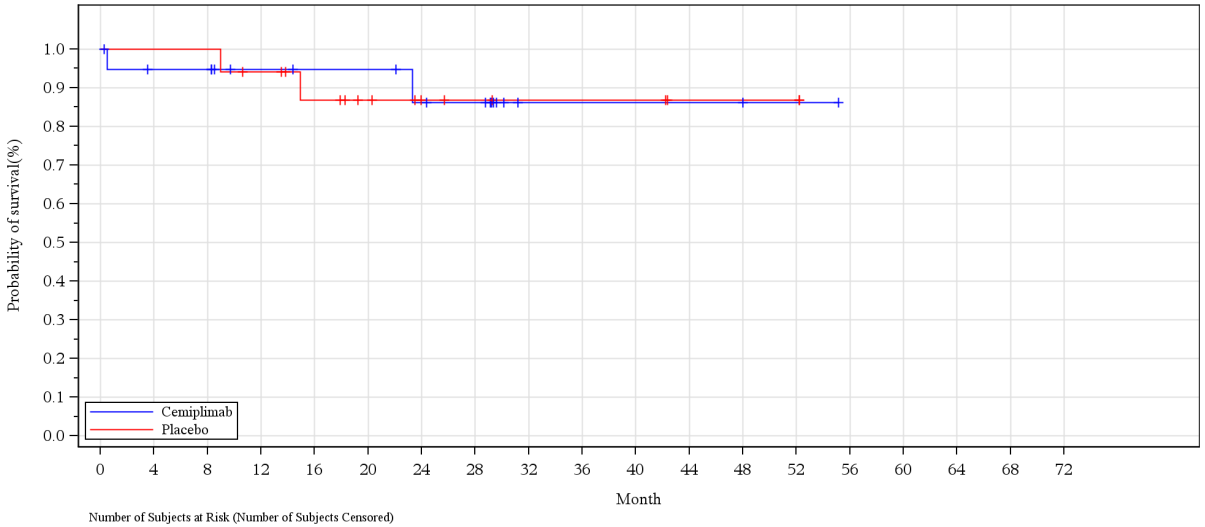
Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Race: Non-white



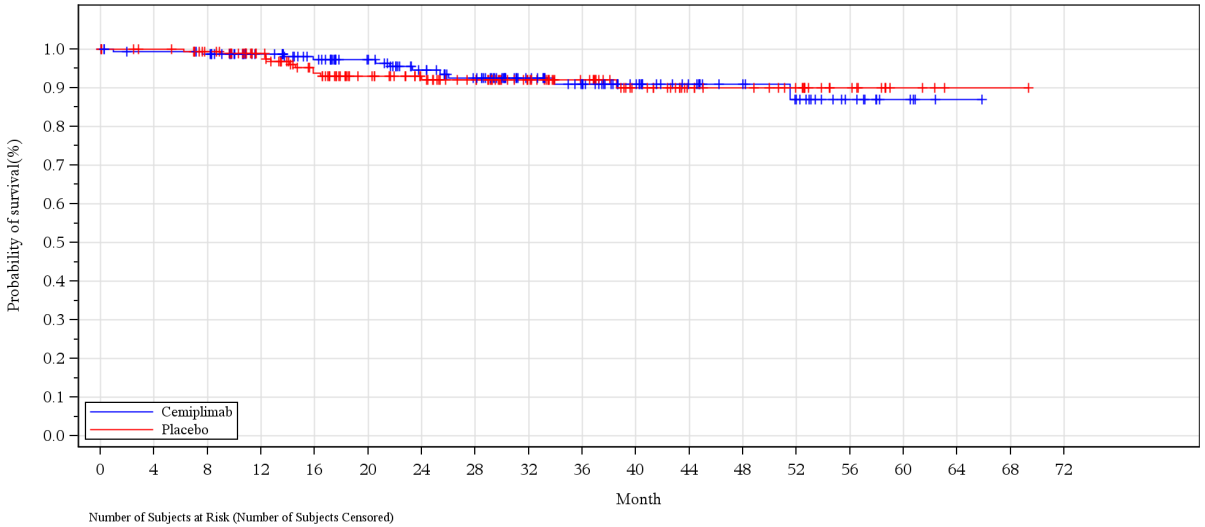
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	17 (2)	17 (2)	13 (6)	12 (7)	12 (7)	10 (8)	9 (9)	2 (16)	2 (16)	2 (16)	2 (16)	2 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	17 (0)	17 (0)	17 (0)	15 (1)	12 (3)	9 (6)	6 (9)	5 (10)	4 (11)	4 (11)	4 (11)	2 (13)	2 (13)	2 (13)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



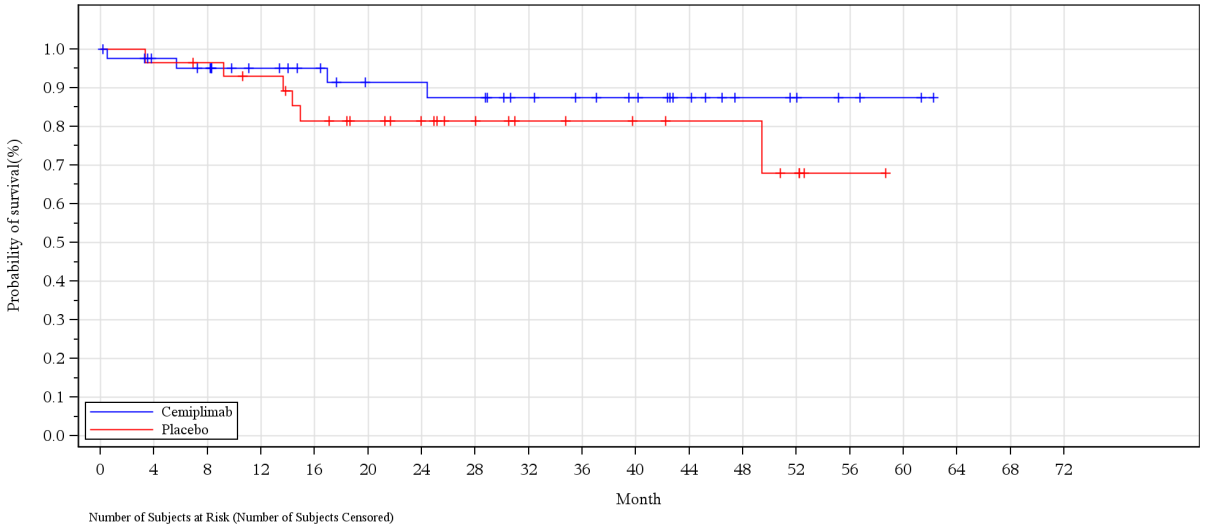
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	161 (4)	159 (5)	141 (23)	126 (36)	113 (49)	97 (62)	87 (70)	66 (91)	56 (100)	42 (114)	31 (125)	25 (132)	20 (135)	11 (144)	5 (150)	1 (154)	0 (155)	0 (155)
Placebo	177 (0)	173 (4)	165 (11)	145 (30)	124 (44)	106 (61)	93 (73)	83 (83)	66 (100)	54 (112)	39 (126)	28 (137)	25 (140)	20 (145)	11 (154)	4 (161)	1 (164)	1 (164)	0 (165)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



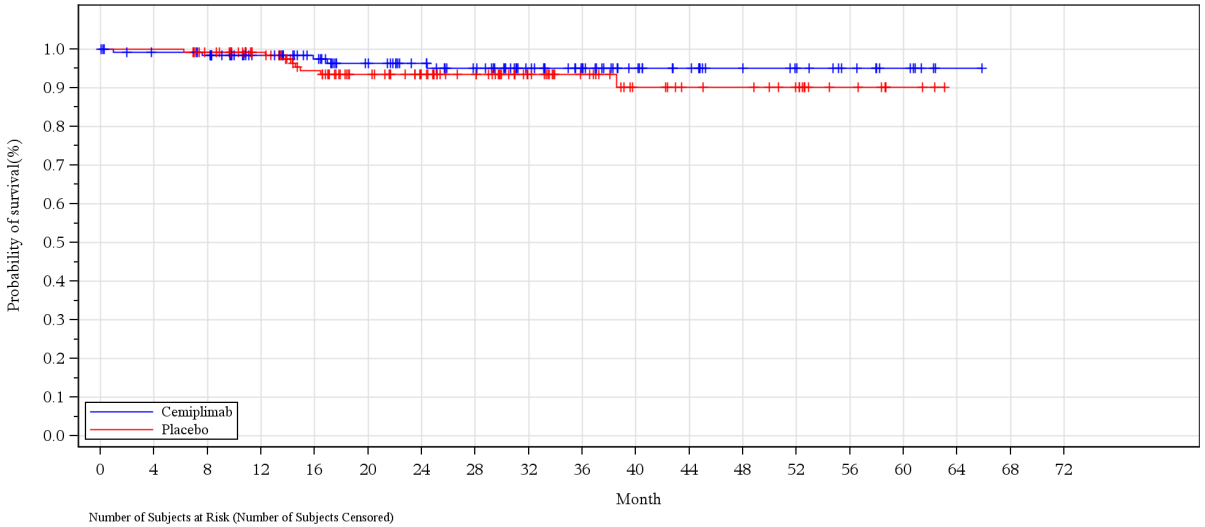
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	38 (4)	36 (5)	30 (11)	27 (14)	23 (17)	23 (17)	22 (17)	18 (21)	16 (23)	14 (25)	10 (29)	6 (33)	5 (34)	3 (36)	2 (37)	0 (39)	0 (39)	0 (39)
Placebo	29 (0)	28 (0)	27 (1)	25 (2)	21 (3)	18 (6)	15 (9)	12 (12)	9 (15)	8 (16)	7 (17)	6 (18)	6 (18)	4 (19)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 0



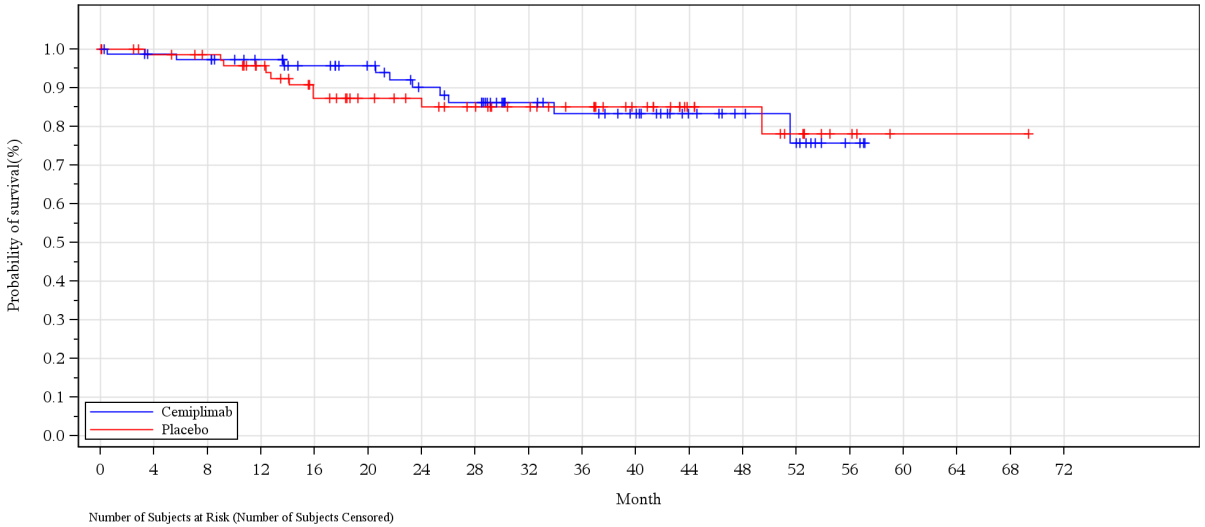
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	127 (5)	124 (7)	106 (25)	95 (35)	83 (46)	74 (55)	66 (62)	52 (76)	43 (85)	31 (97)	25 (103)	19 (110)	16 (112)	11 (117)	7 (121)	1 (127)	0 (128)	0 (128)
Placebo	131 (0)	131 (0)	125 (5)	110 (20)	95 (30)	80 (44)	68 (56)	58 (66)	43 (81)	34 (90)	24 (99)	20 (103)	19 (104)	15 (108)	8 (115)	3 (120)	0 (123)	0 (123)	0 (123)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

ECOG status: 1



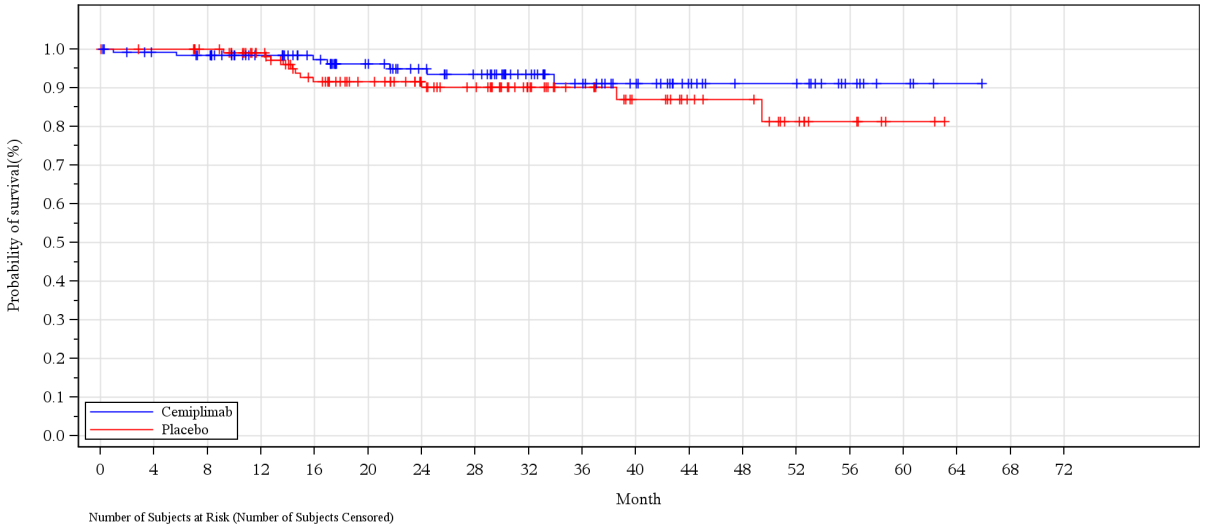
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	72 (3)	71 (3)	65 (9)	58 (15)	53 (20)	46 (24)	43 (25)	32 (36)	29 (38)	25 (42)	16 (51)	12 (55)	9 (57)	3 (63)	0 (66)	0 (66)	0 (66)	0 (66)
Placebo	75 (0)	70 (4)	67 (7)	60 (12)	50 (17)	44 (23)	40 (26)	37 (29)	32 (34)	28 (38)	22 (44)	14 (52)	12 (54)	9 (56)	4 (61)	1 (64)	1 (64)	1 (64)	0 (65)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal



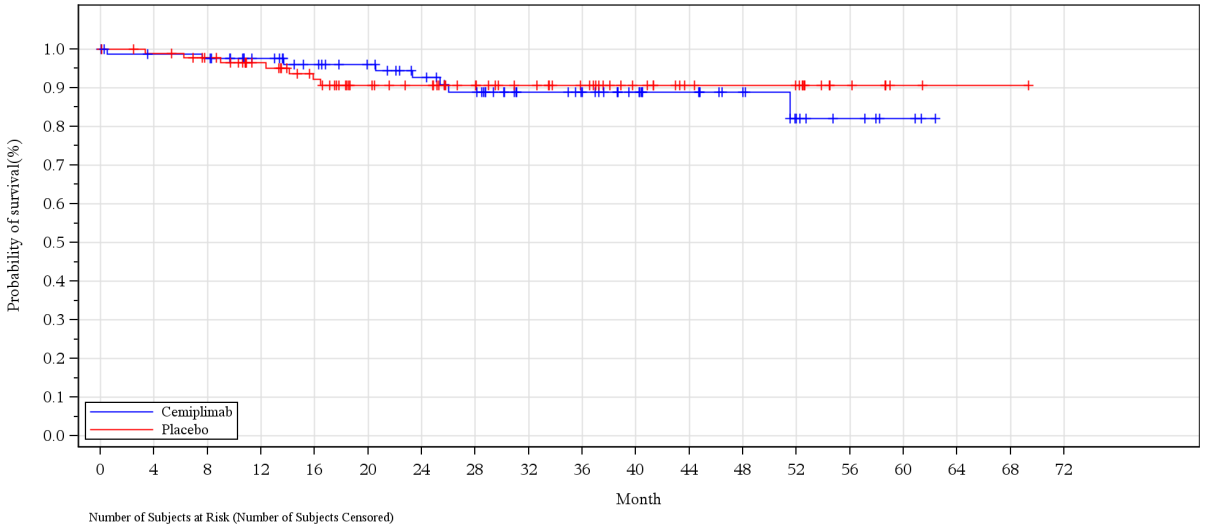
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	119 (5)	116 (7)	100 (23)	89 (33)	77 (44)	68 (52)	62 (57)	48 (71)	39 (79)	31 (87)	21 (97)	16 (102)	16 (102)	8 (110)	4 (114)	1 (117)	0 (118)	0 (118)
Placebo	117 (0)	115 (2)	111 (6)	99 (17)	83 (26)	72 (37)	60 (48)	54 (54)	40 (68)	32 (76)	24 (83)	18 (89)	16 (91)	10 (96)	6 (100)	2 (104)	0 (106)	0 (106)	0 (106)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

Figure 14.2.2.1.1 Kaplan-Meier Curve of Overall Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	80 (3)	79 (3)	71 (11)	64 (17)	59 (22)	52 (27)	47 (30)	36 (41)	33 (44)	25 (52)	20 (57)	15 (63)	9 (67)	6 (70)	3 (73)	0 (76)	0 (76)	0 (76)
Placebo	89 (0)	86 (2)	81 (6)	71 (15)	62 (21)	52 (30)	48 (34)	41 (41)	35 (47)	30 (52)	22 (60)	16 (66)	15 (67)	14 (68)	6 (76)	2 (80)	1 (81)	1 (81)	0 (82)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-os-sub.sas' (wenju.shi 24NOV2025 12:29 SAS Linux 9.4)

2.2 Krankheitsfreies Überleben

2.2.1 1. Datenschnitt

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	8 (14.3%)	21 (32.3%)
Odds ratio (95% CI)	0.337 (0.133, 0.853)	
P-value for Odds Ratio	0.0217	
Relative Risk (95% CI)	0.45 (0.22, 0.92)	
P-value for Relative Risk	0.0297	
Heterogeneity p-value of RR	0.4683	
Risk difference (95% CI)	-19.14 (-35.44, -2.84)	
P-value for Risk Difference	0.0214	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	16 (10.5%)	44 (31.2%)
Odds ratio (95% CI)	0.247 (0.130, 0.470)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.32 (0.19, 0.55)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.4683	
Risk difference (95% CI)	-20.54 (-29.64, -11.45)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(wenju.shi 22AUG2025 07:25 SAS Linux 9.4)

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	8 (14.3%)	21 (32.3%)
Odds ratio (95% CI)	0.337 (0.133, 0.853)	
P-value for Odds Ratio	0.0217	
Relative Risk (95% CI)	0.45 (0.22, 0.92)	
P-value for Relative Risk	0.0297	
Heterogeneity p-value of RR	0.7027	
Risk difference (95% CI)	-19.14 (-35.44, -2.84)	
P-value for Risk Difference	0.0214	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	9 (11.3%)	21 (30.4%)
Odds ratio (95% CI)	0.270 (0.111, 0.656)	
P-value for Odds Ratio	0.0039	
Relative Risk (95% CI)	0.36 (0.18, 0.74)	
P-value for Relative Risk	0.0053	
Heterogeneity p-value of RR	0.7027	
Risk difference (95% CI)	-20.21 (-32.70, -7.73)	
P-value for Risk Difference	0.0015	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	7 (9.6%)	23 (31.9%)
Odds ratio (95% CI)	0.201 (0.077, 0.526)	
P-value for Odds Ratio	0.0011	
Relative Risk (95% CI)	0.27 (0.12, 0.59)	
P-value for Relative Risk	0.0011	
Heterogeneity p-value of RR	0.7027	
Risk difference (95% CI)	-22.77 (-35.48, -10.07)	
P-value for Risk Difference	0.0004	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	19 (10.9%)	48 (27.6%)
Odds ratio (95% CI)	0.311 (0.173, 0.558)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.38 (0.23, 0.62)	
P-value for Relative Risk	0.0001	
Heterogeneity p-value of RR	0.4020	
Risk difference (95% CI)	-16.52 (-24.67, -8.36)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	5 (14.3%)	17 (53.1%)
Odds ratio (95% CI)	0.132 (0.038, 0.459)	
P-value for Odds Ratio	0.0015	
Relative Risk (95% CI)	0.32 (0.13, 0.77)	
P-value for Relative Risk	0.0114	
Heterogeneity p-value of RR	0.4020	
Risk difference (95% CI)	-37.81 (-63.34, -12.28)	
P-value for Risk Difference	0.0037	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	3 (8.1%)	12 (38.7%)
Odds ratio (95% CI)	0.095 (0.019, 0.473)	
P-value for Odds Ratio	0.0041	
Relative Risk (95% CI)	0.30 (0.10, 0.87)	
P-value for Relative Risk	0.0267	
Heterogeneity p-value of RR	0.1724	
Risk difference (95% CI)	-31.19 (-50.29, -12.10)	
P-value for Risk Difference	0.0014	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	29 (32.2%)
Odds ratio (95% CI)	0.202 (0.086, 0.474)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	0.27 (0.13, 0.56)	
P-value for Relative Risk	0.0004	
Heterogeneity p-value of RR	0.1724	
Risk difference (95% CI)	-23.32 (-34.62, -12.01)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(wenju.shi 22AUG2025 07:25 SAS Linux 9.4)

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	13 (15.9%)	24 (28.2%)
Odds ratio (95% CI)	0.470 (0.219, 1.009)	
P-value for Odds Ratio	0.0528	
Relative Risk (95% CI)	0.56 (0.30, 1.02)	
P-value for Relative Risk	0.0576	
Heterogeneity p-value of RR	0.1724	
Risk difference (95% CI)	-12.85 (-25.31, -0.38)	
P-value for Risk Difference	0.0434	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	22 (11.6%)	60 (31.7%)
Odds ratio (95% CI)	0.267 (0.154, 0.464)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.35 (0.23, 0.55)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.9386	
Risk difference (95% CI)	-20.70 (-28.68, -12.71)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(wenju.shi 22AUG2025 07:25 SAS Linux 9.4)

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	5 (29.4%)
Odds ratio (95% CI)	0.256 (0.036, 1.815)	
P-value for Odds Ratio	0.1729	
Relative Risk (95% CI)	0.30 (0.04, 2.14)	
P-value for Relative Risk	0.2308	
Heterogeneity p-value of RR	0.9386	
Risk difference (95% CI)	-15.03 (-15.03, -15.03)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	17 (10.2%)	54 (30.5%)
Odds ratio (95% CI)	0.261 (0.144, 0.473)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.34 (0.20, 0.56)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.6406	
Risk difference (95% CI)	-20.42 (-28.59, -12.25)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	11 (37.9%)
Odds ratio (95% CI)	0.288 (0.092, 0.900)	
P-value for Odds Ratio	0.0323	
Relative Risk (95% CI)	0.40 (0.17, 0.98)	
P-value for Relative Risk	0.0448	
Heterogeneity p-value of RR	0.6406	
Risk difference (95% CI)	-22.34 (-43.15, -1.54)	
P-value for Risk Difference	0.0353	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	12 (9.0%)	31 (23.7%)
Odds ratio (95% CI)	0.297 (0.143, 0.617)	
P-value for Odds Ratio	0.0011	
Relative Risk (95% CI)	0.35 (0.19, 0.65)	
P-value for Relative Risk	0.0009	
Heterogeneity p-value of RR	0.8724	
Risk difference (95% CI)	-14.57 (-23.82, -5.33)	
P-value for Risk Difference	0.0020	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	12 (15.8%)	34 (45.3%)
Odds ratio (95% CI)	0.223 (0.103, 0.486)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	0.35 (0.20, 0.63)	
P-value for Relative Risk	0.0004	
Heterogeneity p-value of RR	0.8724	
Risk difference (95% CI)	-29.71 (-43.68, -15.73)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	14 (11.2%)	35 (29.9%)
Odds ratio (95% CI)	0.266 (0.132, 0.537)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	0.34 (0.19, 0.59)	
P-value for Relative Risk	0.0002	
Heterogeneity p-value of RR	0.9469	
Risk difference (95% CI)	-18.69 (-28.61, -8.78)	
P-value for Risk Difference	0.0002	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	10 (11.9%)	30 (33.7%)
Odds ratio (95% CI)	0.266 (0.120, 0.591)	
P-value for Odds Ratio	0.0011	
Relative Risk (95% CI)	0.36 (0.19, 0.68)	
P-value for Relative Risk	0.0019	
Heterogeneity p-value of RR	0.9469	
Risk difference (95% CI)	-22.84 (-34.81, -10.88)	
P-value for Risk Difference	0.0002	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Number of events, n (%)	14 (9.0%)	45 (29.2%)
Odds ratio (95% CI)	0.239 (0.124, 0.459)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.31 (0.18, 0.54)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.2900	
Risk difference (95% CI)	-20.13 (-28.58, -11.69)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Number of events, n (%)	8 (19.0%)	16 (37.2%)
Odds ratio (95% CI)	0.359 (0.127, 1.017)	
P-value for Odds Ratio	0.0539	
Relative Risk (95% CI)	0.52 (0.25, 1.08)	
P-value for Relative Risk	0.0805	
Heterogeneity p-value of RR	0.2900	
Risk difference (95% CI)	-18.69 (-36.76, -0.63)	
P-value for Risk Difference	0.0425	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Number of events, n (%)	7 (18.4%)	16 (37.2%)
Odds ratio (95% CI)	0.368 (0.129, 1.056)	
P-value for Odds Ratio	0.0630	
Relative Risk (95% CI)	0.47 (0.22, 1.02)	
P-value for Relative Risk	0.0559	
Heterogeneity p-value of RR	0.4120	
Risk difference (95% CI)	-17.04 (-36.01, 1.93)	
P-value for Risk Difference	0.0783	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Number of events, n (%)	17 (9.9%)	49 (30.1%)
Odds ratio (95% CI)	0.254 (0.138, 0.466)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.33 (0.20, 0.55)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.4120	
Risk difference (95% CI)	-20.79 (-29.03, -12.55)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	8 (14.3%)	21 (32.3%)
Odds ratio (95% CI)	2.968 (1.161, 7.586)	
P-value for Odds Ratio	0.0235	
Relative Risk (95% CI)	1.26 (1.00, 1.58)	
P-value for Relative Risk	0.0466	
Heterogeneity p-value of RR	0.9424	
Risk difference (95% CI)	19.47 (2.68, 36.27)	
P-value for Risk Difference	0.0235	
Disease recurrences, n (%)	6 (10.7%)	21 (32.3%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	48 (85.7%)	44 (67.7%)
Q1 (95% CI), (months)[a]	NR (13.7, NE)	6.7 (5.0, 11.6)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (11.6, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0262	
HR (95% CI) [c][d]	0.395 (0.169, 0.921)	
Heterogeneity p-value [c][e]	0.5712	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	92.5 (81.1, 97.1)	90.4 (79.9, 95.6)
6 months	90.5 (78.6, 95.9)	78.8 (66.3, 87.1)
12 months	88.3 (75.8, 94.6)	63.7 (49.7, 74.8)
18 months	85.9 (72.5, 93.0)	63.7 (49.7, 74.8)
24 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
30 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
36 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
42 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
48 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	16 (10.5%)	44 (31.2%)
Odds ratio (95% CI)	4.049 (2.127, 7.710)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	1.30 (1.14, 1.47)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.9424	
Risk difference (95% CI)	20.54 (11.41, 29.68)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	12 (7.8%)	40 (28.4%)
Deaths, n (%)	4 (2.6%)	4 (2.8%)
Number of censored participants, n (%)	137 (89.5%)	97 (68.8%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	10.4 (5.2, 21.7)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (34.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.295 (0.165, 0.526)	
Heterogeneity p-value [c][e]	0.5712	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.2 (92.8, 98.9)	90.0 (83.4, 94.1)
6 months	95.7 (90.6, 98.0)	80.4 (72.4, 86.3)
12 months	94.0 (88.3, 97.0)	72.3 (63.3, 79.4)
18 months	92.8 (86.5, 96.3)	68.8 (59.5, 76.5)
24 months	88.8 (80.6, 93.7)	64.6 (54.5, 73.0)
30 months	85.4 (75.8, 91.4)	62.6 (52.0, 71.5)
36 months	83.4 (72.9, 90.1)	59.1 (46.8, 69.4)
42 months	80.1 (67.3, 88.3)	59.1 (46.8, 69.4)
48 months	80.1 (67.3, 88.3)	59.1 (46.8, 69.4)
54 months	80.1 (67.3, 88.3)	42.2 (21.2, 61.9)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	8 (14.3%)	21 (32.3%)
Odds ratio (95% CI)	2.968 (1.161, 7.586)	
P-value for Odds Ratio	0.0235	
Relative Risk (95% CI)	1.26 (1.00, 1.58)	
P-value for Relative Risk	0.0466	
Heterogeneity p-value of RR	0.9854	
Risk difference (95% CI)	19.47 (2.68, 36.27)	
P-value for Risk Difference	0.0235	
Disease recurrences, n (%)	6 (10.7%)	21 (32.3%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	48 (85.7%)	44 (67.7%)
Q1 (95% CI), (months)[a]	NR (13.7, NE)	6.7 (5.0, 11.6)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (11.6, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0262	
HR (95% CI) [c][d]	0.395 (0.169, 0.921)	
Heterogeneity p-value [c][e]	0.6537	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	92.5 (81.1, 97.1)	90.4 (79.9, 95.6)
6 months	90.5 (78.6, 95.9)	78.8 (66.3, 87.1)
12 months	88.3 (75.8, 94.6)	63.7 (49.7, 74.8)
18 months	85.9 (72.5, 93.0)	63.7 (49.7, 74.8)
24 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
30 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
36 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
42 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
48 months	82.6 (67.5, 91.1)	63.7 (49.7, 74.8)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	9 (11.3%)	21 (30.4%)
Odds ratio (95% CI)	3.706 (1.513, 9.074)	
P-value for Odds Ratio	0.0044	
Relative Risk (95% CI)	1.29 (1.09, 1.53)	
P-value for Relative Risk	0.0040	
Heterogeneity p-value of RR	0.9854	
Risk difference (95% CI)	20.21 (7.63, 32.80)	
P-value for Risk Difference	0.0018	
Disease recurrences, n (%)	6 (7.5%)	19 (27.5%)
Deaths, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	71 (88.8%)	48 (69.6%)
Q1 (95% CI), (months)[a]	NR (25.4, NE)	18.5 (7.3, 34.5)
Median (95% CI), (months)[a]	NR (NE, NE)	48.5 (27.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Stratified log-rank test p-value [b][c]	0.0078	
HR (95% CI) [c][d]	0.349 (0.156, 0.783)	
Heterogeneity p-value [c][e]	0.6537	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.4 (90.0, 99.3)	93.8 (84.3, 97.6)
6 months	95.9 (87.9, 98.7)	87.4 (76.4, 93.5)
12 months	94.4 (85.7, 97.9)	78.1 (65.1, 86.7)
18 months	94.4 (85.7, 97.9)	75.9 (62.5, 85.1)
24 months	89.2 (76.5, 95.2)	68.2 (53.2, 79.3)
30 months	82.7 (66.8, 91.4)	65.0 (49.3, 76.9)
36 months	82.7 (66.8, 91.4)	59.5 (41.5, 73.6)
42 months	77.2 (57.5, 88.6)	59.5 (41.5, 73.6)
48 months	77.2 (57.5, 88.6)	59.5 (41.5, 73.6)
54 months	NE (NE, NE)	35.7 (11.5, 61.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	7 (9.6%)	23 (31.9%)
Odds ratio (95% CI)	4.997 (1.890, 13.210)	
P-value for Odds Ratio	0.0013	
Relative Risk (95% CI)	1.33 (1.12, 1.59)	
P-value for Relative Risk	0.0016	
Heterogeneity p-value of RR	0.9854	
Risk difference (95% CI)	22.77 (9.96, 35.59)	
P-value for Risk Difference	0.0006	
Disease recurrences, n (%)	6 (8.2%)	21 (29.2%)
Deaths, n (%)	1 (1.4%)	2 (2.8%)
Number of censored participants, n (%)	66 (90.4%)	49 (68.1%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	5.4 (3.3, 12.7)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (17.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0006	
HR (95% CI) [c][d]	0.228 (0.092, 0.566)	
Heterogeneity p-value [c][e]	0.6537	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.0 (88.6, 99.2)	86.1 (75.0, 92.5)
6 months	95.3 (86.2, 98.5)	73.4 (60.7, 82.5)
12 months	93.5 (83.6, 97.5)	66.4 (53.2, 76.7)
18 months	91.1 (79.7, 96.3)	61.6 (47.7, 72.9)
24 months	88.4 (75.3, 94.8)	61.6 (47.7, 72.9)
30 months	88.4 (75.3, 94.8)	61.6 (47.7, 72.9)
36 months	84.0 (67.2, 92.6)	61.6 (47.7, 72.9)
42 months	84.0 (67.2, 92.6)	61.6 (47.7, 72.9)
48 months	84.0 (67.2, 92.6)	61.6 (47.7, 72.9)
54 months	84.0 (67.2, 92.6)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	19 (10.9%)	48 (27.6%)
Odds ratio (95% CI)	3.222 (1.789, 5.804)	
P-value for Odds Ratio	0.0001	
Relative Risk (95% CI)	1.23 (1.10, 1.37)	
P-value for Relative Risk	0.0002	
Heterogeneity p-value of RR	0.0205	
Risk difference (95% CI)	16.52 (8.33, 24.70)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	15 (8.6%)	46 (26.4%)
Deaths, n (%)	4 (2.3%)	2 (1.1%)
Number of censored participants, n (%)	155 (89.1%)	126 (72.4%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	10.4 (6.2, 34.5)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (48.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.336 (0.196, 0.574)	
Heterogeneity p-value [c][e]	0.7825	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.0 (92.9, 98.7)	90.7 (85.1, 94.3)
6 months	95.7 (91.1, 97.9)	82.2 (75.3, 87.4)
12 months	93.5 (88.2, 96.5)	72.6 (64.6, 79.1)
18 months	91.7 (85.8, 95.3)	71.6 (63.4, 78.2)
24 months	88.3 (80.9, 92.9)	67.9 (59.0, 75.2)
30 months	85.5 (77.0, 91.0)	67.9 (59.0, 75.2)
36 months	83.6 (74.3, 89.8)	64.9 (54.4, 73.6)
42 months	80.8 (69.7, 88.2)	64.9 (54.4, 73.6)
48 months	80.8 (69.7, 88.2)	64.9 (54.4, 73.6)
54 months	80.8 (69.7, 88.2)	47.3 (24.7, 67.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	5 (14.3%)	17 (53.1%)
Odds ratio (95% CI)	7.567 (2.124, 26.954)	
P-value for Odds Ratio	0.0023	
Heterogeneity p-value of RR	0.0205	
Risk difference (95% CI)	39.70 (13.85, 65.55)	
P-value for Risk Difference	0.0032	
Disease recurrences, n (%)	3 (8.6%)	15 (46.9%)
Deaths, n (%)	2 (5.7%)	2 (6.3%)
Number of censored participants, n (%)	30 (85.7%)	15 (46.9%)
Q1 (95% CI), (months)[a]	NR (2.2, NE)	5.2 (2.8, 9.5)
Median (95% CI), (months)[a]	NR (NE, NE)	14.1 (5.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (27.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Stratified log-rank test p-value [b][c]	0.0309	
HR (95% CI) [c][d]	0.339 (0.122, 0.947)	
Heterogeneity p-value [c][e]	0.7825	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	90.3 (72.9, 96.8)	87.5 (70.0, 95.1)
6 months	86.7 (68.3, 94.8)	68.8 (49.7, 81.8)
12 months	86.7 (68.3, 94.8)	54.8 (35.7, 70.4)
18 months	86.7 (68.3, 94.8)	46.7 (27.9, 63.5)
24 months	80.0 (56.4, 91.7)	46.7 (27.9, 63.5)
30 months	80.0 (56.4, 91.7)	40.0 (20.7, 58.7)
36 months	80.0 (56.4, 91.7)	40.0 (20.7, 58.7)
42 months	80.0 (56.4, 91.7)	40.0 (20.7, 58.7)
48 months	NE (NE, NE)	40.0 (20.7, 58.7)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	3 (8.1%)	12 (38.7%)
Odds ratio (95% CI)	10.568 (2.049, 54.502)	
P-value for Odds Ratio	0.0055	
Relative Risk (95% CI)	1.49 (1.11, 2.00)	
P-value for Relative Risk	0.0095	
Heterogeneity p-value of RR	0.2869	
Risk difference (95% CI)	31.22 (11.79, 50.66)	
P-value for Risk Difference	0.0021	
Disease recurrences, n (%)	2 (5.4%)	11 (35.5%)
Deaths, n (%)	1 (2.7%)	1 (3.2%)
Number of censored participants, n (%)	34 (91.9%)	19 (61.3%)
Q1 (95% CI), (months)[a]	NR (26.0, NE)	5.5 (1.7, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (5.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0026	
HR (95% CI) [c][d]	0.176 (0.049, 0.628)	
Heterogeneity p-value [c][e]	0.1549	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.3 (79.0, 98.5)	87.0 (68.9, 94.9)
6 months	94.3 (79.0, 98.5)	68.5 (48.0, 82.3)
12 months	94.3 (79.0, 98.5)	59.7 (38.6, 75.6)
18 months	94.3 (79.0, 98.5)	59.7 (38.6, 75.6)
24 months	94.3 (79.0, 98.5)	59.7 (38.6, 75.6)
30 months	87.0 (60.9, 96.2)	59.7 (38.6, 75.6)
36 months	87.0 (60.9, 96.2)	59.7 (38.6, 75.6)
42 months	87.0 (60.9, 96.2)	59.7 (38.6, 75.6)
48 months	87.0 (60.9, 96.2)	59.7 (38.6, 75.6)
54 months	87.0 (60.9, 96.2)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	29 (32.2%)
Odds ratio (95% CI)	4.967 (2.101, 11.743)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	1.34 (1.15, 1.57)	
P-value for Relative Risk	0.0003	
Heterogeneity p-value of RR	0.2869	
Risk difference (95% CI)	23.32 (11.93, 34.70)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	7 (7.8%)	28 (31.1%)
Deaths, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	82 (91.1%)	61 (67.8%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	9.7 (5.3, 18.5)
Median (95% CI), (months)[a]	NR (NE, NE)	48.5 (22.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.238 (0.109, 0.521)	
Heterogeneity p-value [c][e]	0.1549	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.6 (90.7, 99.4)	91.6 (83.2, 95.9)
6 months	95.1 (87.4, 98.1)	84.3 (74.5, 90.6)
12 months	95.1 (87.4, 98.1)	68.6 (56.8, 77.9)
18 months	95.1 (87.4, 98.1)	66.8 (54.7, 76.4)
24 months	88.3 (76.2, 94.5)	62.4 (49.5, 72.9)
30 months	88.3 (76.2, 94.5)	62.4 (49.5, 72.9)
36 months	85.0 (70.9, 92.7)	58.0 (43.0, 70.3)
42 months	85.0 (70.9, 92.7)	58.0 (43.0, 70.3)
48 months	85.0 (70.9, 92.7)	58.0 (43.0, 70.3)
54 months	85.0 (70.9, 92.7)	46.4 (23.0, 66.9)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	13 (15.9%)	24 (28.2%)
Odds ratio (95% CI)	2.126 (0.985, 4.588)	
P-value for Odds Ratio	0.0545	
Relative Risk (95% CI)	1.18 (1.00, 1.39)	
P-value for Relative Risk	0.0485	
Heterogeneity p-value of RR	0.2869	
Risk difference (95% CI)	12.86 (0.30, 25.41)	
P-value for Risk Difference	0.0448	
Disease recurrences, n (%)	9 (11.0%)	22 (25.9%)
Deaths, n (%)	4 (4.9%)	2 (2.4%)
Number of censored participants, n (%)	69 (84.1%)	61 (71.8%)
Q1 (95% CI), (months)[a]	37.6 (13.7, NE)	9.5 (4.4, 27.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (27.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0483	
HR (95% CI) [c][d]	0.512 (0.260, 1.007)	
Heterogeneity p-value [c][e]	0.1549	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.9 (87.1, 98.1)	89.9 (80.9, 94.8)
6 months	93.4 (84.8, 97.2)	79.5 (68.7, 86.9)
12 months	88.4 (77.9, 94.1)	73.8 (62.3, 82.2)
18 months	84.0 (71.8, 91.2)	69.9 (57.6, 79.2)
24 months	81.6 (68.6, 89.6)	67.1 (53.9, 77.2)
30 months	78.6 (64.3, 87.6)	63.1 (48.3, 74.7)
36 months	78.6 (64.3, 87.6)	63.1 (48.3, 74.7)
42 months	71.4 (50.6, 84.7)	63.1 (48.3, 74.7)
48 months	71.4 (50.6, 84.7)	63.1 (48.3, 74.7)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	22 (11.6%)	60 (31.7%)
Odds ratio (95% CI)	3.743 (2.154, 6.505)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	1.30 (1.17, 1.45)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.9932	
Risk difference (95% CI)	20.70 (12.68, 28.71)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	17 (9.0%)	56 (29.6%)
Deaths, n (%)	5 (2.6%)	4 (2.1%)
Number of censored participants, n (%)	167 (88.4%)	129 (68.3%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	9.1 (5.3, 14.1)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (48.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.311 (0.190, 0.510)	
Heterogeneity p-value [c][e]	0.7594	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.1 (92.0, 98.1)	89.2 (83.6, 93.0)
6 months	94.3 (89.6, 96.9)	79.7 (72.9, 85.0)
12 months	92.3 (87.1, 95.5)	69.6 (61.8, 76.1)
18 months	91.5 (86.0, 94.9)	67.1 (59.1, 73.9)
24 months	87.4 (80.4, 92.0)	63.8 (55.3, 71.1)
30 months	84.9 (77.0, 90.3)	62.3 (53.5, 70.0)
36 months	83.3 (74.8, 89.2)	59.9 (50.1, 68.4)
42 months	80.5 (70.0, 87.7)	59.9 (50.1, 68.4)
48 months	80.5 (70.0, 87.7)	59.9 (50.1, 68.4)
54 months	80.5 (70.0, 87.7)	47.2 (29.4, 63.1)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	5 (29.4%)
Odds ratio (95% CI)	3.902 (0.510, 29.841)	
P-value for Odds Ratio	0.1824	
Relative Risk (95% CI)	1.18 (0.78, 1.80)	
P-value for Relative Risk	0.4236	
Heterogeneity p-value of RR	0.9932	
Risk difference (95% CI)	14.21 (-14.70, 43.13)	
P-value for Risk Difference	0.3242	
Disease recurrences, n (%)	1 (5.0%)	5 (29.4%)
Deaths, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	18 (90.0%)	12 (70.6%)
Q1 (95% CI), (months)[a]	NR (0.5, NE)	9.5 (4.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (6.4, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.3382	
HR (95% CI) [c][d]	0.407 (0.063, 2.636)	
Heterogeneity p-value [c][e]	0.7594	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.4 (66.6, 99.2)	100 (100, 100)
6 months	94.4 (66.6, 99.2)	82.4 (54.7, 93.9)
12 months	94.4 (66.6, 99.2)	69.1 (40.7, 85.9)
18 months	85.9 (52.9, 96.4)	69.1 (40.7, 85.9)
24 months	85.9 (52.9, 96.4)	69.1 (40.7, 85.9)
30 months	85.9 (52.9, 96.4)	69.1 (40.7, 85.9)
36 months	85.9 (52.9, 96.4)	69.1 (40.7, 85.9)
42 months	85.9 (52.9, 96.4)	NE (NE, NE)
48 months	85.9 (52.9, 96.4)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	17 (10.2%)	54 (30.5%)
Odds ratio (95% CI)	3.841 (2.113, 6.983)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	1.30 (1.16, 1.45)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.7674	
Risk difference (95% CI)	20.42 (12.22, 28.62)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	12 (7.2%)	51 (28.8%)
Deaths, n (%)	5 (3.0%)	3 (1.7%)
Number of censored participants, n (%)	149 (89.8%)	123 (69.5%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	9.7 (5.4, 17.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.283 (0.164, 0.489)	
Heterogeneity p-value [c][e]	0.4345	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (93.4, 99.0)	90.9 (85.4, 94.4)
6 months	96.8 (92.5, 98.7)	80.8 (73.8, 86.1)
12 months	95.4 (90.5, 97.8)	70.6 (62.5, 77.2)
18 months	93.5 (87.7, 96.6)	67.8 (59.4, 74.8)
24 months	88.6 (80.7, 93.4)	64.2 (55.3, 71.8)
30 months	85.5 (76.3, 91.3)	62.5 (53.2, 70.5)
36 months	83.4 (73.3, 90.0)	59.8 (49.3, 68.8)
42 months	80.1 (67.6, 88.2)	59.8 (49.3, 68.8)
48 months	80.1 (67.6, 88.2)	59.8 (49.3, 68.8)
54 months	80.1 (67.6, 88.2)	52.3 (35.2, 66.9)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	11 (37.9%)
Odds ratio (95% CI)	3.475 (1.088, 11.095)	
P-value for Odds Ratio	0.0359	
Relative Risk (95% CI)	1.35 (0.98, 1.85)	
P-value for Relative Risk	0.0623	
Heterogeneity p-value of RR	0.7674	
Risk difference (95% CI)	22.34 (1.15, 43.52)	
P-value for Risk Difference	0.0391	
Disease recurrences, n (%)	6 (14.0%)	10 (34.5%)
Deaths, n (%)	1 (2.3%)	1 (3.4%)
Number of censored participants, n (%)	36 (83.7%)	18 (62.1%)
Q1 (95% CI), (months)[a]	NR (2.2, NE)	6.0 (2.4, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (6.4, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.1179	
HR (95% CI) [c][d]	0.475 (0.183, 1.233)	
Heterogeneity p-value [c][e]	0.4345	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	89.5 (74.3, 95.9)	85.7 (66.3, 94.4)
6 months	83.4 (66.6, 92.2)	75.0 (54.6, 87.2)
12 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
18 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
24 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
30 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
36 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
42 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
48 months	79.9 (62.2, 90.0)	63.5 (42.7, 78.5)
54 months	79.9 (62.2, 90.0)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	12 (9.0%)	31 (23.7%)
Odds ratio (95% CI)	3.376 (1.621, 7.032)	
P-value for Odds Ratio	0.0012	
Relative Risk (95% CI)	1.20 (1.06, 1.36)	
P-value for Relative Risk	0.0045	
Heterogeneity p-value of RR	0.0526	
Risk difference (95% CI)	14.57 (5.29, 23.86)	
P-value for Risk Difference	0.0022	
Disease recurrences, n (%)	11 (8.3%)	30 (22.9%)
Deaths, n (%)	1 (0.8%)	1 (0.8%)
Number of censored participants, n (%)	121 (91.0%)	100 (76.3%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	10.8 (6.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0011	
HR (95% CI) [c][d]	0.343 (0.175, 0.671)	
Heterogeneity p-value [c][e]	0.6152	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.6 (92.7, 99.2)	94.4 (88.5, 97.3)
6 months	95.8 (90.1, 98.2)	85.0 (77.3, 90.3)
12 months	92.8 (86.0, 96.3)	74.6 (65.4, 81.6)
18 months	92.8 (86.0, 96.3)	74.6 (65.4, 81.6)
24 months	89.6 (81.0, 94.4)	71.2 (61.2, 79.1)
30 months	89.6 (81.0, 94.4)	71.2 (61.2, 79.1)
36 months	86.7 (75.5, 93.0)	71.2 (61.2, 79.1)
42 months	82.1 (66.5, 90.9)	71.2 (61.2, 79.1)
48 months	82.1 (66.5, 90.9)	71.2 (61.2, 79.1)
54 months	82.1 (66.5, 90.9)	71.2 (61.2, 79.1)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	12 (15.8%)	34 (45.3%)
Odds ratio (95% CI)	4.478 (2.045, 9.803)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	1.55 (1.23, 1.95)	
P-value for Relative Risk	0.0002	
Heterogeneity p-value of RR	0.0526	
Risk difference (95% CI)	29.71 (15.61, 43.80)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	7 (9.2%)	31 (41.3%)
Deaths, n (%)	5 (6.6%)	3 (4.0%)
Number of censored participants, n (%)	64 (84.2%)	41 (54.7%)
Q1 (95% CI), (months)[a]	NR (20.6, NE)	5.1 (2.8, 9.7)
Median (95% CI), (months)[a]	NR (NE, NE)	27.1 (10.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Q3 (95% CI), (months)[a]	NR (NE, NE)	48.5 (48.5, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.285 (0.147, 0.556)	
Heterogeneity p-value [c][e]	0.6152	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	93.2 (84.3, 97.1)	82.7 (71.6, 89.8)
6 months	91.7 (82.5, 96.2)	70.9 (58.5, 80.1)
12 months	91.7 (82.5, 96.2)	60.8 (47.8, 71.5)
18 months	87.9 (77.0, 93.8)	54.9 (41.7, 66.4)
24 months	83.1 (70.2, 90.8)	52.2 (38.6, 64.2)
30 months	77.3 (62.3, 86.9)	49.3 (35.4, 61.8)
36 months	77.3 (62.3, 86.9)	44.4 (29.0, 58.6)
42 months	77.3 (62.3, 86.9)	44.4 (29.0, 58.6)
48 months	77.3 (62.3, 86.9)	44.4 (29.0, 58.6)
54 months	77.3 (62.3, 86.9)	0.0 (NE, NE)
60 months	NE (NE, NE)	0.0 (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	14 (11.2%)	35 (29.9%)
Odds ratio (95% CI)	3.759 (1.857, 7.612)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	1.26 (1.10, 1.44)	
P-value for Relative Risk	0.0007	
Heterogeneity p-value of RR	0.5888	
Risk difference (95% CI)	18.69 (8.73, 28.66)	
P-value for Risk Difference	0.0003	
Disease recurrences, n (%)	13 (10.4%)	33 (28.2%)
Deaths, n (%)	1 (0.8%)	2 (1.7%)
Number of censored participants, n (%)	111 (88.8%)	82 (70.1%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	9.4 (5.3, 48.5)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (48.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0008	
HR (95% CI) [c][d]	0.359 (0.192, 0.671)	
Heterogeneity p-value [c][e]	0.6041	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.0 (87.8, 97.1)	91.9 (85.0, 95.7)
6 months	91.1 (84.2, 95.1)	79.9 (71.1, 86.3)
12 months	90.2 (82.9, 94.4)	71.2 (61.3, 79.0)
18 months	90.2 (82.9, 94.4)	68.5 (58.2, 76.7)
24 months	86.7 (77.7, 92.3)	66.7 (56.1, 75.3)
30 months	86.7 (77.7, 92.3)	66.7 (56.1, 75.3)
36 months	83.6 (72.0, 90.7)	66.7 (56.1, 75.3)
42 months	83.6 (72.0, 90.7)	66.7 (56.1, 75.3)
48 months	83.6 (72.0, 90.7)	66.7 (56.1, 75.3)
54 months	83.6 (72.0, 90.7)	45.7 (20.5, 68.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	10 (11.9%)	30 (33.7%)
Odds ratio (95% CI)	3.763 (1.684, 8.408)	
P-value for Odds Ratio	0.0014	
Relative Risk (95% CI)	1.36 (1.15, 1.60)	
P-value for Relative Risk	0.0004	
Heterogeneity p-value of RR	0.5888	
Risk difference (95% CI)	22.84 (10.79, 34.89)	
P-value for Risk Difference	0.0003	
Disease recurrences, n (%)	5 (6.0%)	28 (31.5%)
Deaths, n (%)	5 (6.0%)	2 (2.2%)
Number of censored participants, n (%)	74 (88.1%)	59 (66.3%)
Q1 (95% CI), (months)[a]	NR (25.4, NE)	7.2 (3.8, 18.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (22.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0002	
HR (95% CI) [c][d]	0.271 (0.132, 0.559)	
Heterogeneity p-value [c][e]	0.6041	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.6, 99.8)	87.9 (78.7, 93.3)
6 months	98.8 (91.6, 99.8)	80.1 (69.6, 87.3)
12 months	95.7 (87.2, 98.6)	67.3 (55.4, 76.7)
18 months	92.1 (81.9, 96.7)	65.4 (53.2, 75.1)
24 months	87.7 (75.6, 94.1)	60.3 (47.0, 71.2)
30 months	82.7 (68.7, 90.8)	56.9 (42.7, 68.8)
36 months	82.7 (68.7, 90.8)	51.8 (35.5, 65.8)
42 months	78.1 (61.0, 88.3)	51.8 (35.5, 65.8)
48 months	78.1 (61.0, 88.3)	51.8 (35.5, 65.8)
54 months	78.1 (61.0, 88.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Number of events, n (%)	14 (9.0%)	45 (29.2%)
Odds ratio (95% CI)	4.201 (2.178, 8.102)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	1.29 (1.15, 1.44)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.9455	
Risk difference (95% CI)	20.13 (11.65, 28.62)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	9 (5.8%)	42 (27.3%)
Deaths, n (%)	5 (3.2%)	3 (1.9%)
Number of censored participants, n (%)	141 (91.0%)	109 (70.8%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	9.7 (5.5, 34.5)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (48.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.281 (0.154, 0.515)	
Heterogeneity p-value [c][e]	0.4310	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.6 (92.0, 98.6)	89.6 (83.3, 93.6)
6 months	96.6 (92.0, 98.6)	80.9 (73.4, 86.5)
12 months	95.0 (89.8, 97.6)	70.2 (61.6, 77.3)
18 months	92.9 (86.7, 96.3)	69.2 (60.4, 76.4)
24 months	90.4 (83.1, 94.7)	67.9 (59.0, 75.4)
30 months	86.9 (77.6, 92.5)	67.9 (59.0, 75.4)
36 months	84.4 (73.6, 91.1)	64.5 (53.4, 73.7)
42 months	84.4 (73.6, 91.1)	64.5 (53.4, 73.7)
48 months	84.4 (73.6, 91.1)	64.5 (53.4, 73.7)
54 months	84.4 (73.6, 91.1)	46.1 (23.1, 66.4)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Number of events, n (%)	8 (19.0%)	16 (37.2%)
Odds ratio (95% CI)	2.783 (0.968, 8.006)	
P-value for Odds Ratio	0.0574	
Heterogeneity p-value of RR	0.9455	
Risk difference (95% CI)	19.20 (1.03, 37.37)	
P-value for Risk Difference	0.0387	
Disease recurrences, n (%)	7 (16.7%)	15 (34.9%)
Deaths, n (%)	1 (2.4%)	1 (2.3%)
Number of censored participants, n (%)	34 (81.0%)	27 (62.8%)
Q1 (95% CI), (months)[a]	37.6 (5.6, NE)	6.4 (3.3, 17.1)
Median (95% CI), (months)[a]	NR (37.6, NE)	27.1 (14.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Stratified log-rank test p-value [b][c]	0.0181	
HR (95% CI) [c][d]	0.324 (0.122, 0.860)	
Heterogeneity p-value [c][e]	0.4310	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.7 (80.6, 98.7)	90.2 (75.9, 96.2)
6 months	89.1 (73.4, 95.8)	77.5 (61.2, 87.6)
12 months	85.7 (68.7, 93.8)	68.8 (51.4, 81.0)
18 months	85.7 (68.7, 93.8)	60.1 (41.0, 74.8)
24 months	75.6 (54.0, 88.1)	54.1 (33.6, 70.7)
30 months	75.6 (54.0, 88.1)	47.3 (26.0, 66.0)
36 months	75.6 (54.0, 88.1)	47.3 (26.0, 66.0)
42 months	66.1 (38.8, 83.5)	47.3 (26.0, 66.0)
48 months	66.1 (38.8, 83.5)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Number of events, n (%)	7 (18.4%)	16 (37.2%)
Odds ratio (95% CI)	2.714 (0.931, 7.908)	
P-value for Odds Ratio	0.0669	
Relative Risk (95% CI)	1.25 (0.94, 1.66)	
P-value for Relative Risk	0.1202	
Heterogeneity p-value of RR	0.9882	
Risk difference (95% CI)	17.04 (-2.24, 36.31)	
P-value for Risk Difference	0.0824	
Disease recurrences, n (%)	6 (15.8%)	15 (34.9%)
Deaths, n (%)	1 (2.6%)	1 (2.3%)
Number of censored participants, n (%)	31 (81.6%)	27 (62.8%)
Q1 (95% CI), (months)[a]	NR (5.2, NE)	6.4 (1.9, 48.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0692	
HR (95% CI) [c][d]	0.443 (0.180, 1.091)	
Heterogeneity p-value [c][e]	0.3578	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	92.1 (77.5, 97.4)	85.7 (70.9, 93.3)
6 months	89.3 (74.0, 95.9)	76.2 (60.3, 86.4)
12 months	89.3 (74.0, 95.9)	71.4 (55.2, 82.6)
18 months	86.4 (70.4, 94.1)	71.4 (55.2, 82.6)
24 months	83.6 (66.9, 92.3)	68.8 (52.3, 80.5)
30 months	83.6 (66.9, 92.3)	68.8 (52.3, 80.5)
36 months	80.7 (63.6, 90.3)	65.9 (49.2, 78.3)
42 months	80.7 (63.6, 90.3)	65.9 (49.2, 78.3)
48 months	80.7 (63.6, 90.3)	65.9 (49.2, 78.3)
54 months	80.7 (63.6, 90.3)	51.9 (29.9, 70.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Number of events, n (%)	17 (9.9%)	49 (30.1%)
Odds ratio (95% CI)	3.949 (2.143, 7.276)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	1.30 (1.16, 1.45)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.9882	
Risk difference (95% CI)	20.79 (12.51, 29.06)	
P-value for Risk Difference	<0.0001	
Disease recurrences, n (%)	12 (7.0%)	46 (28.2%)
Deaths, n (%)	5 (2.9%)	3 (1.8%)
Number of censored participants, n (%)	154 (90.1%)	114 (69.9%)
Q1 (95% CI), (months)[a]	37.6 (26.0, NE)	9.4 (5.4, 12.7)
Median (95% CI), (months)[a]	NR (37.6, NE)	NR (27.1, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.252 (0.141, 0.451)	
Heterogeneity p-value [c][e]	0.3578	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.9 (92.6, 98.7)	91.4 (85.6, 94.9)
6 months	95.5 (90.7, 97.8)	80.9 (73.6, 86.4)
12 months	93.2 (87.6, 96.3)	68.4 (59.7, 75.6)
18 months	92.0 (85.9, 95.6)	65.0 (55.8, 72.7)
24 months	87.7 (79.3, 92.8)	61.7 (51.8, 70.2)
30 months	83.6 (73.2, 90.2)	58.6 (47.4, 68.3)
36 months	83.6 (73.2, 90.2)	58.6 (47.4, 68.3)
42 months	69.7 (36.4, 87.9)	58.6 (47.4, 68.3)
48 months	NE (NE, NE)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	8 (14.3%)	21 (32.3%)
Disease recurrences, n (%)	6 (10.7%)	21 (32.3%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	48 (85.7%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.1784	
Hazard ratio(interaction)	1.736 (0.777, 3.876)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	16 (10.5%)	44 (31.2%)
Disease recurrences, n (%)	12 (7.8%)	40 (28.4%)
Deaths, n (%)	4 (2.6%)	4 (2.8%)
Number of censored participants, n (%)	137 (89.5%)	97 (68.8%)
Proportionality Test p-value[a][b]	0.3055	
Hazard ratio(interaction)	0.747 (0.427, 1.305)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	8 (14.3%)	21 (32.3%)
Disease recurrences, n (%)	6 (10.7%)	21 (32.3%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	48 (85.7%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.1784	
Hazard ratio(interaction)	1.736 (0.777, 3.876)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	9 (11.3%)	21 (30.4%)
Disease recurrences, n (%)	6 (7.5%)	19 (27.5%)
Deaths, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	71 (88.8%)	48 (69.6%)
Proportionality Test p-value[a][b]	0.7463	
Hazard ratio(interaction)	0.876 (0.391, 1.958)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	7 (9.6%)	23 (31.9%)
Disease recurrences, n (%)	6 (8.2%)	21 (29.2%)
Deaths, n (%)	1 (1.4%)	2 (2.8%)
Number of censored participants, n (%)	66 (90.4%)	49 (68.1%)
Proportionality Test p-value[a][b]	0.3184	
Hazard ratio(interaction)	0.597 (0.217, 1.644)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	19 (10.9%)	48 (27.6%)
Disease recurrences, n (%)	15 (8.6%)	46 (26.4%)
Deaths, n (%)	4 (2.3%)	2 (1.1%)
Number of censored participants, n (%)	155 (89.1%)	126 (72.4%)
Proportionality Test p-value[a][b]	0.3224	
Hazard ratio(interaction)	0.770 (0.459, 1.292)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	5 (14.3%)	17 (53.1%)
Disease recurrences, n (%)	3 (8.6%)	15 (46.9%)
Deaths, n (%)	2 (5.7%)	2 (6.3%)
Number of censored participants, n (%)	30 (85.7%)	15 (46.9%)
Proportionality Test p-value[a][b]	0.1896	
Hazard ratio(interaction)	2.174 (0.681, 6.938)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	3 (8.1%)	12 (38.7%)
Disease recurrences, n (%)	2 (5.4%)	11 (35.5%)
Deaths, n (%)	1 (2.7%)	1 (3.2%)
Number of censored participants, n (%)	34 (91.9%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.7849	
Hazard ratio(interaction)	1.163 (0.393, 3.445)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	29 (32.2%)
Disease recurrences, n (%)	7 (7.8%)	28 (31.1%)
Deaths, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	82 (91.1%)	61 (67.8%)
Proportionality Test p-value[a][b]	0.8097	
Hazard ratio(interaction)	0.903 (0.393, 2.076)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	13 (15.9%)	24 (28.2%)
Disease recurrences, n (%)	9 (11.0%)	22 (25.9%)
Deaths, n (%)	4 (4.9%)	2 (2.4%)
Number of censored participants, n (%)	69 (84.1%)	61 (71.8%)
Proportionality Test p-value[a][b]	0.8956	
Hazard ratio(interaction)	0.959 (0.512, 1.797)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	22 (11.6%)	60 (31.7%)
Disease recurrences, n (%)	17 (9.0%)	56 (29.6%)
Deaths, n (%)	5 (2.6%)	4 (2.1%)
Number of censored participants, n (%)	167 (88.4%)	129 (68.3%)
Proportionality Test p-value[a][b]	0.6251	
Hazard ratio(interaction)	0.892 (0.563, 1.412)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	5 (29.4%)
Disease recurrences, n (%)	1 (5.0%)	5 (29.4%)
Deaths, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	18 (90.0%)	12 (70.6%)
Proportionality Test p-value[a][b]	0.1591	
Hazard ratio(interaction)	3.162 (0.637, 15.696)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	17 (10.2%)	54 (30.5%)
Disease recurrences, n (%)	12 (7.2%)	51 (28.8%)
Deaths, n (%)	5 (3.0%)	3 (1.7%)
Number of censored participants, n (%)	149 (89.8%)	123 (69.5%)
Proportionality Test p-value[a][b]	0.2134	
Hazard ratio(interaction)	0.698 (0.396, 1.230)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	11 (37.9%)
Disease recurrences, n (%)	6 (14.0%)	10 (34.5%)
Deaths, n (%)	1 (2.3%)	1 (3.4%)
Number of censored participants, n (%)	36 (83.7%)	18 (62.1%)
Proportionality Test p-value[a][b]	0.1436	
Hazard ratio(interaction)	2.515 (0.731, 8.660)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	12 (9.0%)	31 (23.7%)
Disease recurrences, n (%)	11 (8.3%)	30 (22.9%)
Deaths, n (%)	1 (0.8%)	1 (0.8%)
Number of censored participants, n (%)	121 (91.0%)	100 (76.3%)
Proportionality Test p-value[a][b]	0.3498	
Hazard ratio(interaction)	0.680 (0.303, 1.527)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	12 (15.8%)	34 (45.3%)
Disease recurrences, n (%)	7 (9.2%)	31 (41.3%)
Deaths, n (%)	5 (6.6%)	3 (4.0%)
Number of censored participants, n (%)	64 (84.2%)	41 (54.7%)
Proportionality Test p-value[a][b]	0.5449	
Hazard ratio(interaction)	1.184 (0.686, 2.044)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	14 (11.2%)	35 (29.9%)
Disease recurrences, n (%)	13 (10.4%)	33 (28.2%)
Deaths, n (%)	1 (0.8%)	2 (1.7%)
Number of censored participants, n (%)	111 (88.8%)	82 (70.1%)
Proportionality Test p-value[a][b]	0.1345	
Hazard ratio(interaction)	1.692 (0.850, 3.370)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	10 (11.9%)	30 (33.7%)
Disease recurrences, n (%)	5 (6.0%)	28 (31.5%)
Deaths, n (%)	5 (6.0%)	2 (2.2%)
Number of censored participants, n (%)	74 (88.1%)	59 (66.3%)
Proportionality Test p-value[a][b]	0.0876	
Hazard ratio(interaction)	0.465 (0.193, 1.119)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Number of events, n (%)	14 (9.0%)	45 (29.2%)
Disease recurrences, n (%)	9 (5.8%)	42 (27.3%)
Deaths, n (%)	5 (3.2%)	3 (1.9%)
Number of censored participants, n (%)	141 (91.0%)	109 (70.8%)
Proportionality Test p-value[a][b]	0.7037	
Hazard ratio(interaction)	0.892 (0.495, 1.609)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Number of events, n (%)	8 (19.0%)	16 (37.2%)
Disease recurrences, n (%)	7 (16.7%)	15 (34.9%)
Deaths, n (%)	1 (2.4%)	1 (2.3%)
Number of censored participants, n (%)	34 (81.0%)	27 (62.8%)
Proportionality Test p-value[a][b]	0.8401	
Hazard ratio(interaction)	0.912 (0.373, 2.232)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Number of events, n (%)	7 (18.4%)	16 (37.2%)
Disease recurrences, n (%)	6 (15.8%)	15 (34.9%)
Deaths, n (%)	1 (2.6%)	1 (2.3%)
Number of censored participants, n (%)	31 (81.6%)	27 (62.8%)
Proportionality Test p-value[a][b]	0.7775	
Hazard ratio(interaction)	1.095 (0.582, 2.062)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

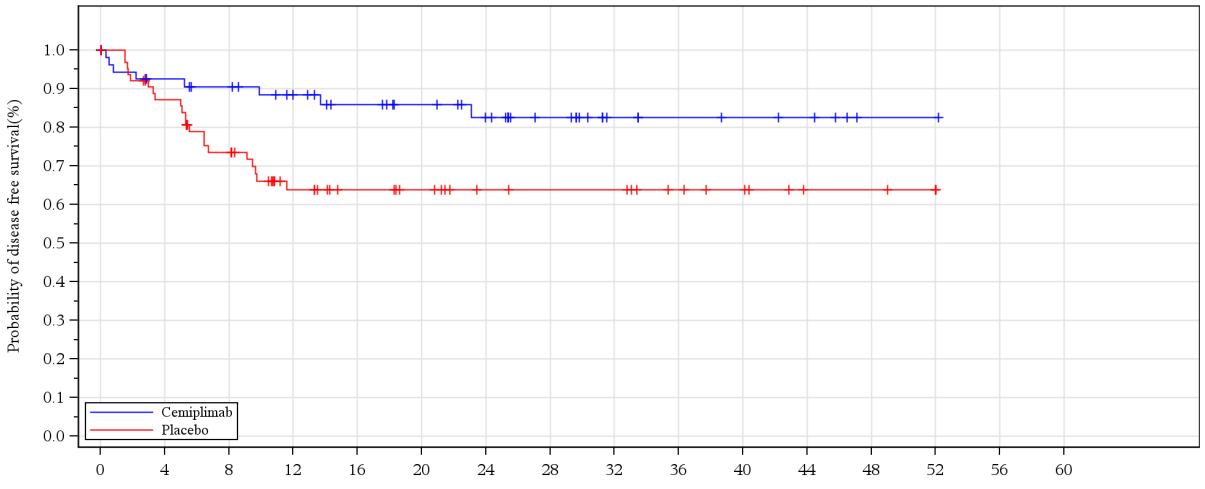
Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Number of events, n (%)	17 (9.9%)	49 (30.1%)
Disease recurrences, n (%)	12 (7.0%)	46 (28.2%)
Deaths, n (%)	5 (2.9%)	3 (1.8%)
Number of censored participants, n (%)	154 (90.1%)	114 (69.9%)
Proportionality Test p-value[a][b]	0.9394	
Hazard ratio(interaction)	1.025 (0.537, 1.956)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65



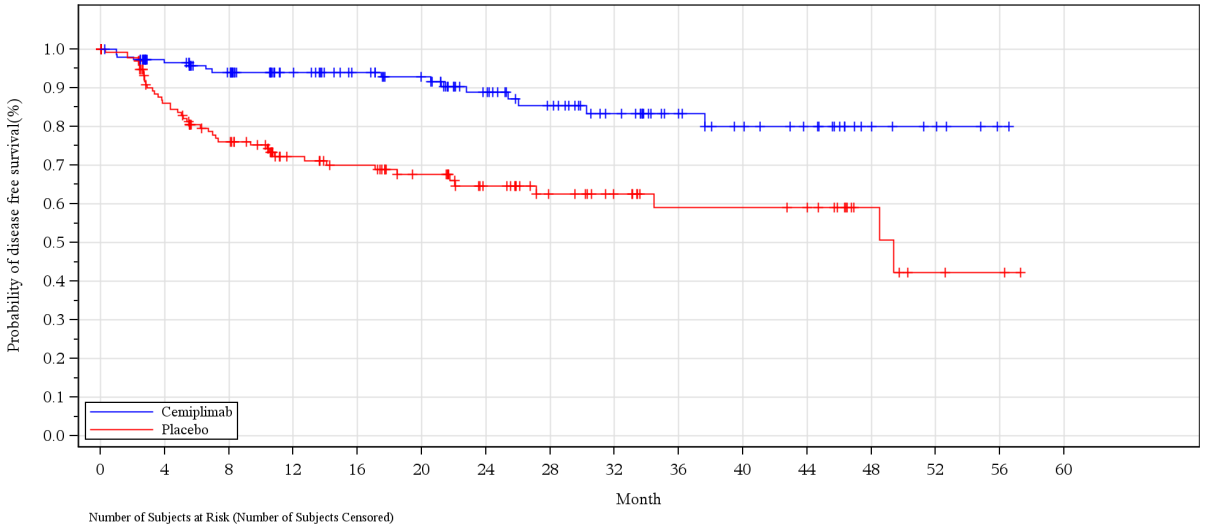
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	47 (5)	44 (7)	38 (12)	33 (16)	29 (20)	24 (24)	17 (31)	9 (39)	7 (41)	6 (42)	5 (43)	1 (47)	1 (47)	0 (48)	0 (48)
Placebo	65 (0)	53 (4)	42 (7)	28 (16)	22 (22)	19 (25)	14 (30)	13 (31)	13 (31)	9 (35)	7 (37)	3 (41)	3 (41)	1 (43)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65



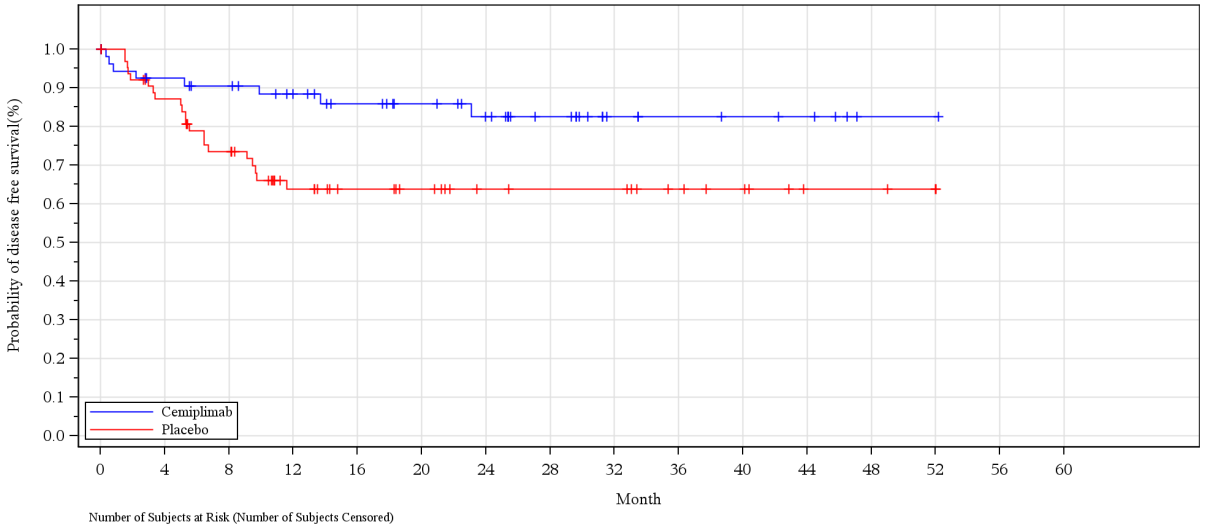
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	125 (23)	113 (32)	94 (51)	83 (62)	75 (69)	59 (82)	49 (90)	38 (100)	26 (112)	21 (116)	17 (120)	8 (130)	5 (132)	1 (136)	0 (137)
Placebo	141 (0)	108 (15)	88 (23)	66 (41)	60 (45)	50 (53)	39 (62)	29 (71)	23 (77)	17 (82)	17 (82)	15 (84)	7 (92)	3 (94)	2 (95)	0 (97)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65



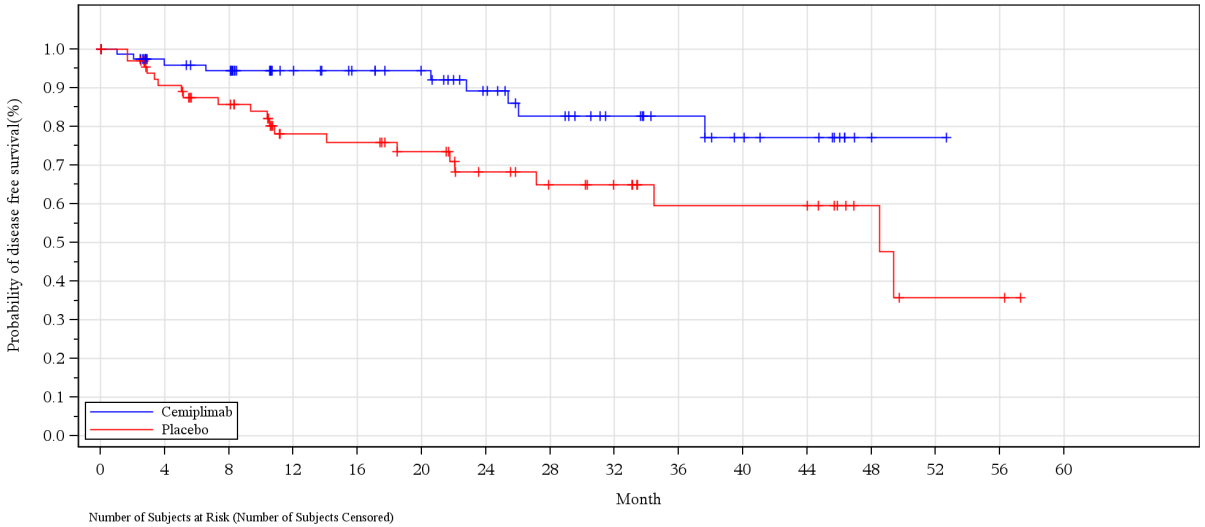
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	47 (5)	44 (7)	38 (12)	33 (16)	29 (20)	24 (24)	17 (31)	9 (39)	7 (41)	6 (42)	5 (43)	1 (47)	1 (47)	0 (48)	0 (48)
Placebo	65 (0)	53 (4)	42 (7)	28 (16)	22 (22)	19 (25)	14 (30)	13 (31)	13 (31)	9 (35)	7 (37)	3 (41)	3 (41)	1 (43)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



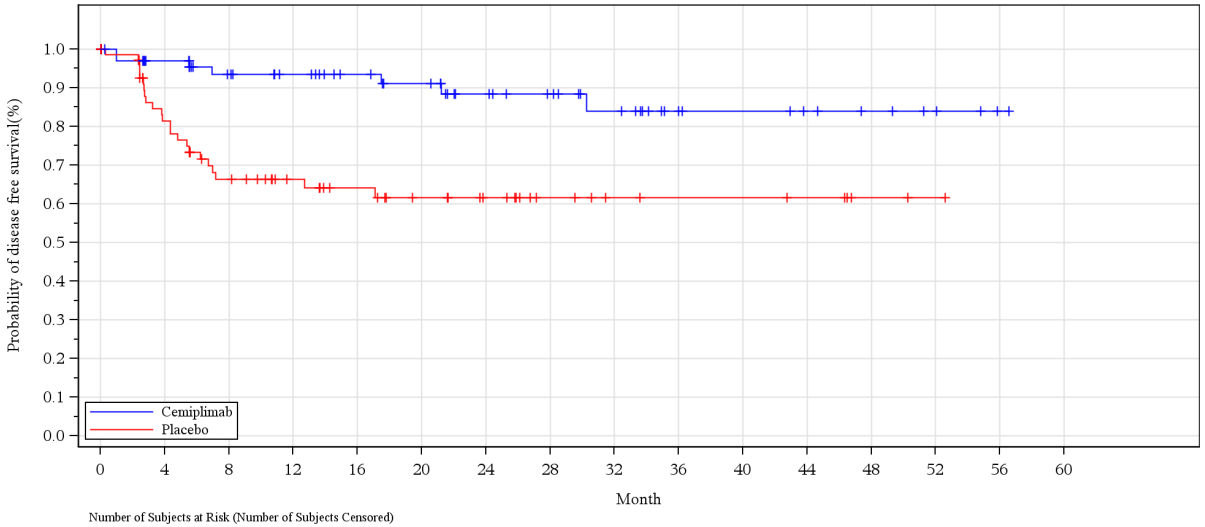
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	65 (12)	62 (14)	48 (28)	43 (33)	39 (37)	31 (43)	25 (47)	19 (53)	15 (57)	11 (60)	9 (62)	2 (70)	1 (70)	0 (71)	0 (71)
Placebo	69 (0)	57 (6)	50 (10)	36 (20)	35 (20)	30 (24)	23 (29)	19 (32)	16 (35)	11 (39)	11 (39)	10 (40)	5 (45)	2 (46)	2 (46)	0 (48)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75



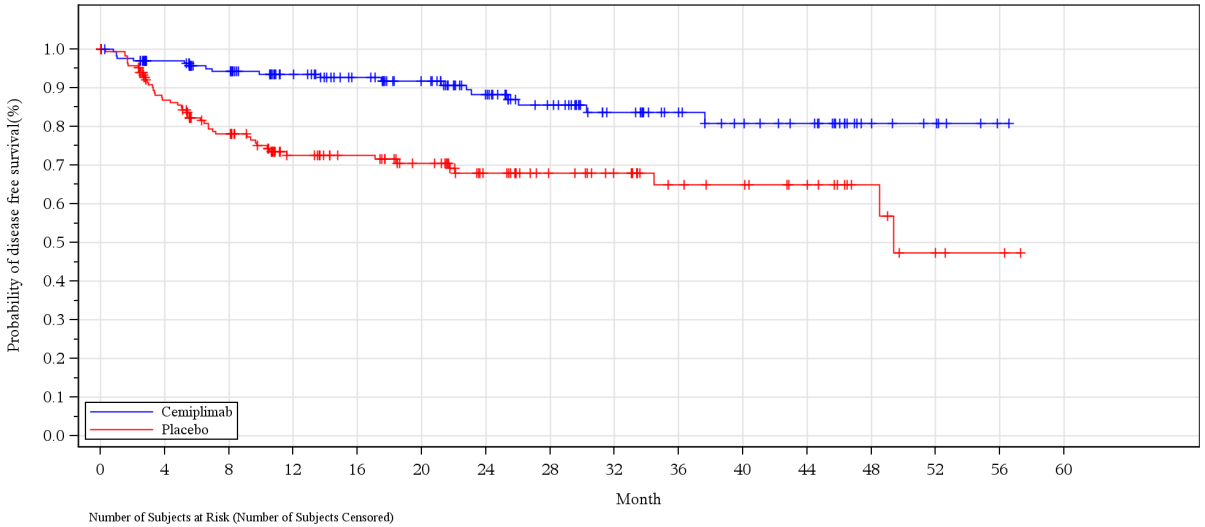
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	60 (11)	51 (18)	46 (23)	40 (29)	36 (32)	28 (39)	24 (43)	19 (47)	11 (55)	10 (56)	8 (58)	6 (60)	4 (62)	1 (65)	0 (66)
Placebo	72 (0)	51 (9)	38 (13)	30 (21)	25 (25)	20 (29)	16 (33)	10 (39)	7 (42)	6 (43)	6 (43)	5 (44)	2 (47)	1 (48)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male



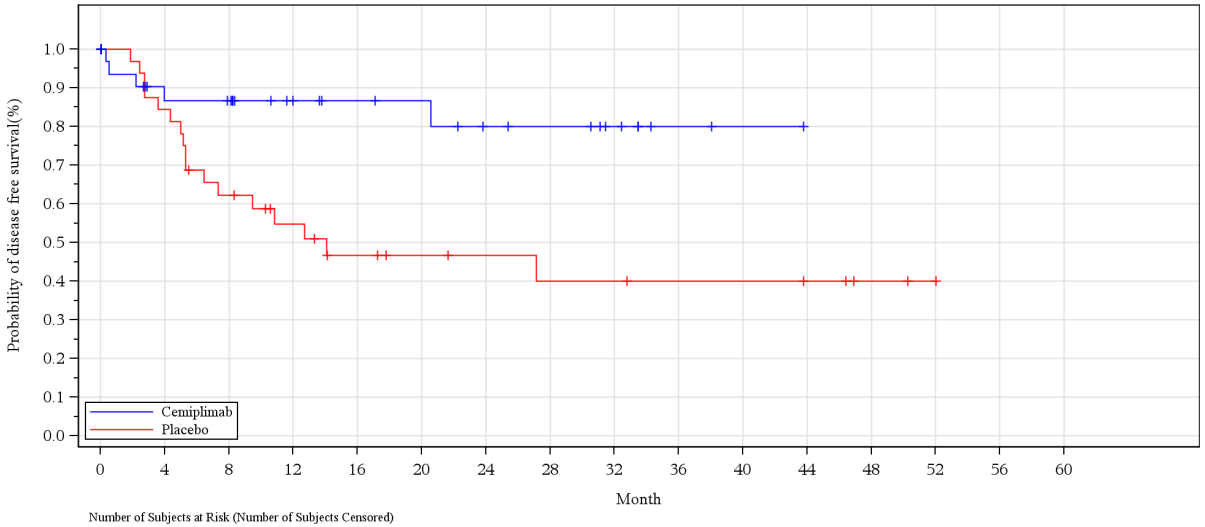
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	148 (21)	134 (31)	116 (48)	102 (61)	91 (71)	73 (86)	57 (100)	41 (115)	31 (125)	26 (129)	22 (133)	9 (147)	6 (149)	1 (154)	0 (155)
Placebo	174 (0)	134 (19)	111 (29)	80 (53)	72 (61)	61 (70)	46 (83)	36 (93)	30 (99)	21 (107)	19 (109)	14 (114)	8 (120)	3 (123)	2 (124)	0 (126)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female



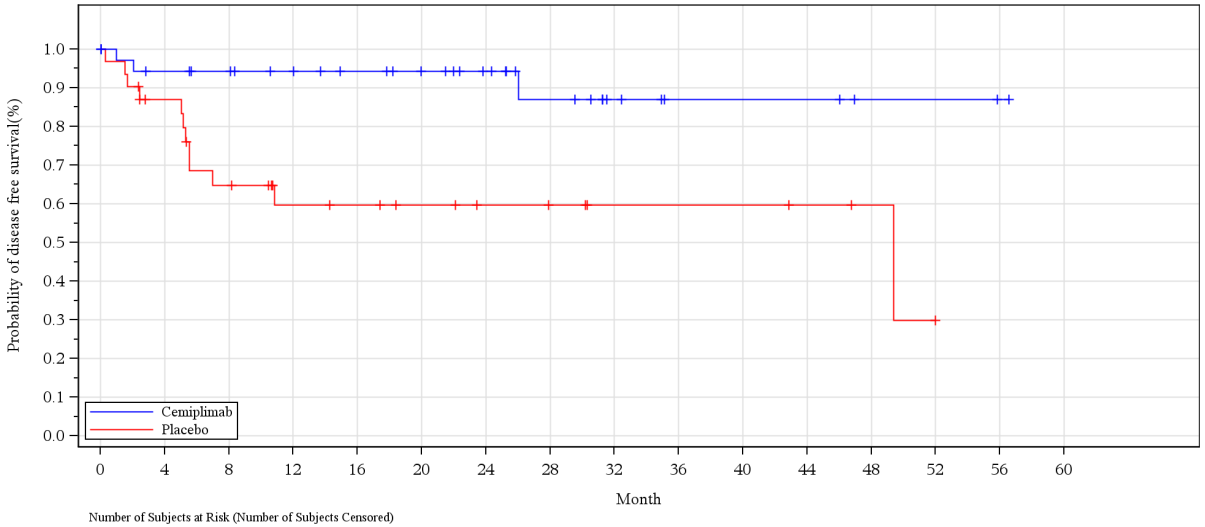
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	24 (7)	23 (8)	16 (15)	14 (17)	13 (18)	10 (20)	9 (21)	6 (24)	2 (28)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)	0 (30)
Placebo	32 (0)	27 (0)	19 (1)	14 (4)	10 (6)	8 (8)	7 (9)	6 (9)	6 (9)	5 (10)	5 (10)	4 (11)	2 (13)	1 (14)	0 (15)	0 (15)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



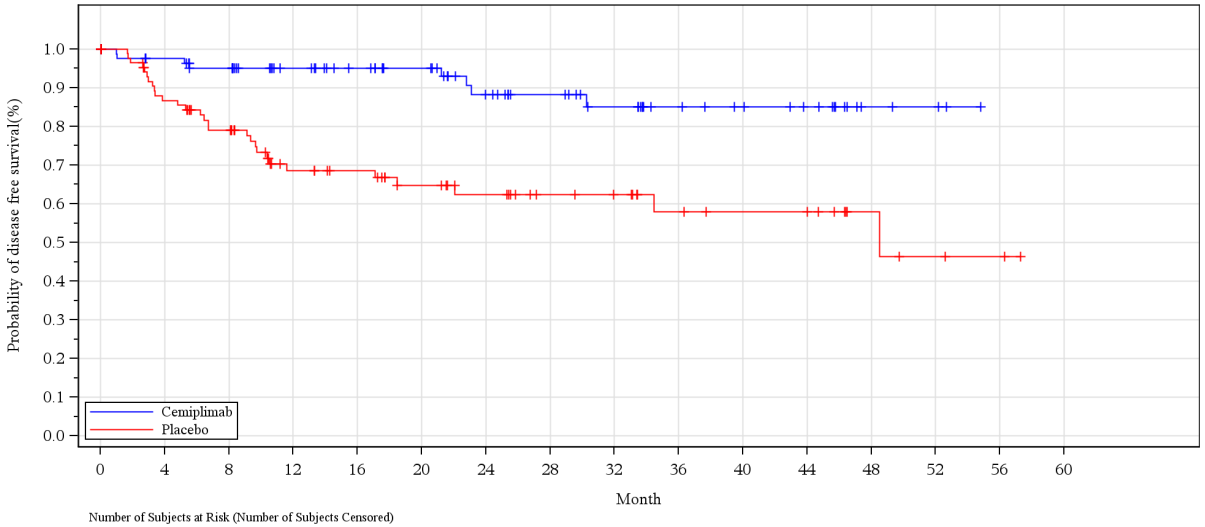
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	32 (3)	30 (5)	27 (8)	24 (11)	21 (14)	17 (18)	12 (22)	7 (27)	4 (30)	4 (30)	4 (30)	2 (32)	2 (32)	1 (33)	0 (34)
Placebo	31 (0)	24 (3)	17 (4)	12 (8)	11 (9)	9 (11)	7 (13)	6 (14)	4 (16)	4 (16)	4 (16)	3 (17)	2 (18)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



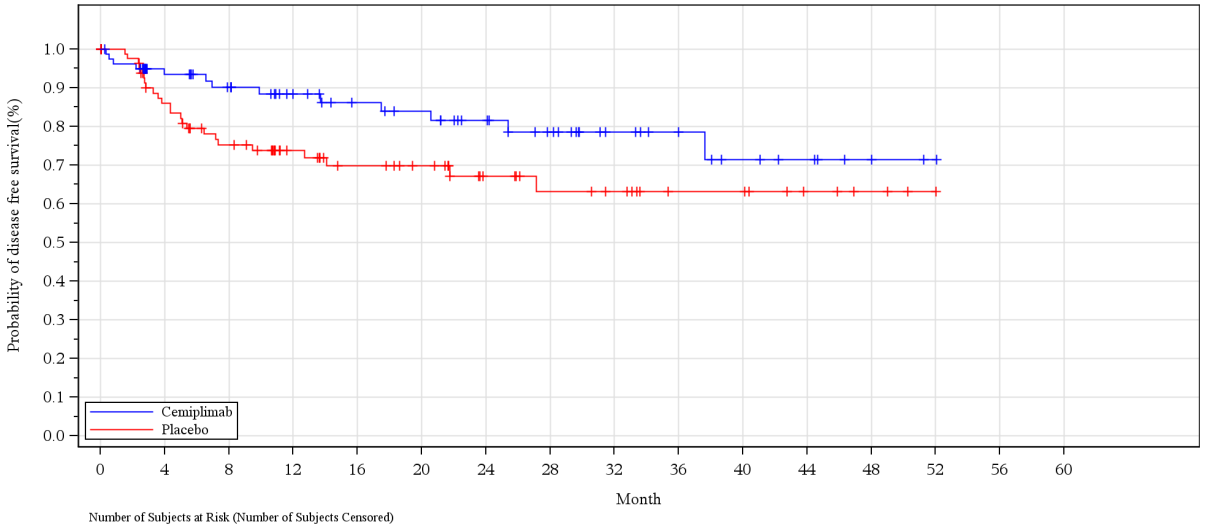
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	79 (9)	73 (13)	61 (25)	54 (32)	48 (38)	37 (46)	31 (52)	25 (57)	18 (64)	15 (67)	12 (70)	4 (78)	3 (79)	0 (82)	0 (82)
Placebo	90 (0)	71 (8)	60 (13)	42 (24)	38 (28)	31 (33)	26 (37)	20 (43)	18 (45)	13 (49)	11 (51)	10 (52)	5 (57)	3 (58)	2 (59)	0 (61)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



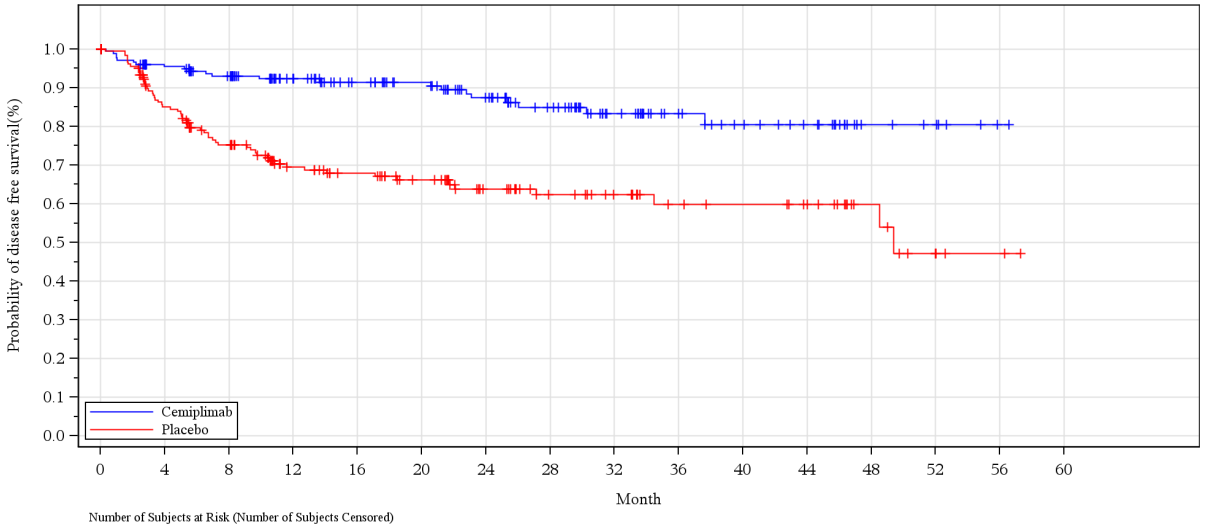
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	61 (16)	54 (21)	44 (30)	38 (35)	35 (37)	29 (42)	23 (47)	15 (55)	11 (59)	8 (61)	6 (63)	3 (67)	1 (68)	0 (69)	0 (69)
Placebo	85 (0)	66 (8)	53 (13)	40 (25)	33 (30)	29 (34)	20 (42)	16 (45)	14 (47)	9 (52)	9 (52)	5 (56)	3 (58)	1 (60)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Race: White



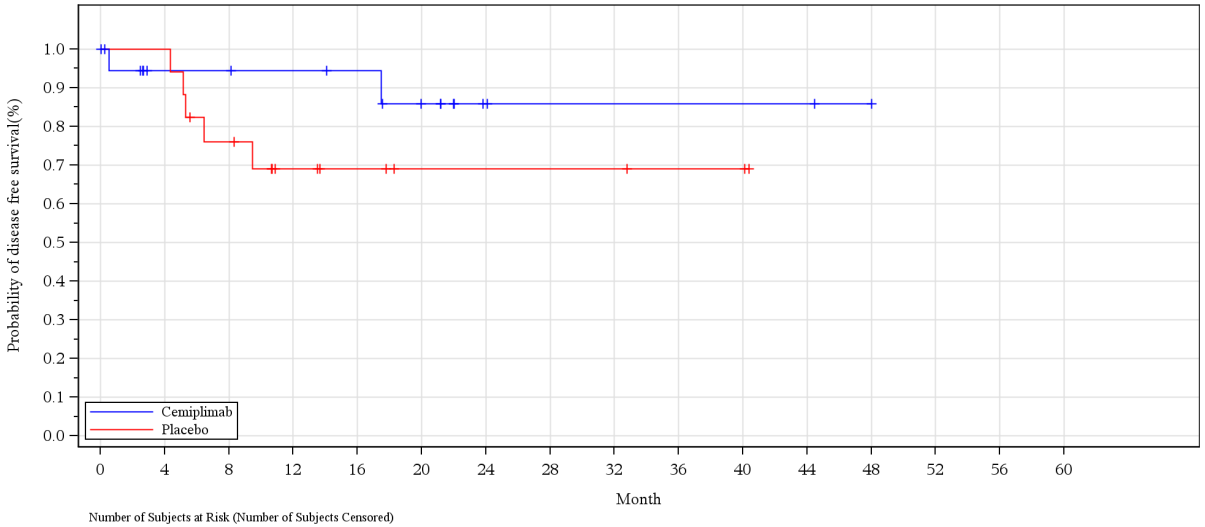
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	159 (22)	144 (33)	120 (56)	105 (70)	96 (79)	80 (91)	64 (105)	45 (123)	31 (137)	25 (142)	20 (147)	8 (159)	6 (161)	1 (166)	0 (167)
Placebo	189 (0)	144 (19)	118 (29)	87 (52)	77 (60)	66 (69)	50 (83)	39 (93)	33 (99)	24 (107)	22 (109)	18 (113)	10 (121)	4 (125)	2 (127)	0 (129)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white



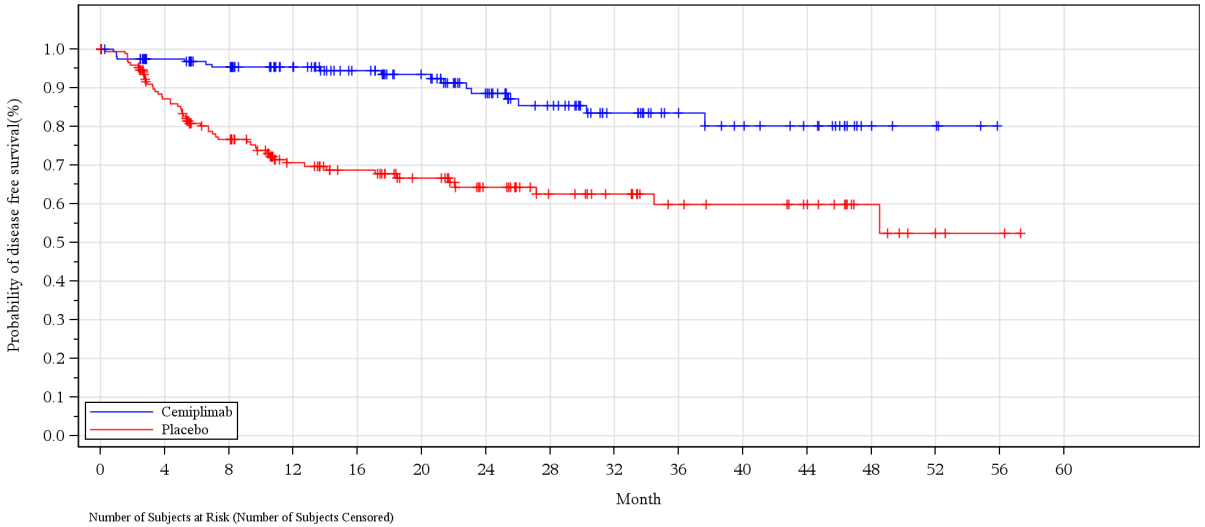
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	13 (6)	13 (6)	12 (7)	11 (8)	8 (10)	3 (15)	2 (16)	2 (16)	2 (16)	2 (16)	2 (16)	1 (18)	0 (18)	0 (18)	0 (18)
Placebo	17 (0)	17 (0)	12 (1)	7 (5)	5 (7)	3 (9)	3 (9)	3 (9)	3 (9)	2 (10)	2 (10)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



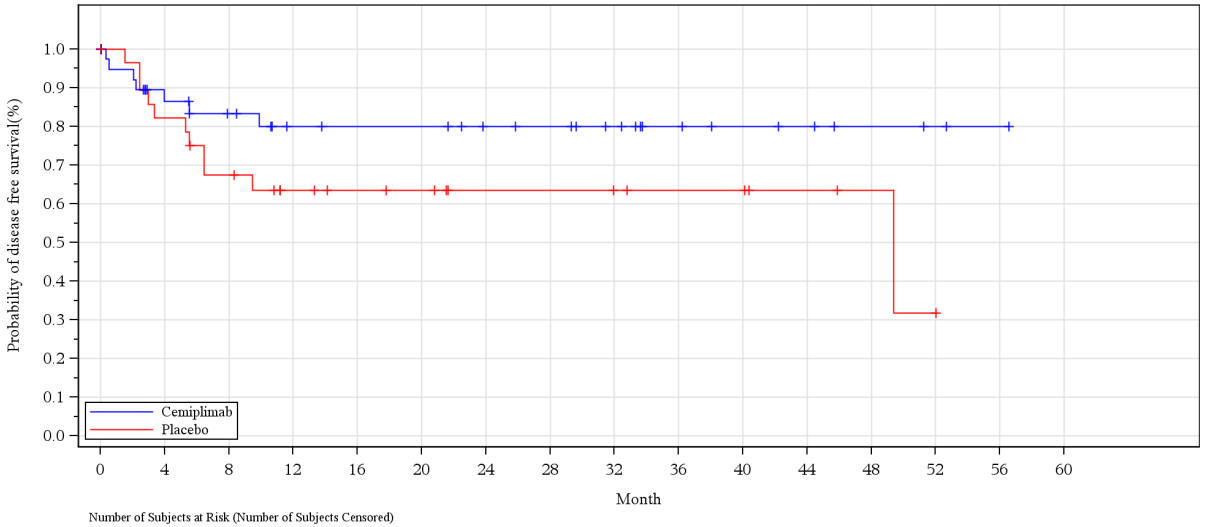
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	143 (19)	132 (27)	112 (47)	97 (61)	85 (72)	67 (86)	51 (100)	35 (115)	25 (125)	21 (128)	17 (132)	6 (144)	4 (145)	0 (149)	0 (149)
Placebo	177 (0)	138 (18)	112 (28)	81 (51)	71 (59)	59 (69)	46 (80)	35 (90)	30 (95)	21 (103)	19 (105)	15 (109)	8 (116)	3 (120)	2 (121)	0 (123)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



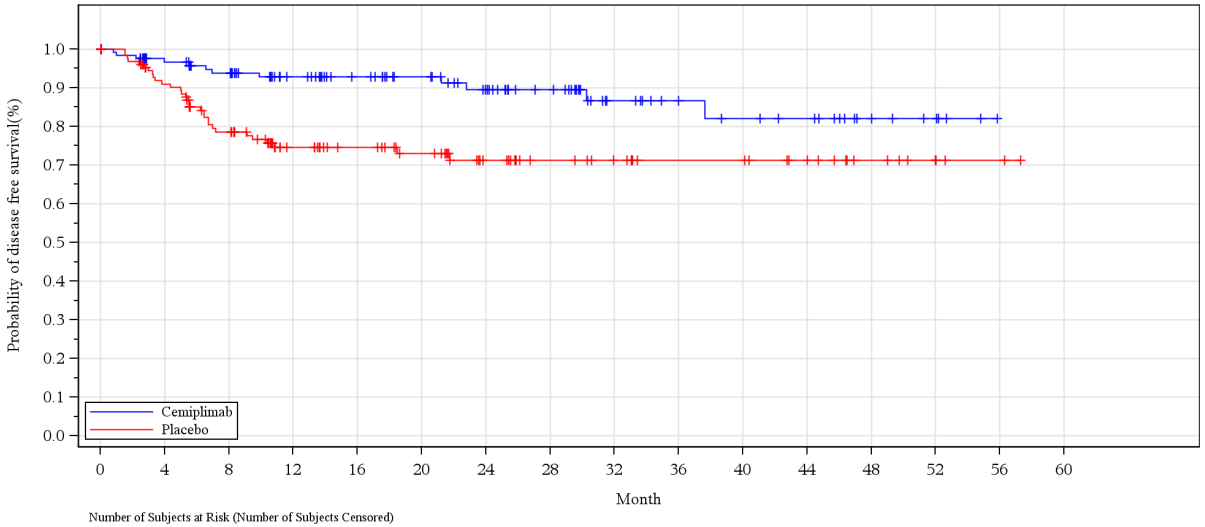
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (9)	25 (12)	20 (16)	19 (17)	19 (17)	16 (20)	15 (21)	12 (24)	8 (28)	6 (30)	5 (31)	3 (33)	2 (34)	1 (35)	0 (36)
Placebo	29 (0)	23 (1)	18 (2)	13 (6)	11 (8)	10 (9)	7 (12)	7 (12)	6 (13)	5 (14)	5 (14)	3 (16)	2 (17)	1 (17)	0 (18)	0 (18)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0



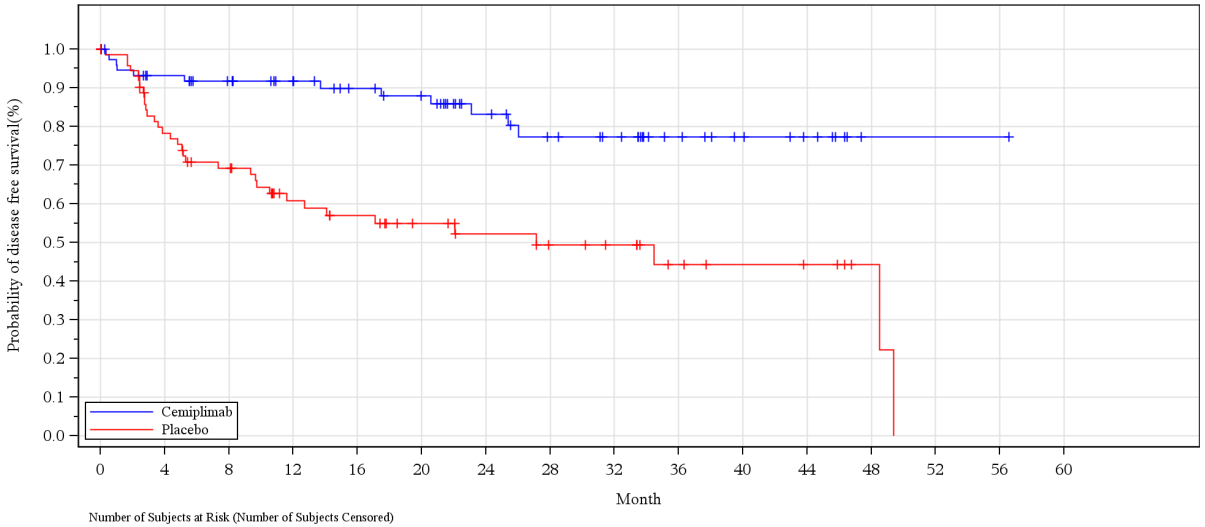
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	107 (22)	98 (28)	80 (45)	70 (55)	62 (63)	52 (71)	41 (82)	25 (97)	19 (103)	17 (104)	15 (106)	8 (114)	5 (116)	0 (121)	0 (121)
Placebo	131 (0)	108 (12)	86 (20)	62 (40)	54 (48)	47 (54)	35 (65)	27 (73)	23 (77)	18 (82)	18 (82)	13 (87)	8 (92)	4 (96)	2 (98)	0 (100)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1



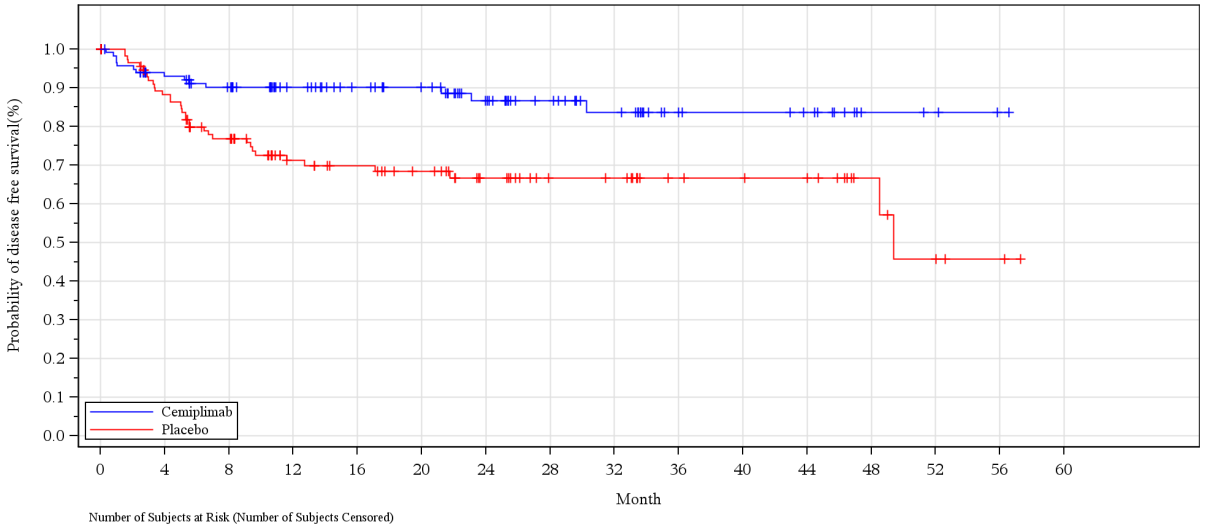
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	65 (6)	59 (11)	52 (18)	46 (23)	42 (26)	31 (35)	25 (39)	22 (42)	14 (50)	10 (54)	7 (57)	1 (63)	1 (63)	1 (63)	0 (64)
Placebo	75 (0)	53 (7)	44 (10)	32 (17)	28 (19)	22 (24)	18 (27)	15 (29)	13 (31)	8 (35)	6 (37)	5 (38)	2 (41)	0 (41)	0 (41)	0 (41)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal



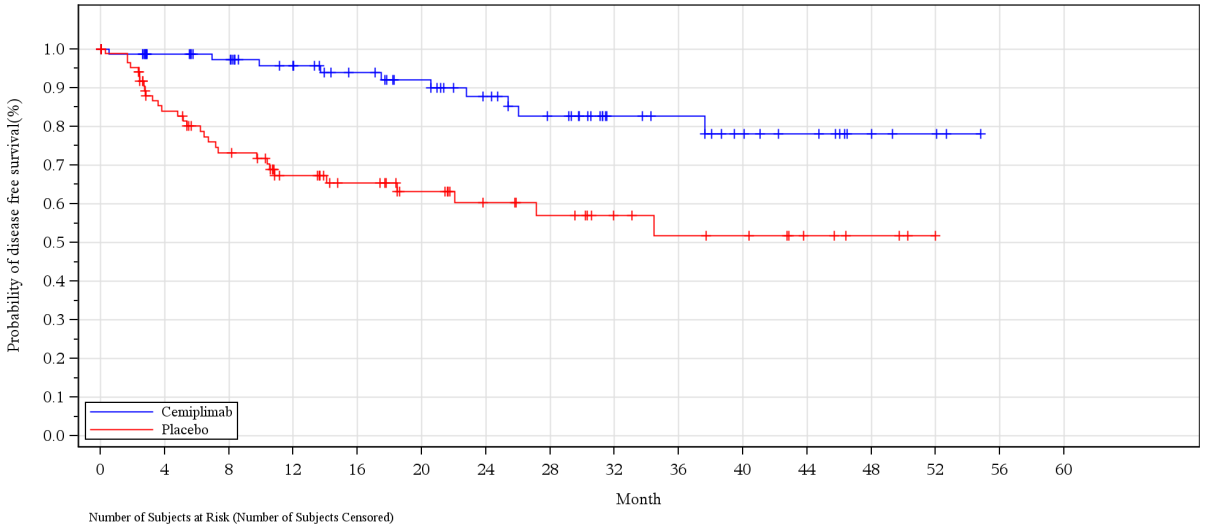
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	100 (17)	90 (24)	74 (40)	65 (49)	59 (55)	46 (66)	35 (77)	27 (84)	15 (96)	14 (97)	12 (99)	4 (107)	3 (108)	1 (110)	0 (111)
Placebo	117 (0)	96 (8)	77 (15)	54 (33)	49 (37)	43 (42)	33 (51)	25 (59)	24 (60)	16 (68)	15 (69)	13 (71)	7 (77)	4 (78)	2 (80)	0 (82)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	72 (11)	67 (15)	58 (23)	51 (29)	45 (34)	37 (40)	31 (44)	20 (55)	18 (57)	13 (61)	10 (64)	5 (70)	3 (71)	0 (74)	0 (74)
Placebo	89 (0)	65 (11)	53 (15)	40 (24)	33 (30)	26 (36)	20 (41)	17 (43)	12 (48)	10 (49)	9 (50)	5 (54)	3 (56)	0 (59)	0 (59)	0 (59)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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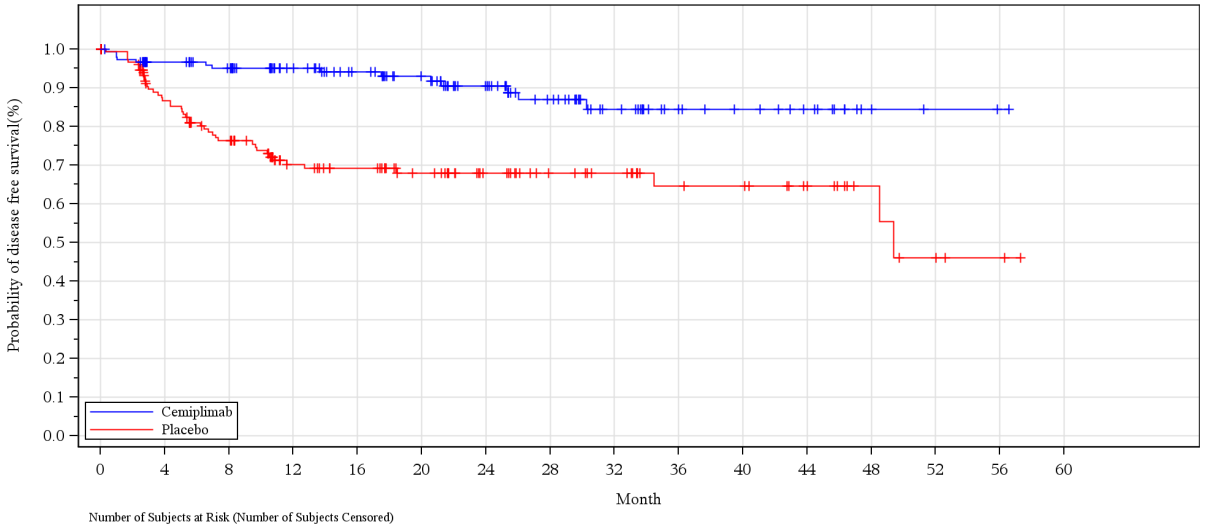
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%



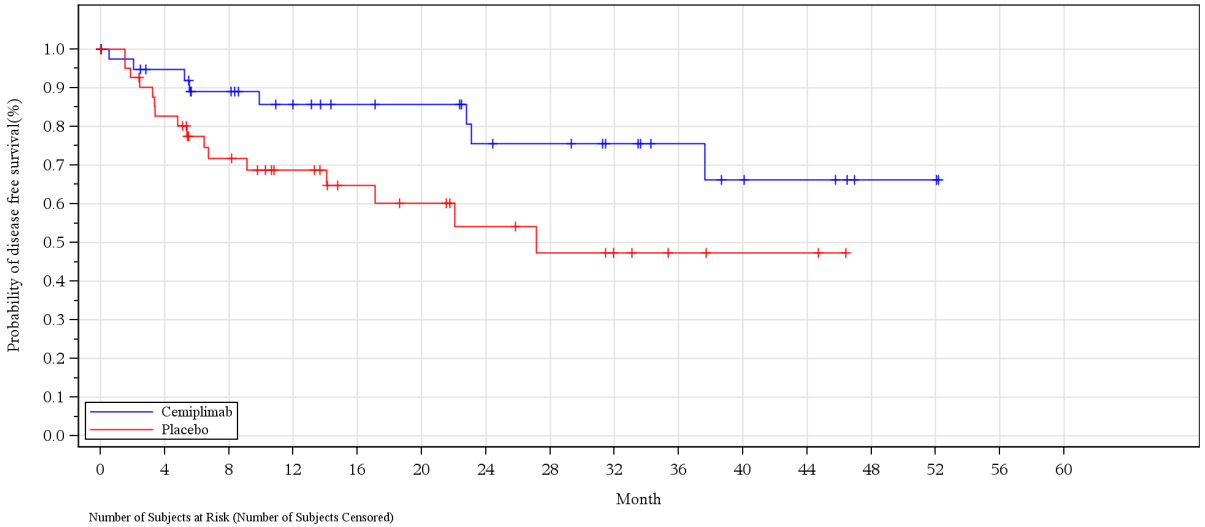
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	155 (0)	129 (21)	120 (28)	101 (47)	88 (59)	77 (69)	61 (83)	45 (97)	30 (111)	19 (122)	16 (125)	12 (129)	4 (138)	2 (139)	1 (140)	0 (141)
Placebo	154 (0)	120 (15)	99 (22)	70 (44)	63 (50)	52 (60)	40 (72)	31 (81)	27 (85)	19 (92)	18 (93)	12 (99)	7 (104)	4 (105)	2 (107)	0 (109)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%



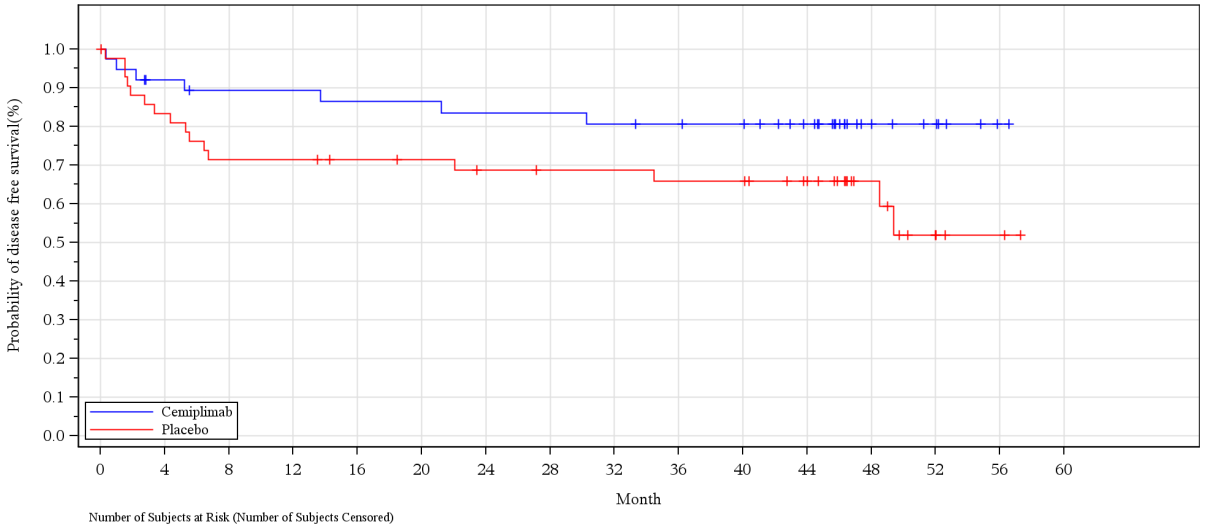
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	42 (0)	34 (6)	29 (9)	23 (14)	20 (17)	19 (18)	15 (20)	14 (21)	11 (24)	8 (27)	6 (28)	5 (29)	2 (32)	2 (32)	0 (34)	0 (34)
Placebo	43 (0)	33 (3)	25 (7)	19 (12)	14 (16)	12 (17)	9 (19)	7 (20)	5 (22)	3 (24)	2 (25)	2 (25)	0 (27)	0 (27)	0 (27)	0 (27)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only



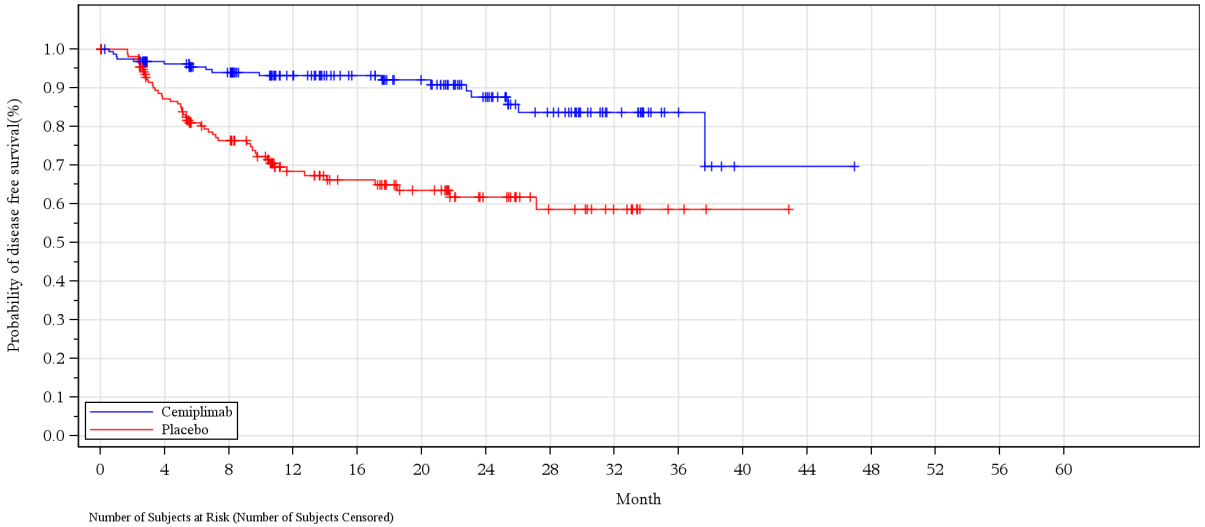
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	38 (0)	33 (2)	31 (3)	31 (3)	30 (3)	30 (3)	29 (3)	29 (3)	28 (3)	27 (4)	26 (5)	21 (10)	9 (23)	6 (25)	1 (30)	0 (31)
Placebo	43 (0)	35 (1)	30 (1)	30 (1)	28 (3)	27 (4)	25 (5)	24 (6)	24 (6)	23 (6)	23 (6)	18 (11)	10 (19)	4 (23)	2 (25)	0 (27)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	171 (0)	139 (26)	126 (36)	101 (60)	86 (75)	74 (86)	54 (103)	37 (118)	19 (136)	6 (149)	1 (153)	1 (153)	0 (154)	0 (154)	0 (154)	0 (154)
Placebo	163 (0)	126 (18)	100 (29)	64 (56)	54 (64)	42 (74)	28 (87)	18 (96)	12 (102)	3 (111)	1 (113)	0 (114)	0 (114)	0 (114)	0 (114)	0 (114)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 11:12 SAS Linux 9.4)

2.2.2 2. Datenschnitt

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	9 (16.1%)	22 (33.8%)
Odds ratio (95% CI)	0.360 (0.148, 0.880)	
P-value for Odds Ratio	0.0250	
Relative Risk (95% CI)	0.48 (0.24, 0.95)	
P-value for Relative Risk	0.0348	
Heterogeneity p-value of RR	0.6281	
Risk difference (95% CI)	-19.67 (-36.30, -3.03)	
P-value for Risk Difference	0.0205	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	20 (13.1%)	46 (32.6%)
Odds ratio (95% CI)	0.305 (0.168, 0.554)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.40 (0.25, 0.64)	
P-value for Relative Risk	0.0001	
Heterogeneity p-value of RR	0.6281	
Risk difference (95% CI)	-19.26 (-28.68, -9.83)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	9 (16.1%)	22 (33.8%)
Odds ratio (95% CI)	0.360 (0.148, 0.880)	
P-value for Odds Ratio	0.0250	
Relative Risk (95% CI)	0.48 (0.24, 0.95)	
P-value for Relative Risk	0.0348	
Heterogeneity p-value of RR	0.6001	
Risk difference (95% CI)	-19.67 (-36.30, -3.03)	
P-value for Risk Difference	0.0205	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	12 (15.0%)	21 (30.4%)
Odds ratio (95% CI)	0.384 (0.169, 0.876)	
P-value for Odds Ratio	0.0229	
Relative Risk (95% CI)	0.50 (0.26, 0.94)	
P-value for Relative Risk	0.0304	
Heterogeneity p-value of RR	0.6001	
Risk difference (95% CI)	-16.71 (-29.78, -3.64)	
P-value for Risk Difference	0.0122	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	8 (11.0%)	25 (34.7%)
Odds ratio (95% CI)	0.204 (0.081, 0.512)	
P-value for Odds Ratio	0.0007	
Relative Risk (95% CI)	0.29 (0.14, 0.60)	
P-value for Relative Risk	0.0010	
Heterogeneity p-value of RR	0.6001	
Risk difference (95% CI)	-24.69 (-37.63, -11.74)	
P-value for Risk Difference	0.0002	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	23 (13.2%)	51 (29.3%)
Odds ratio (95% CI)	0.362 (0.209, 0.628)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	0.44 (0.28, 0.69)	
P-value for Relative Risk	0.0004	
Heterogeneity p-value of RR	0.4194	
Risk difference (95% CI)	-16.30 (-24.75, -7.84)	
P-value for Risk Difference	0.0002	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	6 (17.1%)	17 (53.1%)
Odds ratio (95% CI)	0.178 (0.056, 0.569)	
P-value for Odds Ratio	0.0036	
Relative Risk (95% CI)	0.35 (0.15, 0.81)	
P-value for Relative Risk	0.0148	
Heterogeneity p-value of RR	0.4194	
Risk difference (95% CI)	-35.42 (-56.61, -14.24)	
P-value for Risk Difference	0.0010	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	12 (38.7%)
Odds ratio (95% CI)	0.149 (0.037, 0.597)	
P-value for Odds Ratio	0.0072	
Relative Risk (95% CI)	0.34 (0.13, 0.92)	
P-value for Relative Risk	0.0341	
Heterogeneity p-value of RR	0.1486	
Risk difference (95% CI)	-28.42 (-48.16, -8.68)	
P-value for Risk Difference	0.0048	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	9 (10.0%)	30 (33.3%)
Odds ratio (95% CI)	0.220 (0.097, 0.499)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	0.30 (0.15, 0.59)	
P-value for Relative Risk	0.0005	
Heterogeneity p-value of RR	0.1486	
Risk difference (95% CI)	-23.33 (-34.87, -11.78)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	16 (19.5%)	26 (30.6%)
Odds ratio (95% CI)	0.554 (0.270, 1.136)	
P-value for Odds Ratio	0.1068	
Relative Risk (95% CI)	0.64 (0.37, 1.11)	
P-value for Relative Risk	0.1106	
Heterogeneity p-value of RR	0.1486	
Risk difference (95% CI)	-10.97 (-24.11, 2.16)	
P-value for Risk Difference	0.1016	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	26 (13.8%)	62 (32.8%)
Odds ratio (95% CI)	0.315 (0.187, 0.531)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.41 (0.27, 0.62)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.8838	
Risk difference (95% CI)	-19.55 (-27.80, -11.30)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	6 (35.3%)
Odds ratio (95% CI)	0.316 (0.059, 1.689)	
P-value for Odds Ratio	0.1778	
Relative Risk (95% CI)	0.36 (0.08, 1.68)	
P-value for Relative Risk	0.1924	
Heterogeneity p-value of RR	0.8838	
Risk difference (95% CI)	-17.99 (-17.99, -17.99)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	22 (13.3%)	57 (32.2%)
Odds ratio (95% CI)	0.323 (0.187, 0.560)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.42 (0.27, 0.65)	
P-value for Relative Risk	0.0001	
Heterogeneity p-value of RR	0.9332	
Risk difference (95% CI)	-19.17 (-27.70, -10.63)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	11 (37.9%)
Odds ratio (95% CI)	0.288 (0.092, 0.900)	
P-value for Odds Ratio	0.0323	
Relative Risk (95% CI)	0.40 (0.17, 0.98)	
P-value for Relative Risk	0.0448	
Heterogeneity p-value of RR	0.9332	
Risk difference (95% CI)	-22.34 (-43.15, -1.54)	
P-value for Risk Difference	0.0353	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	15 (11.3%)	33 (25.2%)
Odds ratio (95% CI)	0.362 (0.185, 0.711)	
P-value for Odds Ratio	0.0032	
Relative Risk (95% CI)	0.43 (0.24, 0.75)	
P-value for Relative Risk	0.0030	
Heterogeneity p-value of RR	0.7789	
Risk difference (95% CI)	-14.48 (-24.10, -4.85)	
P-value for Risk Difference	0.0032	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	14 (18.4%)	35 (46.7%)
Odds ratio (95% CI)	0.258 (0.123, 0.543)	
P-value for Odds Ratio	0.0004	
Relative Risk (95% CI)	0.40 (0.23, 0.68)	
P-value for Relative Risk	0.0007	
Heterogeneity p-value of RR	0.7789	
Risk difference (95% CI)	-28.18 (-42.56, -13.80)	
P-value for Risk Difference	0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	17 (13.6%)	37 (31.6%)
Odds ratio (95% CI)	0.320 (0.166, 0.616)	
P-value for Odds Ratio	0.0006	
Relative Risk (95% CI)	0.40 (0.24, 0.67)	
P-value for Relative Risk	0.0005	
Heterogeneity p-value of RR	0.9657	
Risk difference (95% CI)	-17.94 (-28.32, -7.56)	
P-value for Risk Difference	0.0007	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	12 (14.3%)	31 (34.8%)
Odds ratio (95% CI)	0.315 (0.148, 0.671)	
P-value for Odds Ratio	0.0027	
Relative Risk (95% CI)	0.42 (0.23, 0.76)	
P-value for Relative Risk	0.0042	
Heterogeneity p-value of RR	0.9657	
Risk difference (95% CI)	-21.87 (-34.29, -9.46)	
P-value for Risk Difference	0.0006	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Number of events, n (%)	18 (11.6%)	47 (30.5%)
Odds ratio (95% CI)	0.299 (0.163, 0.547)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.39 (0.24, 0.64)	
P-value for Relative Risk	0.0002	
Heterogeneity p-value of RR	0.4308	
Risk difference (95% CI)	-19.18 (-27.88, -10.49)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Number of events, n (%)	9 (21.4%)	17 (39.5%)
Odds ratio (95% CI)	0.394 (0.145, 1.067)	
P-value for Odds Ratio	0.0668	
Relative Risk (95% CI)	0.56 (0.28, 1.11)	
P-value for Relative Risk	0.0944	
Heterogeneity p-value of RR	0.4308	
Risk difference (95% CI)	-19.70 (-38.03, -1.38)	
P-value for Risk Difference	0.0351	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Number of events, n (%)	8 (21.1%)	16 (37.2%)
Odds ratio (95% CI)	0.444 (0.160, 1.235)	
P-value for Odds Ratio	0.1198	
Relative Risk (95% CI)	0.54 (0.26, 1.13)	
P-value for Relative Risk	0.1031	
Heterogeneity p-value of RR	0.3885	
Risk difference (95% CI)	-14.59 (-33.61, 4.42)	
P-value for Risk Difference	0.1326	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1a Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Number of events, n (%)	21 (12.3%)	52 (31.9%)
Odds ratio (95% CI)	0.302 (0.171, 0.533)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.39 (0.25, 0.63)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.3885	
Risk difference (95% CI)	-20.13 (-28.72, -11.54)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	9 (16.1%)	22 (33.8%)
Disease recurrences, n (%)	7 (12.5%)	22 (33.8%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	47 (83.9%)	43 (66.2%)
Q1 (95% CI), (months)[a]	NR (13.7, NE)	6.7 (5.0, 27.0)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (27.0, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0291	
HR (95% CI) [c][d]	0.423 (0.191, 0.936)	
Heterogeneity p-value [c][e]	0.6491	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	92.7 (81.8, 97.2)	90.6 (80.3, 95.7)
6 months	90.9 (79.5, 96.1)	79.7 (67.6, 87.7)
12 months	89.0 (77.1, 94.9)	66.4 (53.1, 76.6)
18 months	86.9 (74.3, 93.5)	66.4 (53.1, 76.6)
24 months	81.2 (66.5, 90.0)	66.4 (53.1, 76.6)
30 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
36 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
42 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
48 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
54 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	20 (13.1%)	46 (32.6%)
Disease recurrences, n (%)	15 (9.8%)	42 (29.8%)
Deaths, n (%)	5 (3.3%)	4 (2.8%)
Number of censored participants, n (%)	133 (86.9%)	95 (67.4%)
Q1 (95% CI), (months)[a]	NR (30.8, NE)	10.8 (5.5, 22.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.326 (0.190, 0.560)	
Heterogeneity p-value [c][e]	0.6491	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.3 (93.1, 99.0)	90.6 (84.4, 94.4)
6 months	96.0 (91.3, 98.2)	81.9 (74.4, 87.4)
12 months	94.6 (89.5, 97.3)	73.9 (65.6, 80.6)
18 months	92.6 (86.6, 96.0)	71.0 (62.3, 78.1)
24 months	88.3 (80.7, 93.0)	67.2 (57.9, 75.0)
30 months	85.9 (77.7, 91.3)	64.1 (54.1, 72.4)
36 months	82.8 (73.4, 89.1)	61.5 (50.6, 70.7)
42 months	80.6 (70.2, 87.7)	61.5 (50.6, 70.7)
48 months	80.6 (70.2, 87.7)	61.5 (50.6, 70.7)
54 months	75.2 (59.4, 85.6)	53.0 (38.2, 65.8)
60 months	75.2 (59.4, 85.6)	53.0 (38.2, 65.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	9 (16.1%)	22 (33.8%)
Disease recurrences, n (%)	7 (12.5%)	22 (33.8%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	47 (83.9%)	43 (66.2%)
Q1 (95% CI), (months)[a]	NR (13.7, NE)	6.7 (5.0, 27.0)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (27.0, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0291	
HR (95% CI) [c][d]	0.423 (0.191, 0.936)	
Heterogeneity p-value [c][e]	0.4059	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	92.7 (81.8, 97.2)	90.6 (80.3, 95.7)
6 months	90.9 (79.5, 96.1)	79.7 (67.6, 87.7)
12 months	89.0 (77.1, 94.9)	66.4 (53.1, 76.6)
18 months	86.9 (74.3, 93.5)	66.4 (53.1, 76.6)
24 months	81.2 (66.5, 90.0)	66.4 (53.1, 76.6)
30 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
36 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
42 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
48 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
54 months	81.2 (66.5, 90.0)	62.4 (47.6, 74.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	12 (15.0%)	21 (30.4%)
Disease recurrences, n (%)	9 (11.3%)	19 (27.5%)
Deaths, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	68 (85.0%)	48 (69.6%)
Q1 (95% CI), (months)[a]	37.6 (22.8, NE)	21.7 (9.4, 48.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0341	
HR (95% CI) [c][d]	0.462 (0.223, 0.959)	
Heterogeneity p-value [c][e]	0.4059	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (90.3, 99.4)	94.1 (85.1, 97.8)
6 months	96.2 (88.6, 98.7)	88.2 (77.8, 93.9)
12 months	94.8 (86.8, 98.0)	80.2 (68.3, 88.0)
18 months	92.9 (83.5, 97.0)	78.3 (66.1, 86.6)
24 months	86.3 (73.9, 93.1)	71.3 (57.4, 81.4)
30 months	81.9 (68.3, 90.0)	68.5 (54.0, 79.3)
36 months	78.7 (63.9, 88.0)	64.7 (49.0, 76.7)
42 months	74.6 (57.7, 85.5)	64.7 (49.0, 76.7)
48 months	74.6 (57.7, 85.5)	64.7 (49.0, 76.7)
54 months	74.6 (57.7, 85.5)	51.8 (31.1, 69.0)
60 months	NE (NE, NE)	51.8 (31.1, 69.0)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	8 (11.0%)	25 (34.7%)
Disease recurrences, n (%)	6 (8.2%)	23 (31.9%)
Deaths, n (%)	2 (2.7%)	2 (2.8%)
Number of censored participants, n (%)	65 (89.0%)	47 (65.3%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	6.2 (3.8, 17.1)
Median (95% CI), (months)[a]	NR (51.5, NE)	NR (29.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0002	
HR (95% CI) [c][d]	0.207 (0.084, 0.510)	
Heterogeneity p-value [c][e]	0.4059	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.2 (89.2, 99.3)	87.2 (76.9, 93.1)
6 months	95.8 (87.4, 98.6)	75.8 (64.0, 84.2)
12 months	94.3 (85.6, 97.8)	67.9 (55.4, 77.6)
18 months	92.3 (82.2, 96.8)	63.8 (50.7, 74.2)
24 months	90.2 (79.1, 95.5)	63.8 (50.7, 74.2)
30 months	90.2 (79.1, 95.5)	60.0 (45.5, 71.8)
36 months	87.0 (73.5, 93.9)	60.0 (45.5, 71.8)
42 months	87.0 (73.5, 93.9)	60.0 (45.5, 71.8)
48 months	87.0 (73.5, 93.9)	60.0 (45.5, 71.8)
54 months	77.3 (49.8, 90.9)	60.0 (45.5, 71.8)
60 months	77.3 (49.8, 90.9)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	23 (13.2%)	51 (29.3%)
Disease recurrences, n (%)	18 (10.3%)	49 (28.2%)
Deaths, n (%)	5 (2.9%)	2 (1.1%)
Number of censored participants, n (%)	151 (86.8%)	123 (70.7%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	11.6 (6.7, 34.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.375 (0.229, 0.617)	
Heterogeneity p-value [c][e]	0.6408	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.1 (93.1, 98.8)	91.2 (85.8, 94.6)
6 months	95.9 (91.6, 98.0)	83.6 (77.1, 88.3)
12 months	94.0 (89.2, 96.7)	74.5 (67.0, 80.5)
18 months	91.7 (86.1, 95.1)	73.6 (66.0, 79.7)
24 months	88.1 (81.3, 92.5)	70.4 (62.2, 77.1)
30 months	86.1 (78.9, 91.0)	67.8 (59.0, 75.0)
36 months	83.5 (75.3, 89.2)	65.6 (56.1, 73.6)
42 months	81.5 (72.3, 87.9)	65.6 (56.1, 73.6)
48 months	81.5 (72.3, 87.9)	65.6 (56.1, 73.6)
54 months	77.2 (63.9, 86.1)	56.8 (42.0, 69.2)
60 months	77.2 (63.9, 86.1)	56.8 (42.0, 69.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	6 (17.1%)	17 (53.1%)
Disease recurrences, n (%)	4 (11.4%)	15 (46.9%)
Deaths, n (%)	2 (5.7%)	2 (6.3%)
Number of censored participants, n (%)	29 (82.9%)	15 (46.9%)
Q1 (95% CI), (months)[a]	NR (4.0, NE)	5.2 (2.8, 9.5)
Median (95% CI), (months)[a]	NR (NE, NE)	14.1 (5.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (27.1, NE)
Stratified log-rank test p-value [b][c]	0.0126	
HR (95% CI) [c][d]	0.316 (0.122, 0.817)	
Heterogeneity p-value [c][e]	0.6408	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	91.2 (75.1, 97.1)	87.5 (70.0, 95.1)
6 months	88.1 (71.4, 95.4)	68.8 (49.7, 81.8)
12 months	88.1 (71.4, 95.4)	56.3 (37.6, 71.3)
18 months	88.1 (71.4, 95.4)	49.2 (30.8, 65.1)
24 months	75.9 (51.6, 89.2)	49.2 (30.8, 65.1)
30 months	75.9 (51.6, 89.2)	42.1 (22.6, 60.5)
36 months	75.9 (51.6, 89.2)	42.1 (22.6, 60.5)
42 months	75.9 (51.6, 89.2)	42.1 (22.6, 60.5)
48 months	75.9 (51.6, 89.2)	42.1 (22.6, 60.5)
54 months	NE (NE, NE)	42.1 (22.6, 60.5)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	12 (38.7%)
Disease recurrences, n (%)	2 (5.4%)	11 (35.5%)
Deaths, n (%)	2 (5.4%)	1 (3.2%)
Number of censored participants, n (%)	33 (89.2%)	19 (61.3%)
Q1 (95% CI), (months)[a]	51.5 (26.0, NE)	5.5 (1.7, 49.4)
Median (95% CI), (months)[a]	NR (51.5, NE)	49.4 (7.0, NE)
Q3 (95% CI), (months)[a]	NR (51.5, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0050	
HR (95% CI) [c][d]	0.222 (0.071, 0.699)	
Heterogeneity p-value [c][e]	0.1279	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.4 (79.6, 98.6)	87.1 (69.2, 95.0)
6 months	94.4 (79.6, 98.6)	70.3 (50.7, 83.3)
12 months	94.4 (79.6, 98.6)	63.1 (43.1, 77.7)
18 months	94.4 (79.6, 98.6)	63.1 (43.1, 77.7)
24 months	94.4 (79.6, 98.6)	63.1 (43.1, 77.7)
30 months	90.2 (71.7, 96.8)	63.1 (43.1, 77.7)
36 months	90.2 (71.7, 96.8)	63.1 (43.1, 77.7)
42 months	90.2 (71.7, 96.8)	63.1 (43.1, 77.7)
48 months	90.2 (71.7, 96.8)	63.1 (43.1, 77.7)
54 months	67.6 (18.0, 91.5)	31.5 (2.0, 71.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	9 (10.0%)	30 (33.3%)
Disease recurrences, n (%)	8 (8.9%)	29 (32.2%)
Deaths, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	81 (90.0%)	60 (66.7%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	10.4 (6.2, 29.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.245 (0.116, 0.517)	
Heterogeneity p-value [c][e]	0.1279	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.7 (91.1, 99.4)	92.0 (84.0, 96.1)
6 months	95.4 (88.2, 98.2)	85.2 (75.9, 91.1)
12 months	95.4 (88.2, 98.2)	71.4 (60.3, 79.9)
18 months	95.4 (88.2, 98.2)	69.8 (58.6, 78.6)
24 months	88.1 (77.2, 94.0)	66.1 (54.2, 75.6)
30 months	88.1 (77.2, 94.0)	63.4 (50.8, 73.7)
36 months	85.5 (73.2, 92.5)	60.1 (46.4, 71.4)
42 months	85.5 (73.2, 92.5)	60.1 (46.4, 71.4)
48 months	85.5 (73.2, 92.5)	60.1 (46.4, 71.4)
54 months	85.5 (73.2, 92.5)	54.6 (38.2, 68.4)
60 months	85.5 (73.2, 92.5)	54.6 (38.2, 68.4)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	16 (19.5%)	26 (30.6%)
Disease recurrences, n (%)	12 (14.6%)	24 (28.2%)
Deaths, n (%)	4 (4.9%)	2 (2.4%)
Number of censored participants, n (%)	66 (80.5%)	59 (69.4%)
Q1 (95% CI), (months)[a]	30.8 (17.5, NE)	11.5 (4.4, 27.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0690	
HR (95% CI) [c][d]	0.564 (0.302, 1.054)	
Heterogeneity p-value [c][e]	0.1279	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	95.1 (87.5, 98.1)	90.5 (81.9, 95.1)
6 months	93.9 (85.9, 97.4)	81.0 (70.8, 87.9)
12 months	89.7 (80.4, 94.7)	74.5 (63.5, 82.6)
18 months	84.0 (72.5, 91.0)	71.3 (59.9, 80.0)
24 months	79.6 (66.9, 87.9)	69.1 (57.1, 78.4)
30 months	77.3 (64.0, 86.2)	64.0 (50.7, 74.5)
36 months	74.4 (60.0, 84.2)	64.0 (50.7, 74.5)
42 months	69.4 (52.2, 81.4)	64.0 (50.7, 74.5)
48 months	69.4 (52.2, 81.4)	64.0 (50.7, 74.5)
54 months	69.4 (52.2, 81.4)	64.0 (50.7, 74.5)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	26 (13.8%)	62 (32.8%)
Disease recurrences, n (%)	20 (10.6%)	58 (30.7%)
Deaths, n (%)	6 (3.2%)	4 (2.1%)
Number of censored participants, n (%)	163 (86.2%)	127 (67.2%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	9.7 (5.5, 21.7)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.347 (0.219, 0.552)	
Heterogeneity p-value [c][e]	0.8165	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.2 (92.3, 98.2)	89.8 (84.4, 93.3)
6 months	94.6 (90.2, 97.1)	81.1 (74.7, 86.1)
12 months	92.9 (88.1, 95.8)	72.3 (65.1, 78.2)
18 months	91.5 (86.2, 94.8)	70.1 (62.7, 76.3)
24 months	86.3 (79.5, 91.0)	67.3 (59.5, 74.0)
30 months	84.5 (77.3, 89.5)	63.8 (55.3, 71.1)
36 months	83.3 (75.8, 88.7)	62.0 (52.9, 69.7)
42 months	81.5 (73.0, 87.5)	62.0 (52.9, 69.7)
48 months	81.5 (73.0, 87.5)	62.0 (52.9, 69.7)
54 months	77.2 (64.3, 85.9)	55.4 (43.2, 66.0)
60 months	77.2 (64.3, 85.9)	55.4 (43.2, 66.0)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	6 (35.3%)
Disease recurrences, n (%)	2 (10.0%)	6 (35.3%)
Deaths, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	17 (85.0%)	11 (64.7%)
Q1 (95% CI), (months)[a]	30.8 (0.5, NE)	9.5 (4.4, NE)
Median (95% CI), (months)[a]	NR (30.8, NE)	NR (6.4, NE)
Q3 (95% CI), (months)[a]	NR (30.8, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.2606	
HR (95% CI) [c][d]	0.388 (0.071, 2.116)	
Heterogeneity p-value [c][e]	0.8165	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.7 (68.1, 99.2)	100 (100, 100)
6 months	94.7 (68.1, 99.2)	82.4 (54.7, 93.9)
12 months	94.7 (68.1, 99.2)	64.2 (36.9, 82.1)
18 months	86.8 (55.7, 96.7)	64.2 (36.9, 82.1)
24 months	86.8 (55.7, 96.7)	64.2 (36.9, 82.1)
30 months	86.8 (55.7, 96.7)	64.2 (36.9, 82.1)
36 months	57.9 (8.4, 88.6)	64.2 (36.9, 82.1)
42 months	57.9 (8.4, 88.6)	64.2 (36.9, 82.1)
48 months	57.9 (8.4, 88.6)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	22 (13.3%)	57 (32.2%)
Disease recurrences, n (%)	16 (9.6%)	54 (30.5%)
Deaths, n (%)	6 (3.6%)	3 (1.7%)
Number of censored participants, n (%)	144 (86.7%)	120 (67.8%)
Q1 (95% CI), (months)[a]	51.5 (30.8, NE)	10.5 (6.2, 21.7)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.335 (0.204, 0.549)	
Heterogeneity p-value [c][e]	0.7057	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (93.6, 99.1)	91.4 (86.1, 94.7)
6 months	96.9 (92.8, 98.7)	82.1 (75.5, 87.1)
12 months	95.7 (91.1, 97.9)	72.6 (65.1, 78.7)
18 months	93.3 (87.8, 96.3)	70.2 (62.5, 76.6)
24 months	87.5 (80.1, 92.2)	67.1 (58.9, 74.0)
30 months	85.4 (77.5, 90.7)	63.2 (54.3, 70.9)
36 months	82.5 (73.6, 88.6)	61.2 (51.6, 69.5)
42 months	80.2 (70.1, 87.2)	61.2 (51.6, 69.5)
48 months	80.2 (70.1, 87.2)	61.2 (51.6, 69.5)
54 months	74.8 (59.2, 85.2)	57.6 (46.0, 67.6)
60 months	74.8 (59.2, 85.2)	57.6 (46.0, 67.6)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	11 (37.9%)
Disease recurrences, n (%)	6 (14.0%)	10 (34.5%)
Deaths, n (%)	1 (2.3%)	1 (3.4%)
Number of censored participants, n (%)	36 (83.7%)	18 (62.1%)
Q1 (95% CI), (months)[a]	NR (4.0, NE)	6.4 (2.5, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (6.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0812	
HR (95% CI) [c][d]	0.438 (0.169, 1.137)	
Heterogeneity p-value [c][e]	0.7057	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	90.5 (76.6, 96.3)	86.2 (67.3, 94.6)
6 months	85.4 (70.4, 93.2)	75.9 (55.9, 87.7)
12 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
18 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
24 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
30 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
36 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
42 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
48 months	82.4 (66.4, 91.2)	65.0 (44.7, 79.4)
54 months	82.4 (66.4, 91.2)	43.3 (10.1, 73.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	15 (11.3%)	33 (25.2%)
Disease recurrences, n (%)	14 (10.5%)	32 (24.4%)
Deaths, n (%)	1 (0.8%)	1 (0.8%)
Number of censored participants, n (%)	118 (88.7%)	98 (74.8%)
Q1 (95% CI), (months)[a]	NR (30.8, NE)	21.7 (6.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0022	
HR (95% CI) [c][d]	0.396 (0.214, 0.730)	
Heterogeneity p-value [c][e]	0.4104	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.7 (93.0, 99.2)	94.7 (89.1, 97.4)
6 months	96.1 (90.9, 98.4)	86.3 (79.1, 91.1)
12 months	93.6 (87.6, 96.8)	77.3 (68.9, 83.6)
18 months	92.5 (86.0, 96.0)	77.3 (68.9, 83.6)
24 months	88.5 (80.2, 93.4)	74.5 (65.4, 81.5)
30 months	88.5 (80.2, 93.4)	70.9 (60.7, 78.8)
36 months	84.6 (74.4, 91.0)	70.9 (60.7, 78.8)
42 months	81.2 (68.5, 89.2)	70.9 (60.7, 78.8)
48 months	81.2 (68.5, 89.2)	70.9 (60.7, 78.8)
54 months	81.2 (68.5, 89.2)	70.9 (60.7, 78.8)
60 months	81.2 (68.5, 89.2)	70.9 (60.7, 78.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	14 (18.4%)	35 (46.7%)
Disease recurrences, n (%)	8 (10.5%)	32 (42.7%)
Deaths, n (%)	6 (7.9%)	3 (4.0%)
Number of censored participants, n (%)	62 (81.6%)	40 (53.3%)
Q1 (95% CI), (months)[a]	51.5 (22.8, NE)	5.1 (2.8, 10.5)
Median (95% CI), (months)[a]	NR (51.5, NE)	34.5 (11.6, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.263 (0.138, 0.501)	
Heterogeneity p-value [c][e]	0.4104	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	93.3 (84.7, 97.2)	83.2 (72.3, 90.1)
6 months	92.0 (83.0, 96.3)	71.9 (60.0, 80.9)
12 months	92.0 (83.0, 96.3)	61.1 (48.6, 71.5)
18 months	88.7 (78.5, 94.2)	55.9 (43.1, 66.9)
24 months	83.0 (71.2, 90.3)	53.6 (40.7, 65.0)
30 months	79.0 (66.2, 87.4)	50.8 (37.4, 62.7)
36 months	79.0 (66.2, 87.4)	47.2 (33.1, 60.1)
42 months	79.0 (66.2, 87.4)	47.2 (33.1, 60.1)
48 months	79.0 (66.2, 87.4)	47.2 (33.1, 60.1)
54 months	69.1 (44.2, 84.6)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	17 (13.6%)	37 (31.6%)
Disease recurrences, n (%)	16 (12.8%)	35 (29.9%)
Deaths, n (%)	1 (0.8%)	2 (1.7%)
Number of censored participants, n (%)	108 (86.4%)	80 (68.4%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	9.7 (5.3, 48.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0009	
HR (95% CI) [c][d]	0.390 (0.219, 0.695)	
Heterogeneity p-value [c][e]	0.7176	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.3 (88.4, 97.2)	92.2 (85.6, 95.9)
6 months	91.8 (85.4, 95.5)	81.0 (72.6, 87.1)
12 months	91.0 (84.3, 94.9)	72.5 (63.2, 79.8)
18 months	89.8 (82.7, 94.1)	70.2 (60.6, 77.9)
24 months	85.7 (77.1, 91.3)	68.7 (58.9, 76.7)
30 months	85.7 (77.1, 91.3)	66.8 (56.4, 75.3)
36 months	81.6 (71.0, 88.6)	66.8 (56.4, 75.3)
42 months	81.6 (71.0, 88.6)	66.8 (56.4, 75.3)
48 months	81.6 (71.0, 88.6)	66.8 (56.4, 75.3)
54 months	81.6 (71.0, 88.6)	55.7 (38.3, 70.0)
60 months	NE (NE, NE)	55.7 (38.3, 70.0)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	12 (14.3%)	31 (34.8%)
Disease recurrences, n (%)	6 (7.1%)	29 (32.6%)
Deaths, n (%)	6 (7.1%)	2 (2.2%)
Number of censored participants, n (%)	72 (85.7%)	58 (65.2%)
Q1 (95% CI), (months)[a]	51.5 (25.4, NE)	9.7 (4.8, 22.1)
Median (95% CI), (months)[a]	NR (51.5, NE)	NR (27.0, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0006	
HR (95% CI) [c][d]	0.324 (0.165, 0.635)	
Heterogeneity p-value [c][e]	0.7176	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	88.5 (79.6, 93.6)
6 months	98.8 (91.7, 99.8)	81.5 (71.6, 88.2)
12 months	96.2 (88.6, 98.8)	70.2 (59.1, 78.8)
18 months	93.0 (83.9, 97.1)	68.6 (57.3, 77.5)
24 months	87.5 (76.3, 93.6)	64.4 (52.2, 74.2)
30 months	83.6 (71.3, 90.9)	58.8 (45.2, 70.1)
36 months	83.6 (71.3, 90.9)	54.2 (38.9, 67.3)
42 months	79.6 (64.5, 88.8)	54.2 (38.9, 67.3)
48 months	79.6 (64.5, 88.8)	54.2 (38.9, 67.3)
54 months	69.6 (43.5, 85.4)	54.2 (38.9, 67.3)
60 months	69.6 (43.5, 85.4)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Number of events, n (%)	18 (11.6%)	47 (30.5%)
Disease recurrences, n (%)	12 (7.7%)	44 (28.6%)
Deaths, n (%)	6 (3.9%)	3 (1.9%)
Number of censored participants, n (%)	137 (88.4%)	107 (69.5%)
Q1 (95% CI), (months)[a]	NR (30.8, NE)	10.5 (6.2, 34.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.315 (0.180, 0.550)	
Heterogeneity p-value [c][e]	0.5991	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.7 (92.3, 98.6)	90.1 (84.1, 93.9)
6 months	96.7 (92.3, 98.6)	82.1 (75.1, 87.4)
12 months	95.3 (90.4, 97.7)	72.0 (64.0, 78.6)
18 months	92.6 (86.6, 96.0)	71.2 (63.1, 77.9)
24 months	89.5 (82.5, 93.9)	70.1 (61.8, 77.0)
30 months	87.2 (79.4, 92.2)	68.5 (59.8, 75.8)
36 months	83.9 (74.6, 90.0)	66.0 (56.0, 74.2)
42 months	83.9 (74.6, 90.0)	66.0 (56.0, 74.2)
48 months	83.9 (74.6, 90.0)	66.0 (56.0, 74.2)
54 months	75.5 (53.4, 88.2)	56.5 (40.8, 69.5)
60 months	NE (NE, NE)	56.5 (40.8, 69.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Number of events, n (%)	9 (21.4%)	17 (39.5%)
Disease recurrences, n (%)	8 (19.0%)	16 (37.2%)
Deaths, n (%)	1 (2.4%)	1 (2.3%)
Number of censored participants, n (%)	33 (78.6%)	26 (60.5%)
Q1 (95% CI), (months)[a]	23.1 (9.9, NE)	6.7 (3.3, 22.1)
Median (95% CI), (months)[a]	NR (37.6, NE)	27.1 (17.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0157	
HR (95% CI) [c][d]	0.357 (0.150, 0.850)	
Heterogeneity p-value [c][e]	0.5991	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	95.1 (81.9, 98.8)	90.5 (76.6, 96.3)
6 months	90.2 (76.1, 96.2)	78.6 (62.9, 88.2)
12 months	87.4 (72.3, 94.6)	71.1 (54.8, 82.5)
18 months	87.4 (72.3, 94.6)	64.5 (47.1, 77.4)
24 months	74.3 (53.8, 86.8)	59.5 (40.8, 74.1)
30 months	74.3 (53.8, 86.8)	47.6 (27.1, 65.6)
36 months	74.3 (53.8, 86.8)	47.6 (27.1, 65.6)
42 months	67.6 (44.2, 82.8)	47.6 (27.1, 65.6)
48 months	67.6 (44.2, 82.8)	47.6 (27.1, 65.6)
54 months	67.6 (44.2, 82.8)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Number of events, n (%)	8 (21.1%)	16 (37.2%)
Disease recurrences, n (%)	6 (15.8%)	15 (34.9%)
Deaths, n (%)	2 (5.3%)	1 (2.3%)
Number of censored participants, n (%)	30 (78.9%)	27 (62.8%)
Q1 (95% CI), (months)[a]	NR (5.2, NE)	6.4 (1.9, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0854	
HR (95% CI) [c][d]	0.477 (0.202, 1.129)	
Heterogeneity p-value [c][e]	0.3961	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	92.1 (77.5, 97.4)	85.7 (70.9, 93.3)
6 months	89.4 (74.2, 95.9)	76.2 (60.3, 86.4)
12 months	89.4 (74.2, 95.9)	71.4 (55.2, 82.6)
18 months	86.6 (70.7, 94.2)	71.4 (55.2, 82.6)
24 months	83.8 (67.4, 92.4)	68.8 (52.3, 80.5)
30 months	83.8 (67.4, 92.4)	68.8 (52.3, 80.5)
36 months	81.0 (64.2, 90.5)	65.9 (49.2, 78.3)
42 months	81.0 (64.2, 90.5)	65.9 (49.2, 78.3)
48 months	81.0 (64.2, 90.5)	65.9 (49.2, 78.3)
54 months	76.5 (57.7, 87.8)	58.8 (41.2, 72.7)
60 months	76.5 (57.7, 87.8)	58.8 (41.2, 72.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Number of events, n (%)	21 (12.3%)	52 (31.9%)
Disease recurrences, n (%)	16 (9.4%)	49 (30.1%)
Deaths, n (%)	5 (2.9%)	3 (1.8%)
Number of censored participants, n (%)	150 (87.7%)	111 (68.1%)
Q1 (95% CI), (months)[a]	NR (30.8, NE)	10.4 (6.2, 18.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.311 (0.185, 0.522)	
Heterogeneity p-value [c][e]	0.3961	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.1.1 Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.0 (93.0, 98.7)	91.9 (86.5, 95.2)
6 months	95.8 (91.4, 98.0)	82.5 (75.7, 87.6)
12 months	93.9 (88.9, 96.6)	71.3 (63.4, 77.8)
18 months	92.0 (86.2, 95.4)	68.6 (60.3, 75.5)
24 months	86.5 (78.7, 91.6)	66.0 (57.3, 73.4)
30 months	84.1 (75.7, 89.8)	60.5 (50.3, 69.3)
36 months	82.1 (72.7, 88.5)	60.5 (50.3, 69.3)
42 months	77.5 (63.6, 86.7)	60.5 (50.3, 69.3)
48 months	77.5 (63.6, 86.7)	60.5 (50.3, 69.3)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	9 (16.1%)	22 (33.8%)
Disease recurrences, n (%)	7 (12.5%)	22 (33.8%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	47 (83.9%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.3469	
Hazard ratio(interaction)	1.415 (0.686, 2.918)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	20 (13.1%)	46 (32.6%)
Disease recurrences, n (%)	15 (9.8%)	42 (29.8%)
Deaths, n (%)	5 (3.3%)	4 (2.8%)
Number of censored participants, n (%)	133 (86.9%)	95 (67.4%)
Proportionality Test p-value[a][b]	0.1619	
Hazard ratio(interaction)	0.685 (0.403, 1.164)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	9 (16.1%)	22 (33.8%)
Disease recurrences, n (%)	7 (12.5%)	22 (33.8%)
Deaths, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	47 (83.9%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.3469	
Hazard ratio(interaction)	1.415 (0.686, 2.918)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	12 (15.0%)	21 (30.4%)
Disease recurrences, n (%)	9 (11.3%)	19 (27.5%)
Deaths, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	68 (85.0%)	48 (69.6%)
Proportionality Test p-value[a][b]	0.3520	
Hazard ratio(interaction)	0.701 (0.331, 1.482)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	8 (11.0%)	25 (34.7%)
Disease recurrences, n (%)	6 (8.2%)	23 (31.9%)
Deaths, n (%)	2 (2.7%)	2 (2.8%)
Number of censored participants, n (%)	65 (89.0%)	47 (65.3%)
Proportionality Test p-value[a][b]	0.5116	
Hazard ratio(interaction)	0.738 (0.298, 1.828)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	23 (13.2%)	51 (29.3%)
Disease recurrences, n (%)	18 (10.3%)	49 (28.2%)
Deaths, n (%)	5 (2.9%)	2 (1.1%)
Number of censored participants, n (%)	151 (86.8%)	123 (70.7%)
Proportionality Test p-value[a][b]	0.1545	
Hazard ratio(interaction)	0.708 (0.440, 1.139)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	6 (17.1%)	17 (53.1%)
Disease recurrences, n (%)	4 (11.4%)	15 (46.9%)
Deaths, n (%)	2 (5.7%)	2 (6.3%)
Number of censored participants, n (%)	29 (82.9%)	15 (46.9%)
Proportionality Test p-value[a][b]	0.2854	
Hazard ratio(interaction)	1.629 (0.665, 3.990)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	12 (38.7%)
Disease recurrences, n (%)	2 (5.4%)	11 (35.5%)
Deaths, n (%)	2 (5.4%)	1 (3.2%)
Number of censored participants, n (%)	33 (89.2%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.6698	
Hazard ratio(interaction)	0.823 (0.336, 2.014)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	9 (10.0%)	30 (33.3%)
Disease recurrences, n (%)	8 (8.9%)	29 (32.2%)
Deaths, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	81 (90.0%)	60 (66.7%)
Proportionality Test p-value[a][b]	0.7345	
Hazard ratio(interaction)	0.875 (0.403, 1.898)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	16 (19.5%)	26 (30.6%)
Disease recurrences, n (%)	12 (14.6%)	24 (28.2%)
Deaths, n (%)	4 (4.9%)	2 (2.4%)
Number of censored participants, n (%)	66 (80.5%)	59 (69.4%)
Proportionality Test p-value[a][b]	0.5077	
Hazard ratio(interaction)	0.823 (0.463, 1.463)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	26 (13.8%)	62 (32.8%)
Disease recurrences, n (%)	20 (10.6%)	58 (30.7%)
Deaths, n (%)	6 (3.2%)	4 (2.1%)
Number of censored participants, n (%)	163 (86.2%)	127 (67.2%)
Proportionality Test p-value[a][b]	0.3223	
Hazard ratio(interaction)	0.808 (0.529, 1.233)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	6 (35.3%)
Disease recurrences, n (%)	2 (10.0%)	6 (35.3%)
Deaths, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	17 (85.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	0.2175	
Hazard ratio(interaction)	2.772 (0.548, 14.008)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	22 (13.3%)	57 (32.2%)
Disease recurrences, n (%)	16 (9.6%)	54 (30.5%)
Deaths, n (%)	6 (3.6%)	3 (1.7%)
Number of censored participants, n (%)	144 (86.7%)	120 (67.8%)
Proportionality Test p-value[a][b]	0.0678	
Hazard ratio(interaction)	0.615 (0.365, 1.036)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	11 (37.9%)
Disease recurrences, n (%)	6 (14.0%)	10 (34.5%)
Deaths, n (%)	1 (2.3%)	1 (3.4%)
Number of censored participants, n (%)	36 (83.7%)	18 (62.1%)
Proportionality Test p-value[a][b]	0.1363	
Hazard ratio(interaction)	2.591 (0.740, 9.065)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	15 (11.3%)	33 (25.2%)
Disease recurrences, n (%)	14 (10.5%)	32 (24.4%)
Deaths, n (%)	1 (0.8%)	1 (0.8%)
Number of censored participants, n (%)	118 (88.7%)	98 (74.8%)
Proportionality Test p-value[a][b]	0.1618	
Hazard ratio(interaction)	0.608 (0.303, 1.221)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	14 (18.4%)	35 (46.7%)
Disease recurrences, n (%)	8 (10.5%)	32 (42.7%)
Deaths, n (%)	6 (7.9%)	3 (4.0%)
Number of censored participants, n (%)	62 (81.6%)	40 (53.3%)
Proportionality Test p-value[a][b]	0.4249	
Hazard ratio(interaction)	1.231 (0.739, 2.052)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	17 (13.6%)	37 (31.6%)
Disease recurrences, n (%)	16 (12.8%)	35 (29.9%)
Deaths, n (%)	1 (0.8%)	2 (1.7%)
Number of censored participants, n (%)	108 (86.4%)	80 (68.4%)
Proportionality Test p-value[a][b]	0.4645	
Hazard ratio(interaction)	1.228 (0.708, 2.128)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	12 (14.3%)	31 (34.8%)
Disease recurrences, n (%)	6 (7.1%)	29 (32.6%)
Deaths, n (%)	6 (7.1%)	2 (2.2%)
Number of censored participants, n (%)	72 (85.7%)	58 (65.2%)
Proportionality Test p-value[a][b]	0.0368	
Hazard ratio(interaction)	0.406 (0.174, 0.946)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%

	Cemiplimab (N=155)	Placebo (N=154)
Number of events, n (%)	18 (11.6%)	47 (30.5%)
Disease recurrences, n (%)	12 (7.7%)	44 (28.6%)
Deaths, n (%)	6 (3.9%)	3 (1.9%)
Number of censored participants, n (%)	137 (88.4%)	107 (69.5%)
Proportionality Test p-value[a][b]	0.4022	
Hazard ratio(interaction)	0.797 (0.468, 1.356)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%

	Cemiplimab (N=42)	Placebo (N=43)
Number of events, n (%)	9 (21.4%)	17 (39.5%)
Disease recurrences, n (%)	8 (19.0%)	16 (37.2%)
Deaths, n (%)	1 (2.4%)	1 (2.3%)
Number of censored participants, n (%)	33 (78.6%)	26 (60.5%)
Proportionality Test p-value[a][b]	0.4059	
Hazard ratio(interaction)	0.712 (0.319, 1.587)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only

	Cemiplimab (N=38)	Placebo (N=43)
Number of events, n (%)	8 (21.1%)	16 (37.2%)
Disease recurrences, n (%)	6 (15.8%)	15 (34.9%)
Deaths, n (%)	2 (5.3%)	1 (2.3%)
Number of censored participants, n (%)	30 (78.9%)	27 (62.8%)
Proportionality Test p-value[a][b]	0.9794	
Hazard ratio(interaction)	0.992 (0.555, 1.773)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.2.1 Test of Proportional Hazards Assumption for Disease Free Survival by Subgroup
(Full Analysis Set)

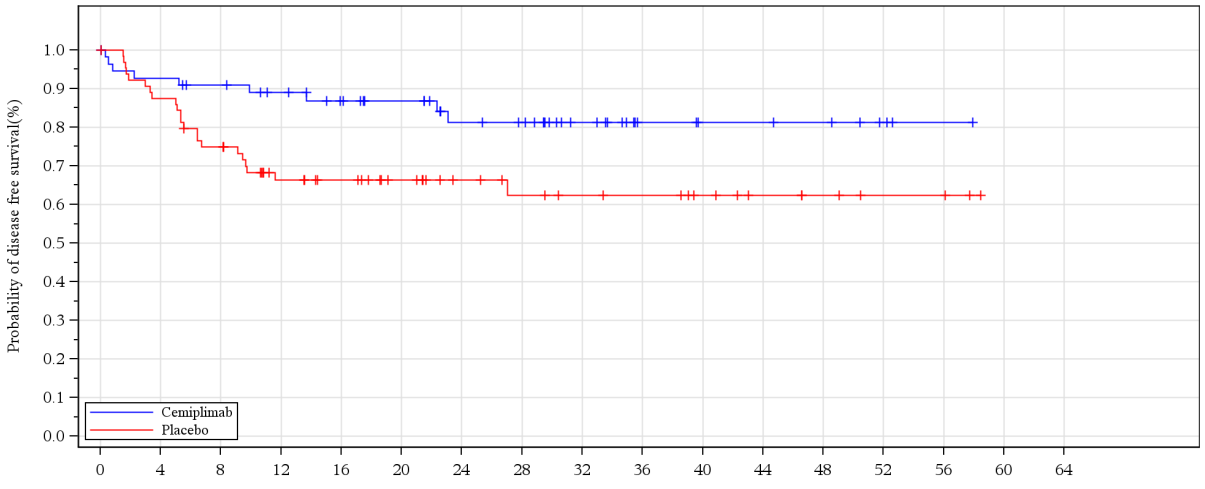
Dosing Regimen: 350 mg Q3W + 700 mg Q6W

	Cemiplimab (N=171)	Placebo (N=163)
Number of events, n (%)	21 (12.3%)	52 (31.9%)
Disease recurrences, n (%)	16 (9.4%)	49 (30.1%)
Deaths, n (%)	5 (2.9%)	3 (1.8%)
Number of censored participants, n (%)	150 (87.7%)	111 (68.1%)
Proportionality Test p-value[a][b]	0.3018	
Hazard ratio(interaction)	0.741 (0.419, 1.310)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	51 (1)	48 (3)	44 (6)	39 (10)	35 (14)	28 (19)	26 (21)	17 (30)	9 (38)	7 (40)	7 (40)	6 (41)	3 (44)	1 (46)	0 (47)	0 (47)
Placebo	65 (0)	56 (1)	47 (2)	35 (9)	31 (13)	25 (19)	19 (25)	16 (27)	14 (29)	13 (30)	10 (33)	7 (36)	5 (38)	3 (40)	3 (40)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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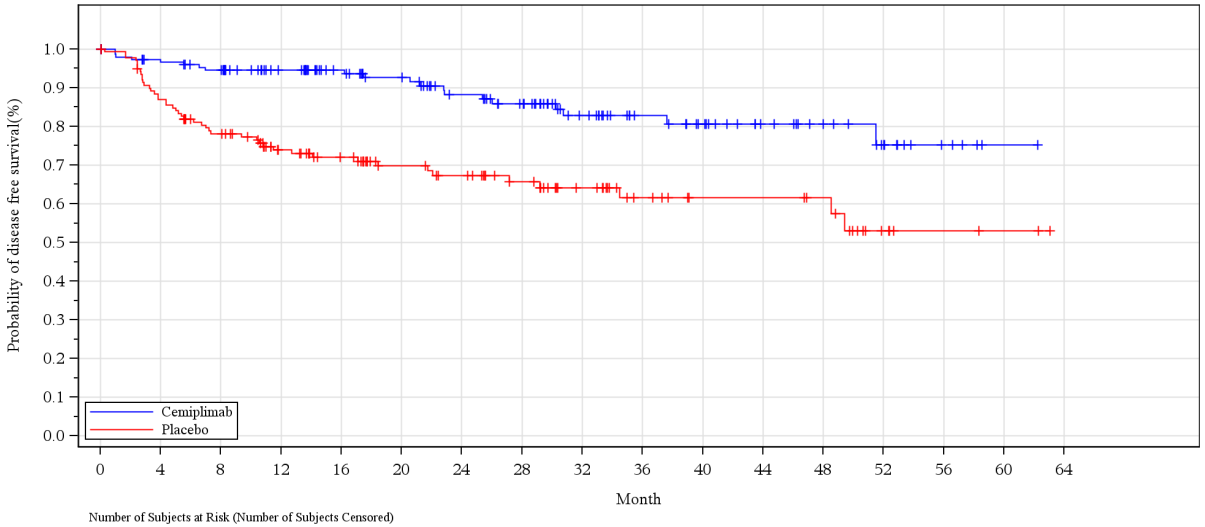
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	142 (6)	136 (9)	116 (29)	99 (46)	90 (53)	77 (62)	68 (69)	50 (85)	38 (97)	32 (102)	23 (111)	18 (117)	12 (121)	5 (128)	1 (132)	0 (133)
Placebo	141 (0)	120 (3)	102 (9)	81 (25)	70 (34)	56 (46)	51 (49)	42 (57)	32 (66)	22 (75)	17 (80)	17 (80)	15 (82)	6 (89)	3 (92)	2 (93)	0 (95)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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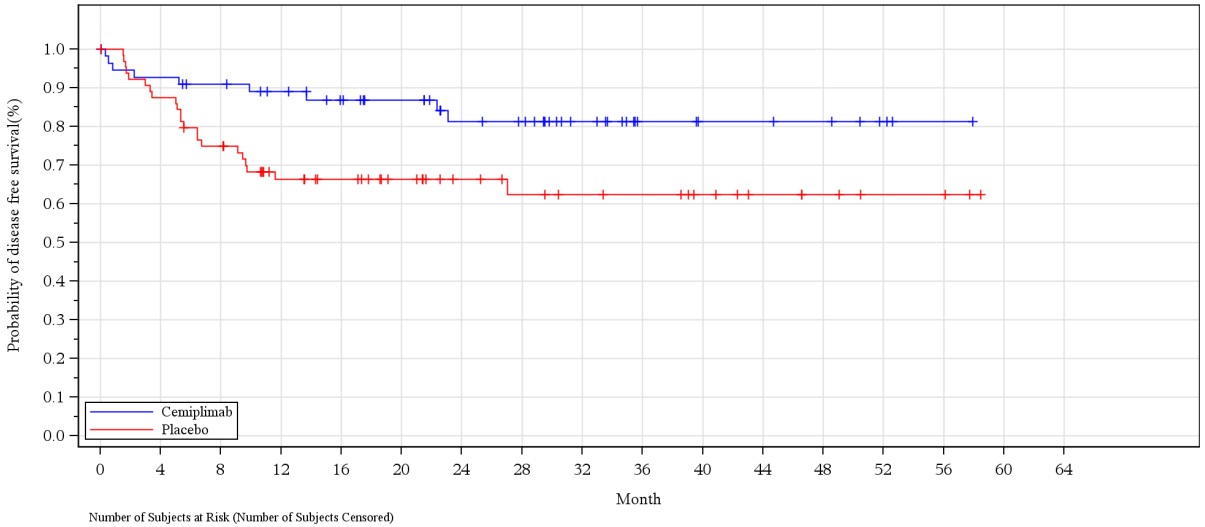
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	51 (1)	48 (3)	44 (6)	39 (10)	35 (14)	28 (19)	26 (21)	17 (30)	9 (38)	7 (40)	7 (40)	6 (41)	3 (44)	1 (46)	0 (47)	0 (47)
Placebo	65 (0)	56 (1)	47 (2)	35 (9)	31 (13)	25 (19)	19 (25)	16 (27)	14 (29)	13 (30)	10 (33)	7 (36)	5 (38)	3 (40)	3 (40)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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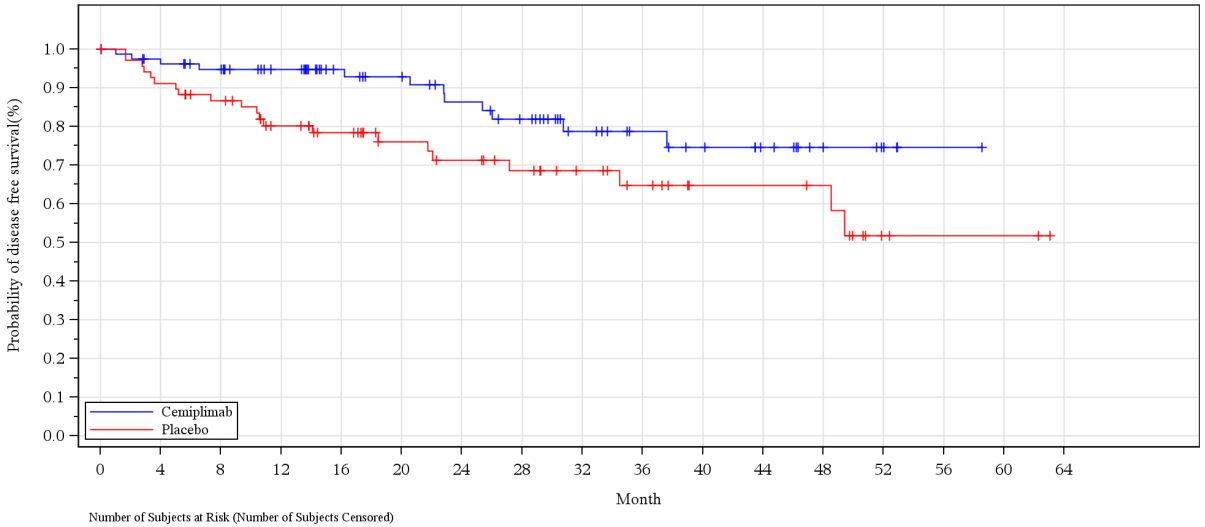
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



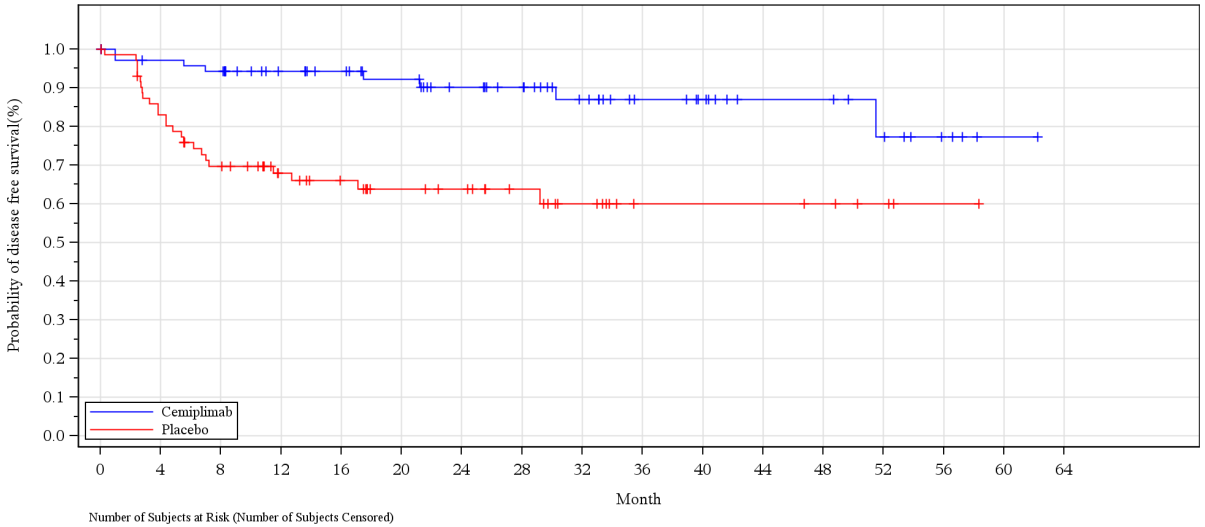
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	74 (3)	70 (6)	61 (15)	49 (27)	45 (30)	39 (33)	34 (36)	24 (45)	19 (50)	16 (52)	12 (56)	7 (62)	4 (64)	1 (67)	0 (68)	0 (68)
Placebo	69 (0)	62 (1)	56 (4)	46 (10)	40 (15)	32 (22)	29 (23)	25 (26)	20 (31)	16 (34)	11 (39)	11 (39)	10 (40)	3 (45)	2 (46)	2 (46)	0 (48)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Age group 2: >=75



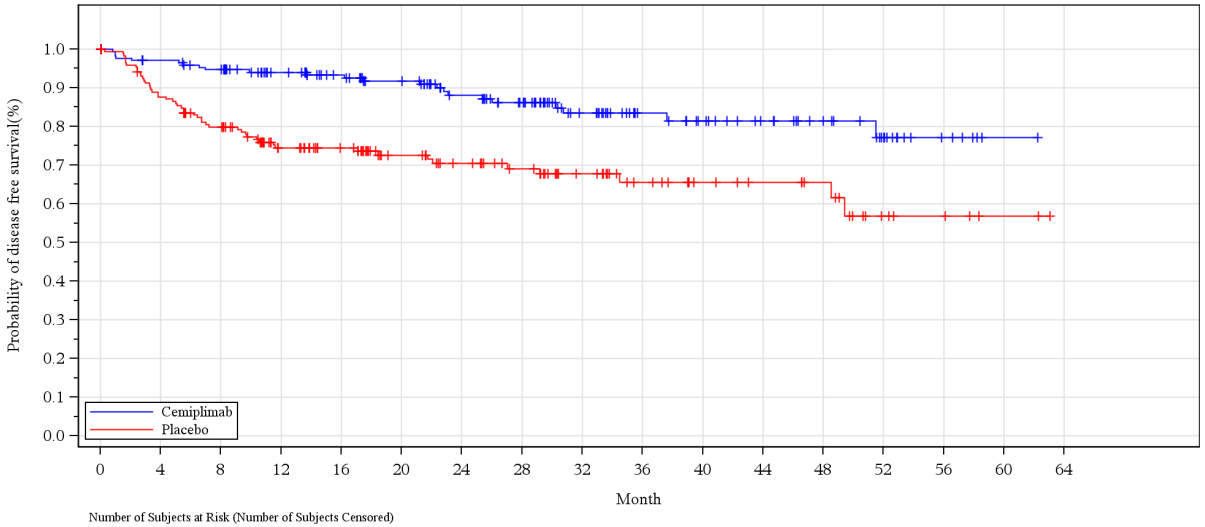
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	68 (3)	66 (3)	55 (14)	50 (19)	45 (23)	38 (29)	34 (33)	26 (40)	19 (47)	16 (50)	11 (55)	11 (55)	8 (57)	4 (61)	1 (64)	0 (65)
Placebo	72 (0)	58 (2)	46 (5)	35 (15)	30 (19)	24 (24)	22 (26)	17 (31)	12 (35)	6 (41)	6 (41)	6 (41)	5 (42)	3 (44)	1 (46)	0 (47)	0 (47)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Gender group: Male



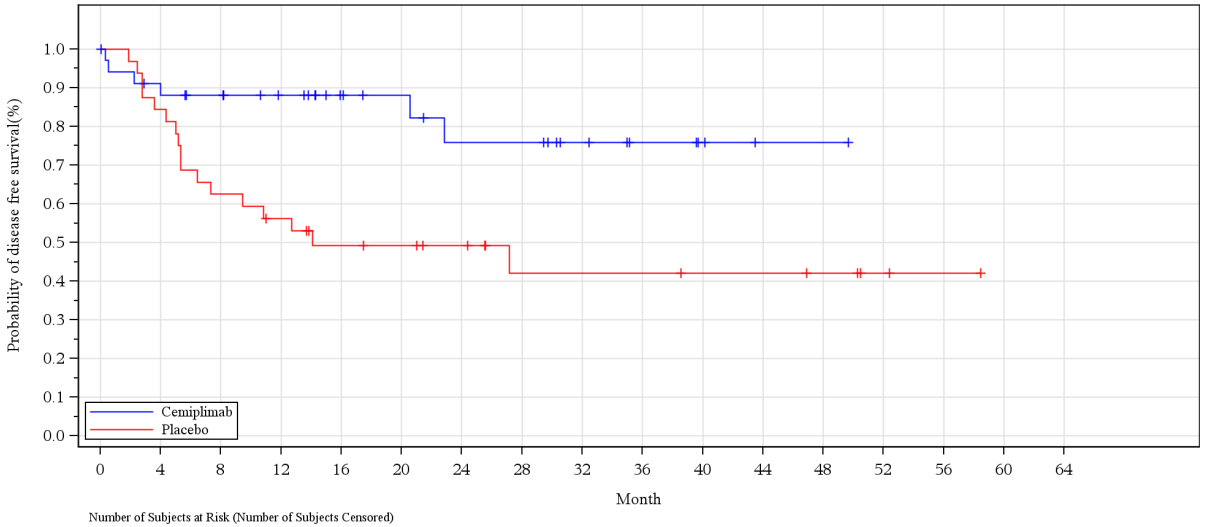
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	164 (5)	157 (8)	137 (27)	121 (42)	110 (51)	93 (64)	82 (73)	59 (94)	42 (111)	36 (116)	29 (123)	23 (130)	15 (136)	6 (145)	1 (150)	0 (151)
Placebo	174 (0)	149 (4)	129 (11)	99 (33)	88 (44)	69 (61)	60 (68)	52 (75)	40 (86)	29 (96)	22 (103)	19 (106)	16 (109)	7 (116)	5 (118)	2 (121)	0 (123)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Gender group: Female



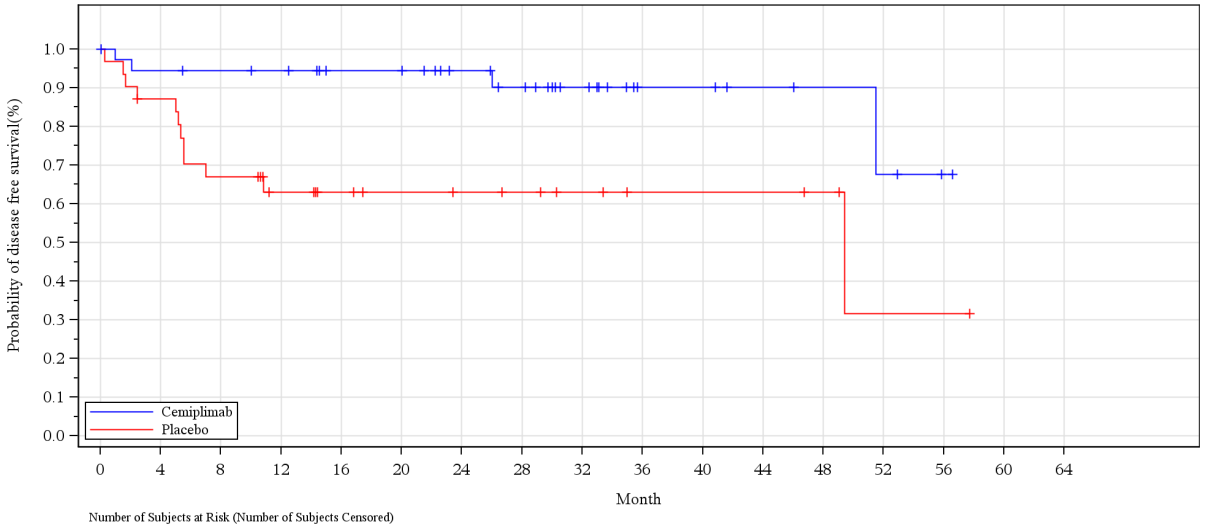
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	29 (2)	27 (4)	23 (8)	17 (14)	15 (16)	12 (17)	12 (17)	8 (21)	5 (24)	3 (26)	1 (28)	1 (28)	0 (29)	0 (29)	0 (29)	0 (29)
Placebo	32 (0)	27 (0)	20 (0)	17 (1)	13 (3)	12 (4)	10 (6)	6 (9)	6 (9)	6 (9)	5 (10)	5 (10)	4 (11)	2 (13)	1 (14)	0 (15)	0 (15)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



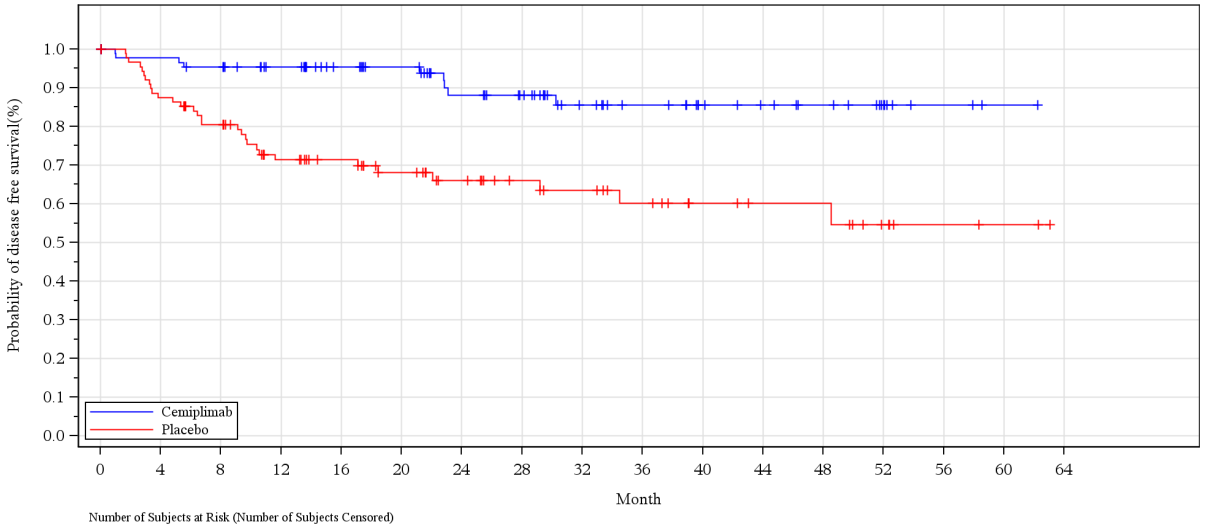
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	34 (1)	33 (2)	32 (3)	28 (7)	28 (7)	23 (12)	20 (14)	14 (20)	7 (27)	7 (27)	5 (29)	4 (30)	3 (30)	1 (32)	0 (33)	0 (33)
Placebo	31 (0)	26 (1)	20 (1)	15 (5)	12 (8)	10 (10)	9 (11)	8 (12)	6 (14)	4 (16)	4 (16)	4 (16)	3 (17)	1 (18)	1 (18)	0 (19)	0 (19)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	85 (3)	82 (4)	74 (12)	63 (23)	58 (28)	47 (35)	42 (40)	30 (51)	25 (56)	19 (62)	16 (65)	13 (68)	8 (73)	3 (78)	1 (80)	0 (81)
Placebo	90 (0)	77 (2)	67 (6)	52 (14)	46 (20)	38 (26)	31 (32)	25 (38)	22 (40)	18 (43)	13 (48)	11 (50)	11 (50)	6 (54)	3 (57)	2 (58)	0 (60)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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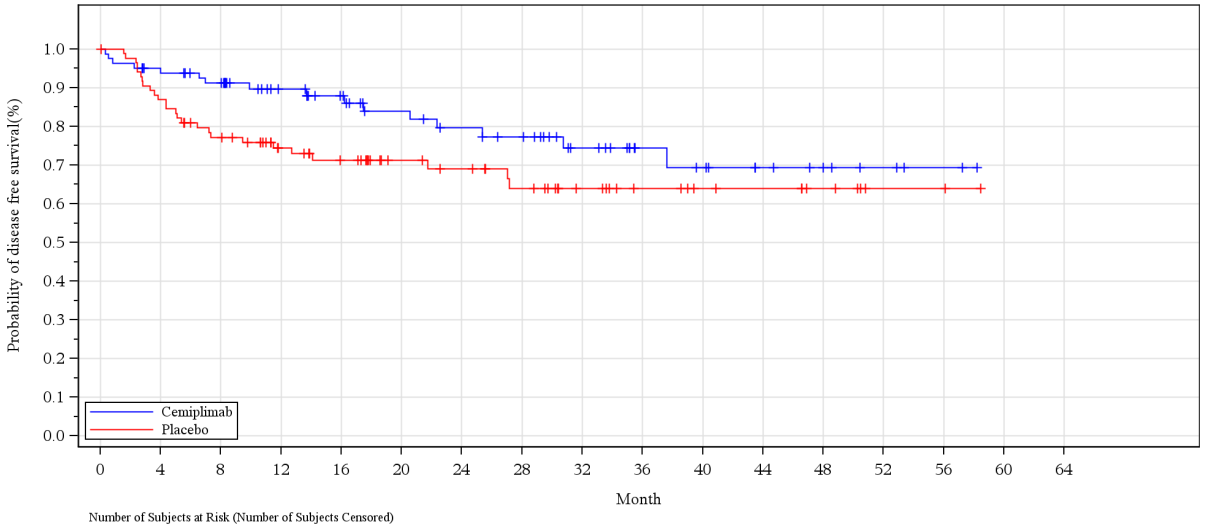
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



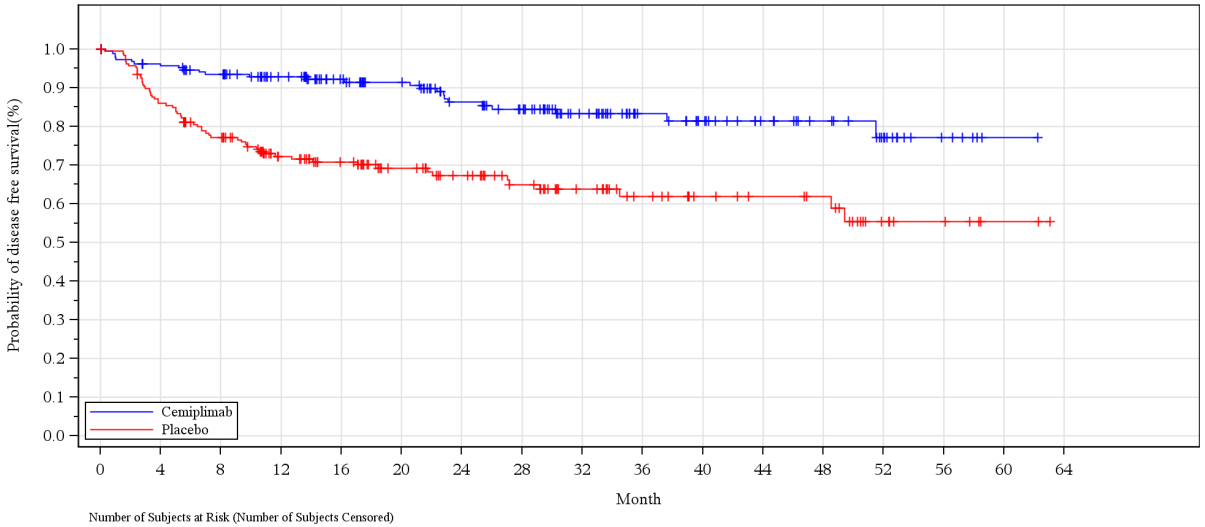
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	74 (3)	69 (6)	54 (20)	47 (26)	39 (32)	35 (34)	32 (36)	23 (44)	15 (52)	13 (53)	9 (57)	7 (60)	4 (62)	2 (64)	0 (66)	0 (66)
Placebo	85 (0)	73 (1)	62 (4)	49 (15)	43 (19)	33 (29)	30 (31)	25 (34)	18 (41)	13 (46)	10 (49)	9 (50)	6 (53)	2 (57)	2 (57)	0 (59)	0 (59)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	176 (5)	167 (10)	147 (29)	126 (49)	114 (60)	96 (72)	87 (79)	65 (100)	45 (120)	37 (127)	28 (136)	22 (142)	15 (148)	6 (157)	1 (162)	0 (163)
Placebo	189 (0)	159 (4)	136 (11)	106 (33)	93 (44)	76 (59)	66 (67)	55 (76)	43 (87)	32 (97)	25 (104)	22 (107)	20 (109)	9 (118)	6 (121)	2 (125)	0 (127)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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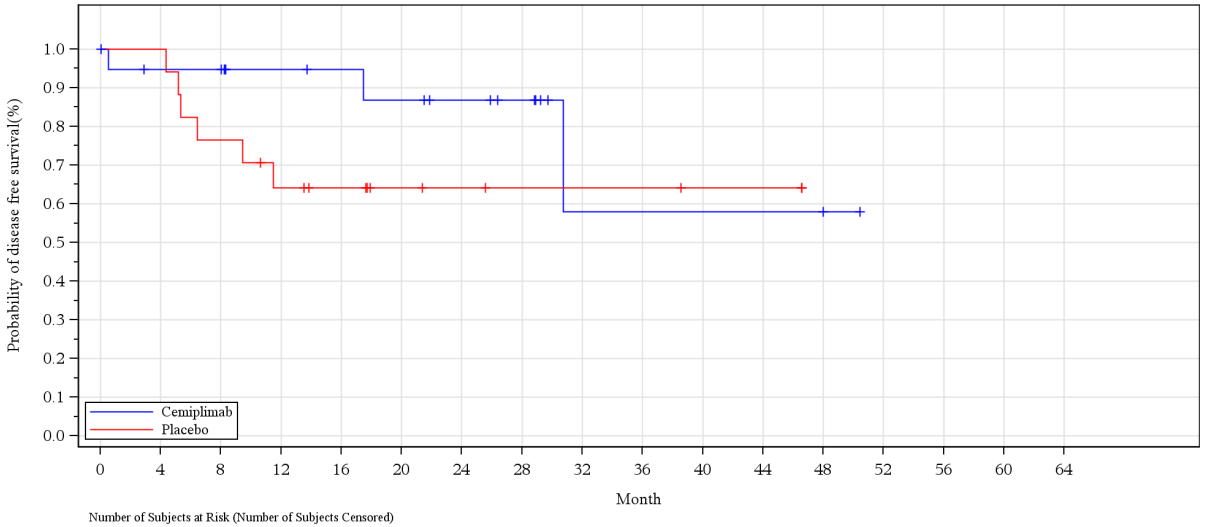
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	17 (2)	17 (2)	13 (6)	12 (7)	11 (7)	9 (9)	7 (11)	2 (15)	2 (15)	2 (15)	2 (15)	2 (16)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	17 (0)	17 (0)	13 (0)	10 (1)	8 (3)	5 (6)	4 (7)	3 (8)	3 (8)	3 (8)	2 (9)	2 (9)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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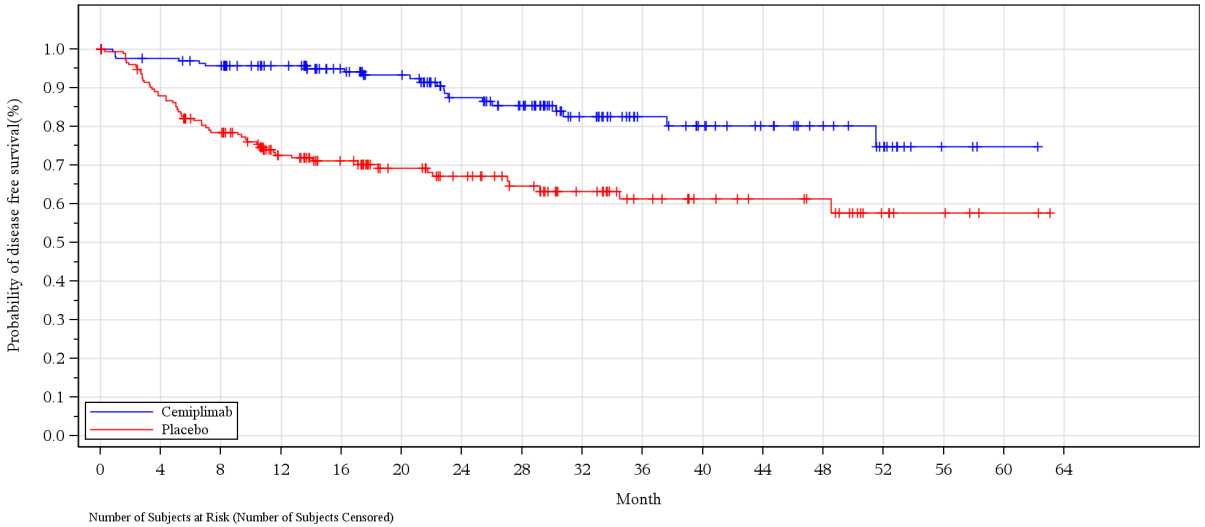
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	158 (4)	153 (6)	137 (22)	117 (41)	106 (50)	86 (64)	76 (72)	52 (94)	36 (110)	30 (115)	24 (121)	18 (128)	12 (132)	3 (141)	1 (143)	0 (144)
Placebo	177 (0)	152 (4)	130 (10)	99 (32)	85 (44)	68 (59)	59 (66)	50 (73)	39 (83)	28 (93)	22 (99)	19 (102)	17 (104)	8 (112)	5 (115)	2 (118)	0 (120)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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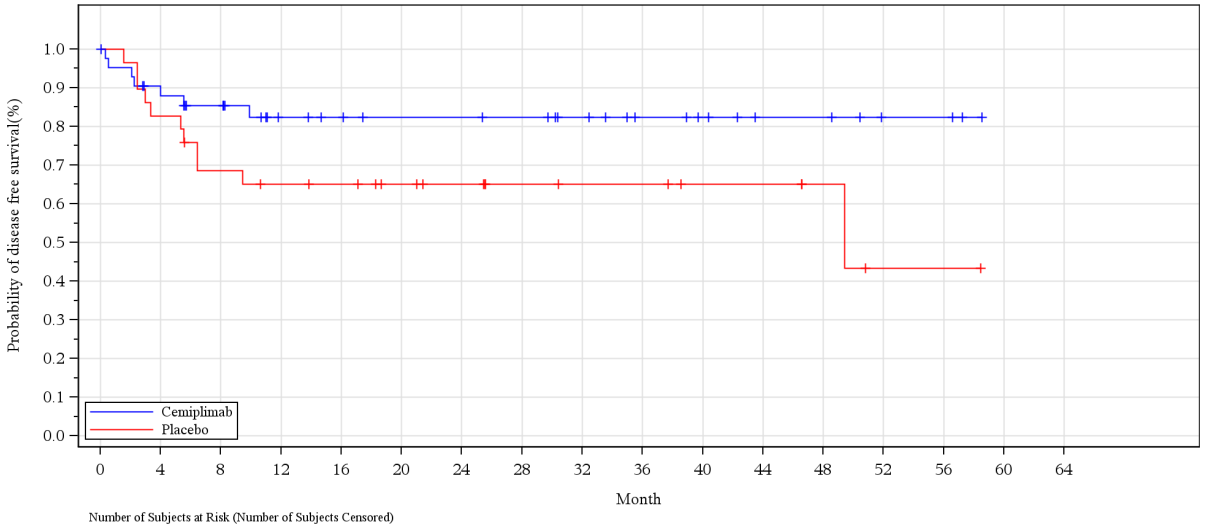
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	35 (3)	31 (6)	23 (13)	21 (15)	19 (17)	19 (17)	18 (18)	15 (21)	11 (25)	9 (27)	6 (30)	6 (30)	3 (33)	3 (33)	0 (36)	0 (36)
Placebo	29 (0)	24 (0)	19 (1)	17 (2)	16 (3)	13 (6)	11 (8)	8 (11)	7 (12)	7 (12)	5 (14)	5 (14)	3 (16)	1 (17)	1 (17)	0 (18)	0 (18)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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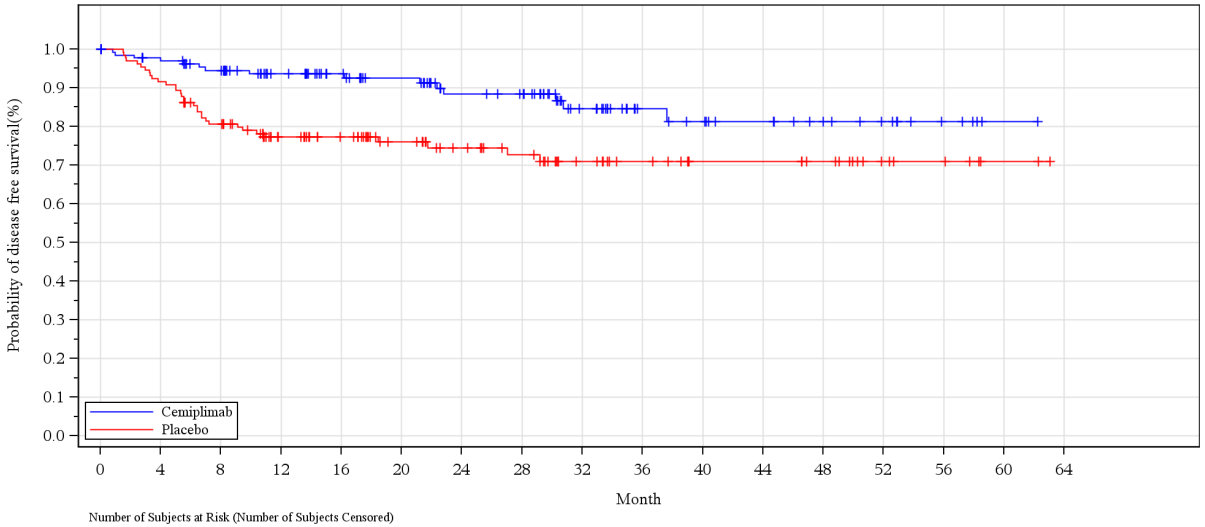
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	124 (5)	116 (10)	98 (27)	85 (40)	76 (48)	62 (59)	59 (62)	39 (80)	25 (94)	22 (96)	18 (100)	14 (105)	10 (108)	5 (113)	1 (117)	0 (118)
Placebo	131 (0)	120 (0)	101 (5)	79 (23)	70 (32)	56 (45)	47 (53)	41 (58)	30 (68)	24 (74)	18 (80)	18 (80)	15 (83)	8 (90)	6 (92)	2 (96)	0 (98)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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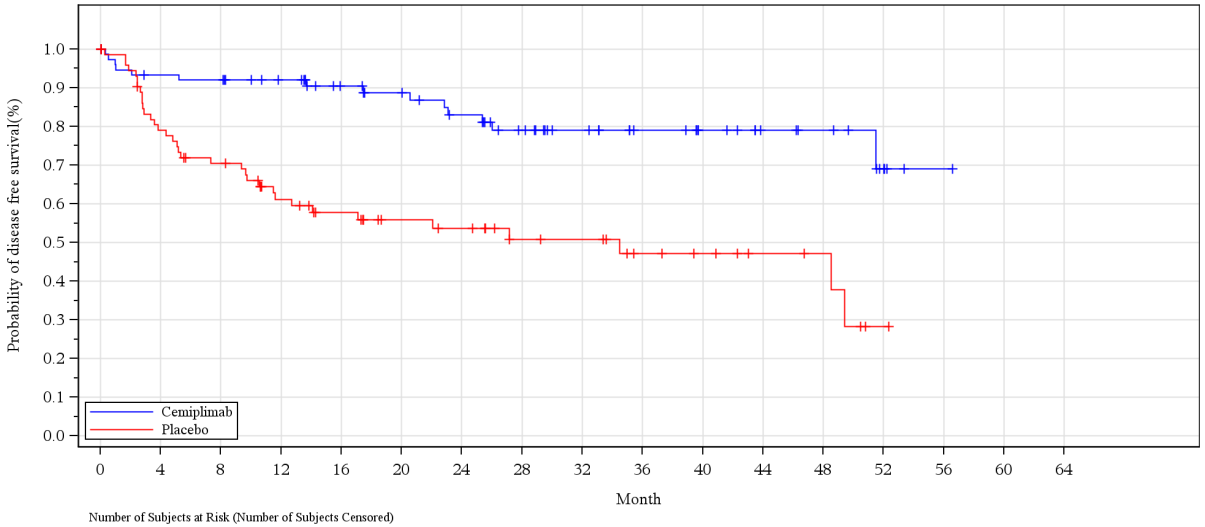
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	69 (2)	68 (2)	62 (8)	53 (16)	49 (19)	43 (22)	35 (28)	28 (35)	22 (41)	17 (46)	12 (51)	10 (53)	5 (57)	1 (61)	0 (62)	0 (62)
Placebo	75 (0)	56 (4)	48 (6)	37 (11)	31 (15)	25 (20)	23 (21)	17 (26)	16 (27)	11 (31)	9 (33)	6 (36)	5 (37)	1 (39)	0 (40)	0 (40)	0 (40)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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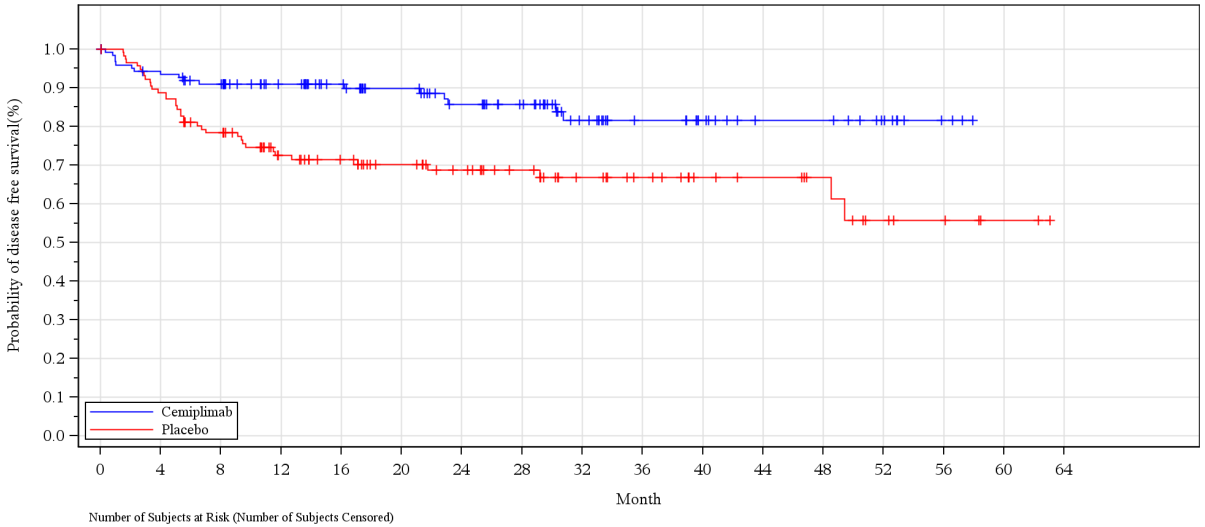
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	114 (3)	107 (7)	92 (22)	80 (34)	70 (43)	60 (50)	53 (57)	36 (72)	26 (82)	20 (88)	14 (94)	14 (94)	9 (99)	3 (105)	0 (108)	0 (108)
Placebo	117 (0)	103 (1)	87 (5)	68 (18)	60 (25)	51 (33)	44 (39)	37 (46)	28 (54)	23 (59)	17 (65)	15 (67)	12 (70)	7 (73)	5 (75)	2 (78)	0 (80)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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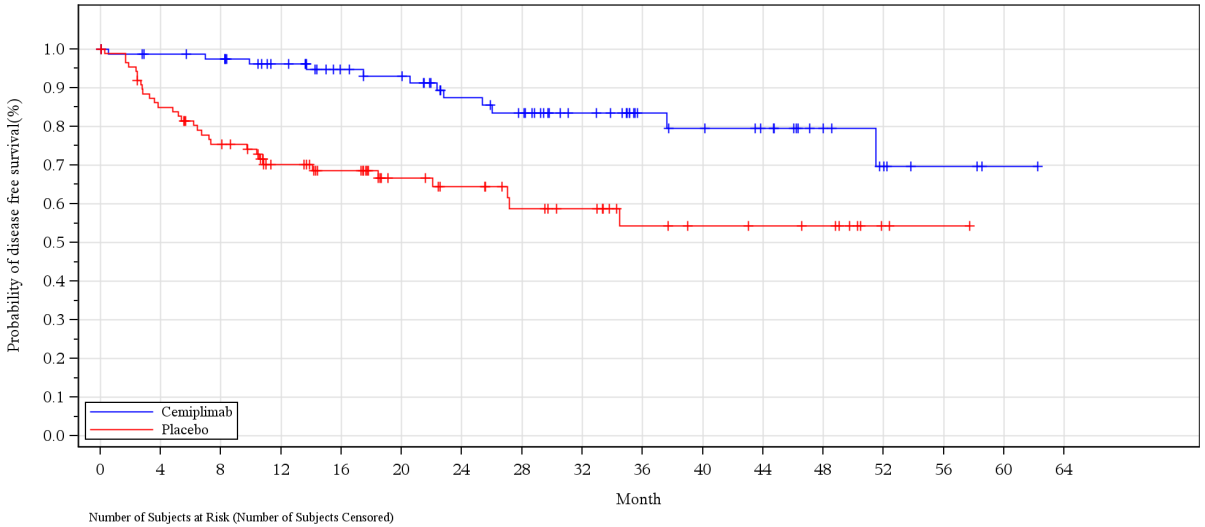
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	79 (4)	77 (5)	68 (13)	58 (22)	55 (24)	45 (31)	41 (33)	31 (43)	21 (53)	19 (54)	16 (57)	10 (64)	6 (66)	3 (69)	1 (71)	0 (72)
Placebo	89 (0)	73 (3)	62 (6)	48 (16)	41 (22)	30 (32)	26 (35)	21 (38)	18 (41)	12 (46)	10 (48)	9 (49)	8 (50)	2 (56)	1 (57)	0 (58)	0 (58)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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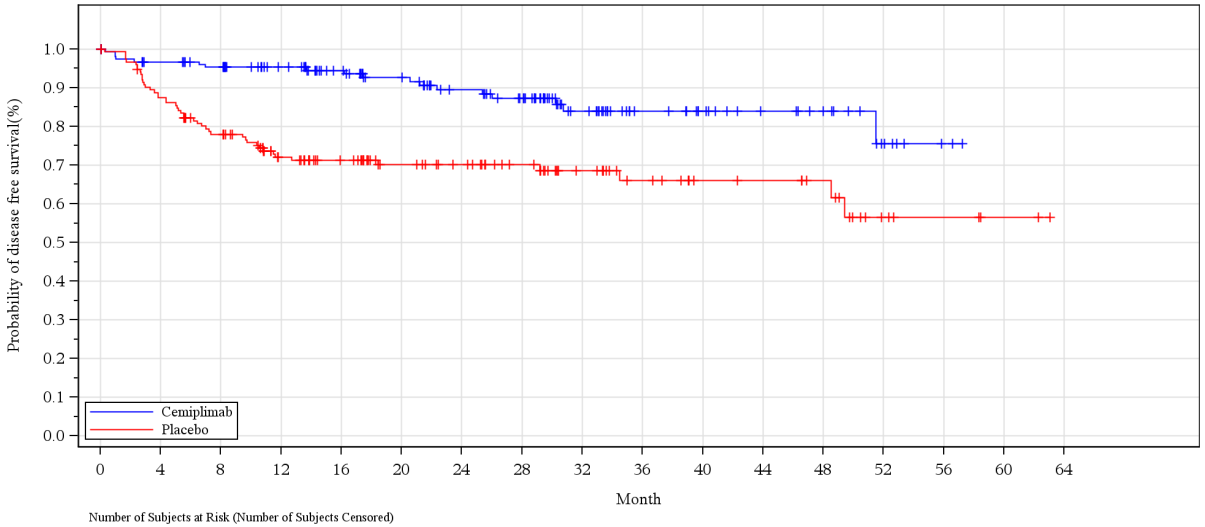
Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS>=1%



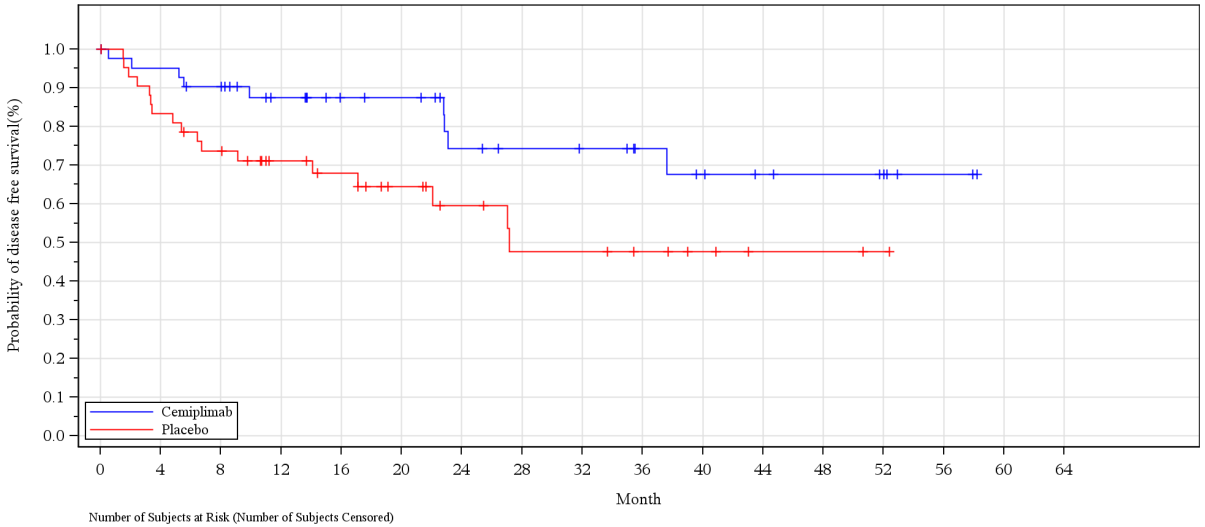
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	155 (0)	144 (6)	138 (10)	122 (26)	106 (41)	94 (51)	80 (62)	71 (69)	46 (92)	30 (108)	24 (114)	18 (120)	15 (124)	7 (130)	2 (135)	0 (137)	0 (137)
Placebo	154 (0)	132 (3)	113 (8)	88 (25)	76 (36)	61 (50)	55 (56)	46 (65)	34 (76)	25 (84)	19 (90)	18 (91)	15 (94)	6 (101)	4 (103)	2 (105)	0 (107)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

PD-L1 Protein Expression: TPS<1%



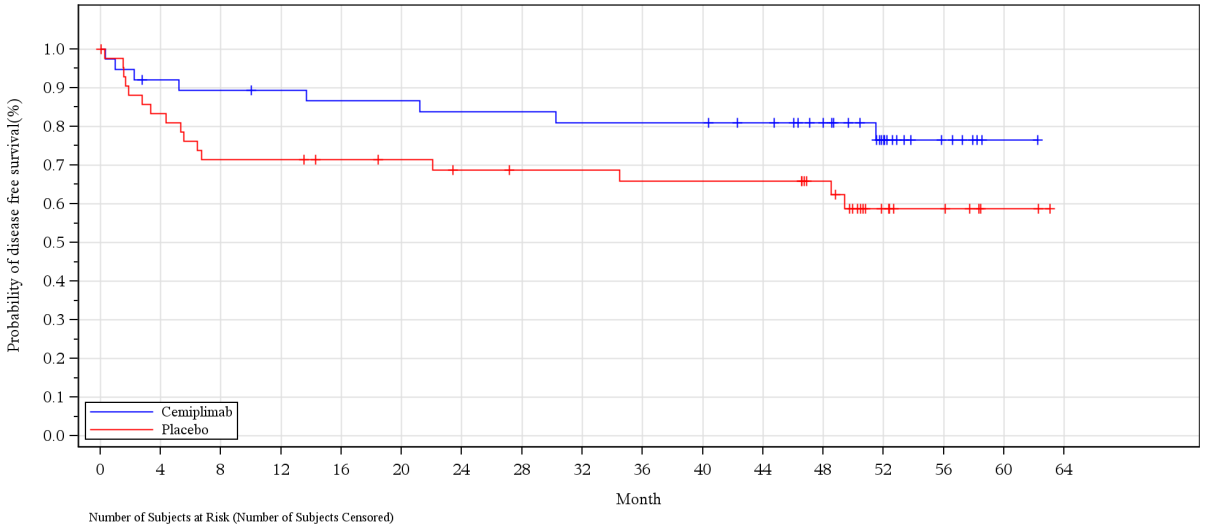
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	42 (0)	39 (1)	36 (2)	29 (8)	24 (13)	23 (14)	17 (17)	15 (19)	14 (20)	11 (23)	9 (24)	7 (26)	6 (27)	5 (28)	2 (31)	0 (33)	0 (33)
Placebo	43 (0)	35 (1)	30 (2)	23 (8)	20 (10)	15 (14)	11 (17)	8 (18)	8 (18)	6 (20)	4 (22)	2 (24)	2 (24)	1 (25)	0 (26)	0 (26)	0 (26)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W only



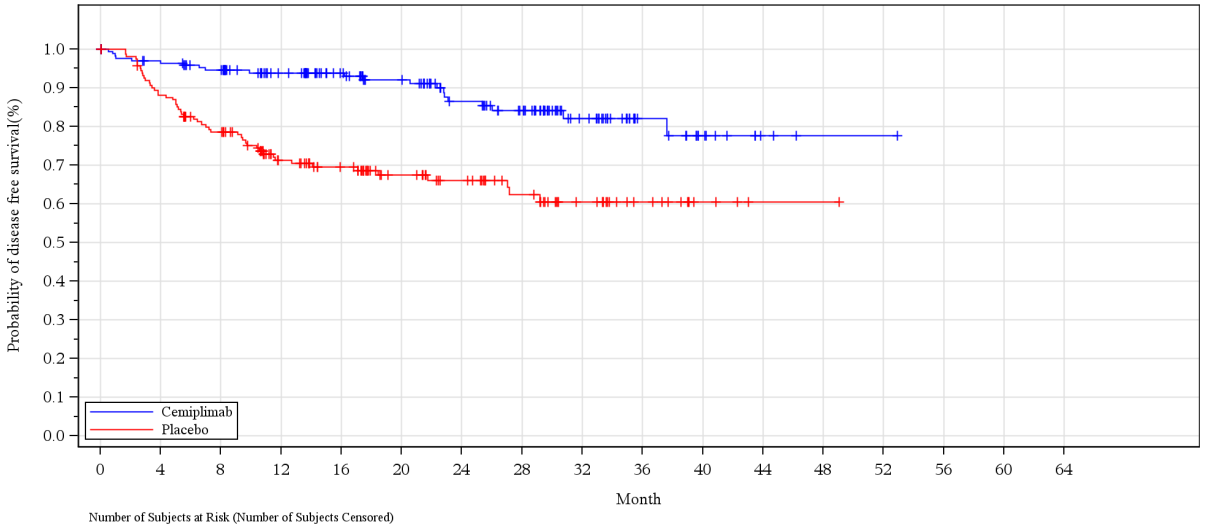
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	38 (0)	34 (1)	33 (1)	32 (2)	31 (2)	31 (2)	30 (2)	30 (2)	29 (2)	29 (2)	29 (2)	27 (4)	23 (9)	14 (16)	6 (24)	1 (29)	0 (30)
Placebo	43 (0)	35 (1)	30 (1)	30 (1)	28 (3)	27 (4)	25 (5)	24 (6)	24 (6)	23 (6)	23 (6)	23 (6)	19 (10)	9 (18)	6 (21)	2 (25)	0 (27)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

Figure 14.2.1.1.1 Kaplan-Meier Curve of Disease-Free Survival by Subgroup
(Full Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	171 (0)	159 (6)	151 (11)	128 (33)	107 (54)	94 (65)	75 (79)	64 (88)	38 (113)	18 (133)	10 (140)	3 (147)	1 (149)	1 (149)	0 (150)	0 (150)	0 (150)
Placebo	163 (0)	141 (3)	119 (10)	86 (33)	73 (44)	54 (61)	45 (69)	34 (78)	22 (89)	12 (99)	4 (107)	1 (110)	1 (110)	0 (111)	0 (111)	0 (111)	0 (111)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-dfs-sub.sas' (wenju.shi 24NOV2025 12:28 SAS Linux 9.4)

2.3 Freiheit von lokoregionären Rezidiven

2.3.1 1. Datenschnitt

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	2 (3.6%)	15 (23.1%)
Odds ratio (95% CI)	0.114 (0.024, 0.536)	
P-value for Odds Ratio	0.0059	
Relative Risk (95% CI)	0.55 (0.55, 0.55)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.5992	
Risk difference (95% CI)	-17.81 (-40.32, 4.71)	
P-value for Risk Difference	0.1212	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	7 (4.6%)	25 (17.7%)
Odds ratio (95% CI)	0.210 (0.086, 0.509)	
P-value for Odds Ratio	0.0006	
Relative Risk (95% CI)	0.24 (0.11, 0.55)	
P-value for Relative Risk	0.0006	
Heterogeneity p-value of RR	0.5992	
Risk difference (95% CI)	-13.24 (-20.39, -6.09)	
P-value for Risk Difference	0.0003	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/Generated/t_14_2_2_7_1a_fflr_binary_sub.sas
(wenju.shi 22AUG2025 07:21 SAS Linux 9.4)

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	2 (3.6%)	15 (23.1%)
Odds ratio (95% CI)	0.114 (0.024, 0.536)	
P-value for Odds Ratio	0.0059	
Relative Risk (95% CI)	0.55 (0.55, 0.55)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.7632	
Risk difference (95% CI)	-17.81 (-40.32, 4.71)	
P-value for Risk Difference	0.1212	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	4 (5.0%)	11 (15.9%)
Odds ratio (95% CI)	0.283 (0.084, 0.949)	
P-value for Odds Ratio	0.0409	
Relative Risk (95% CI)	0.32 (0.11, 0.97)	
P-value for Relative Risk	0.0441	
Heterogeneity p-value of RR	0.7632	
Risk difference (95% CI)	-10.71 (-20.66, -0.76)	
P-value for Risk Difference	0.0349	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	14 (19.4%)
Odds ratio (95% CI)	0.156 (0.041, 0.600)	
P-value for Odds Ratio	0.0069	
Relative Risk (95% CI)	0.17 (0.05, 0.60)	
P-value for Relative Risk	0.0055	
Heterogeneity p-value of RR	0.7632	
Risk difference (95% CI)	-15.90 (-27.58, -4.22)	
P-value for Risk Difference	0.0076	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	8 (4.6%)	28 (16.1%)
Odds ratio (95% CI)	0.239 (0.104, 0.545)	
P-value for Odds Ratio	0.0007	
Relative Risk (95% CI)	0.28 (0.13, 0.59)	
P-value for Relative Risk	0.0009	
Heterogeneity p-value of RR	0.1544	
Risk difference (95% CI)	-11.59 (-18.09, -5.10)	
P-value for Risk Difference	0.0005	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	1 (2.9%)	12 (37.5%)
Odds ratio (95% CI)	0.042 (0.005, 0.371)	
P-value for Odds Ratio	0.0043	
Relative Risk (95% CI)	0.07 (0.01, 0.51)	
P-value for Relative Risk	0.0086	
Heterogeneity p-value of RR	0.1544	
Risk difference (95% CI)	-35.06 (-62.54, -7.58)	
P-value for Risk Difference	0.0124	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Odds ratio (95% CI)	0.064 (0.005, 0.829)	
P-value for Odds Ratio	0.0355	
Relative Risk (95% CI)	0.40 (0.40, 0.40)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.8774	
Risk difference (95% CI)	-16.29 (-32.47, -0.11)	
P-value for Risk Difference	0.0484	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	17 (18.9%)
Odds ratio (95% CI)	0.196 (0.063, 0.610)	
P-value for Odds Ratio	0.0049	
Relative Risk (95% CI)	0.23 (0.08, 0.66)	
P-value for Relative Risk	0.0060	
Heterogeneity p-value of RR	0.8774	
Risk difference (95% CI)	-15.19 (-25.11, -5.28)	
P-value for Risk Difference	0.0027	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	4 (4.9%)	17 (20.0%)
Odds ratio (95% CI)	0.189 (0.060, 0.599)	
P-value for Odds Ratio	0.0046	
Relative Risk (95% CI)	0.23 (0.08, 0.66)	
P-value for Relative Risk	0.0062	
Heterogeneity p-value of RR	0.8774	
Risk difference (95% CI)	-15.33 (-24.84, -5.82)	
P-value for Risk Difference	0.0016	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	9 (4.8%)	37 (19.6%)
Odds ratio (95% CI)	0.185 (0.085, 0.404)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.23 (0.11, 0.46)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.2769	
Risk difference (95% CI)	-14.96 (-21.58, -8.34)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	0	3 (17.6%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.34 (0.05, 2.48)	
P-value for Relative Risk	0.2718	
Heterogeneity p-value of RR	0.2769	
Risk difference (95% CI)	-12.96 (-65.83, 39.91)	
P-value for Risk Difference	0.6309	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	6 (3.6%)	31 (17.5%)
Odds ratio (95% CI)	0.178 (0.072, 0.439)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	0.21 (0.09, 0.49)	
P-value for Relative Risk	0.0003	
Heterogeneity p-value of RR	0.9112	
Risk difference (95% CI)	-14.08 (-21.08, -7.07)	
P-value for Risk Difference	<0.0001	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	9 (31.0%)
Odds ratio (95% CI)	0.147 (0.034, 0.640)	
P-value for Odds Ratio	0.0106	
Relative Risk (95% CI)	0.22 (0.07, 0.74)	
P-value for Relative Risk	0.0145	
Heterogeneity p-value of RR	0.9112	
Risk difference (95% CI)	-25.34 (-47.04, -3.64)	
P-value for Risk Difference	0.0221	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	7 (5.3%)	21 (16.0%)
Odds ratio (95% CI)	0.266 (0.107, 0.659)	
P-value for Odds Ratio	0.0042	
Relative Risk (95% CI)	0.30 (0.13, 0.68)	
P-value for Relative Risk	0.0039	
Heterogeneity p-value of RR	0.1479	
Risk difference (95% CI)	-10.76 (-18.81, -2.72)	
P-value for Risk Difference	0.0088	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	2 (2.6%)	19 (25.3%)
Odds ratio (95% CI)	0.075 (0.017, 0.342)	
P-value for Odds Ratio	0.0008	
Relative Risk (95% CI)	0.10 (0.02, 0.42)	
P-value for Relative Risk	0.0016	
Heterogeneity p-value of RR	0.1479	
Risk difference (95% CI)	-21.48 (-36.77, -6.19)	
P-value for Risk Difference	0.0059	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(wenju.shi 22AUG2025 07:21 SAS Linux 9.4)

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	6 (4.8%)	17 (14.5%)
Odds ratio (95% CI)	0.259 (0.096, 0.698)	
P-value for Odds Ratio	0.0075	
Relative Risk (95% CI)	0.30 (0.12, 0.72)	
P-value for Relative Risk	0.0073	
Heterogeneity p-value of RR	0.2613	
Risk difference (95% CI)	-9.39 (-16.90, -1.89)	
P-value for Risk Difference	0.0141	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	3 (3.6%)	23 (25.8%)
Odds ratio (95% CI)	0.101 (0.029, 0.353)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	0.14 (0.04, 0.44)	
P-value for Relative Risk	0.0008	
Heterogeneity p-value of RR	0.2613	
Risk difference (95% CI)	-21.35 (-33.68, -9.01)	
P-value for Risk Difference	0.0007	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	2 (3.6%)	15 (23.1%)
Locoregional recurrence, n (%)	2 (3.6%)	15 (23.1%)
Number of censored participants, n (%)	54 (96.4%)	50 (76.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.7 (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0039	
HR (95% CI) [c][d]	0.148 (0.033, 0.659)	
Heterogeneity p-value [c][e]	0.5641	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.0 (86.6, 99.7)	93.7 (84.0, 97.6)
6 months	98.0 (86.6, 99.7)	85.2 (73.4, 92.0)
12 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
18 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
24 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
30 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
36 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
42 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
48 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	7 (4.6%)	25 (17.7%)
Locoregional recurrence, n (%)	7 (4.6%)	25 (17.7%)
Number of censored participants, n (%)	146 (95.4%)	116 (82.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	34.5 (7.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0002	
HR (95% CI) [c][d]	0.231 (0.099, 0.540)	
Heterogeneity p-value [c][e]	0.5641	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (94.5, 99.6)	91.5 (85.1, 95.2)
6 months	98.6 (94.5, 99.6)	85.7 (78.2, 90.7)
12 months	96.9 (92.0, 98.8)	81.7 (73.5, 87.6)
18 months	96.9 (92.0, 98.8)	81.7 (73.5, 87.6)
24 months	94.0 (86.6, 97.4)	78.4 (68.9, 85.3)
30 months	94.0 (86.6, 97.4)	78.4 (68.9, 85.3)
36 months	91.8 (82.3, 96.3)	74.0 (60.7, 83.4)
42 months	91.8 (82.3, 96.3)	74.0 (60.7, 83.4)
48 months	91.8 (82.3, 96.3)	74.0 (60.7, 83.4)
54 months	91.8 (82.3, 96.3)	74.0 (60.7, 83.4)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	2 (3.6%)	15 (23.1%)
Locoregional recurrence, n (%)	2 (3.6%)	15 (23.1%)
Number of censored participants, n (%)	54 (96.4%)	50 (76.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.7 (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0039	
HR (95% CI) [c][d]	0.148 (0.033, 0.659)	
Heterogeneity p-value [c][e]	0.7194	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.0 (86.6, 99.7)	93.7 (84.0, 97.6)
6 months	98.0 (86.6, 99.7)	85.2 (73.4, 92.0)
12 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
18 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
24 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
30 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
36 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
42 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
48 months	95.7 (83.9, 98.9)	73.9 (60.3, 83.4)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	4 (5.0%)	11 (15.9%)
Locoregional recurrence, n (%)	4 (5.0%)	11 (15.9%)
Number of censored participants, n (%)	76 (95.0%)	58 (84.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	34.5 (10.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0340	
HR (95% CI) [c][d]	0.304 (0.095, 0.971)	
Heterogeneity p-value [c][e]	0.7194	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.4 (90.0, 99.3)	93.8 (84.3, 97.6)
6 months	97.4 (90.0, 99.3)	90.6 (80.3, 95.7)
12 months	95.9 (87.7, 98.7)	86.6 (74.8, 93.1)
18 months	95.9 (87.7, 98.7)	86.6 (74.8, 93.1)
24 months	93.1 (81.4, 97.5)	80.7 (66.1, 89.5)
30 months	93.1 (81.4, 97.5)	80.7 (66.1, 89.5)
36 months	93.1 (81.4, 97.5)	74.0 (53.3, 86.5)
42 months	93.1 (81.4, 97.5)	74.0 (53.3, 86.5)
48 months	93.1 (81.4, 97.5)	74.0 (53.3, 86.5)
54 months	NE (NE, NE)	74.0 (53.3, 86.5)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	14 (19.4%)
Locoregional recurrence, n (%)	3 (4.1%)	14 (19.4%)
Number of censored participants, n (%)	70 (95.9%)	58 (80.6%)
Q1 (95% CI), (months)[a]	NR (30.3, NE)	NR (3.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0037	
HR (95% CI) [c][d]	0.183 (0.051, 0.651)	
Heterogeneity p-value [c][e]	0.7194	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	89.1 (78.4, 94.6)
6 months	100 (100, 100)	80.5 (68.2, 88.5)
12 months	98.1 (87.6, 99.7)	76.6 (63.5, 85.5)
18 months	98.1 (87.6, 99.7)	76.6 (63.5, 85.5)
24 months	95.3 (81.8, 98.8)	76.6 (63.5, 85.5)
30 months	95.3 (81.8, 98.8)	76.6 (63.5, 85.5)
36 months	90.5 (71.3, 97.1)	76.6 (63.5, 85.5)
42 months	90.5 (71.3, 97.1)	76.6 (63.5, 85.5)
48 months	90.5 (71.3, 97.1)	76.6 (63.5, 85.5)
54 months	90.5 (71.3, 97.1)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	8 (4.6%)	28 (16.1%)
Locoregional recurrence, n (%)	8 (4.6%)	28 (16.1%)
Number of censored participants, n (%)	166 (95.4%)	146 (83.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (18.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0003	
HR (95% CI) [c][d]	0.257 (0.117, 0.565)	
Heterogeneity p-value [c][e]	0.2410	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (95.2, 99.7)	93.2 (88.0, 96.2)
6 months	98.8 (95.2, 99.7)	87.8 (81.5, 92.0)
12 months	96.6 (92.0, 98.6)	83.2 (76.1, 88.4)
18 months	96.6 (92.0, 98.6)	83.2 (76.1, 88.4)
24 months	94.3 (88.0, 97.3)	80.4 (72.2, 86.4)
30 months	94.3 (88.0, 97.3)	80.4 (72.2, 86.4)
36 months	92.2 (84.0, 96.3)	77.0 (66.1, 84.8)
42 months	92.2 (84.0, 96.3)	77.0 (66.1, 84.8)
48 months	92.2 (84.0, 96.3)	77.0 (66.1, 84.8)
54 months	92.2 (84.0, 96.3)	77.0 (66.1, 84.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	1 (2.9%)	12 (37.5%)
Locoregional recurrence, n (%)	1 (2.9%)	12 (37.5%)
Number of censored participants, n (%)	34 (97.1%)	20 (62.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	5.3 (2.8, 10.8)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0062	
HR (95% CI) [c][d]	0.096 (0.012, 0.760)	
Heterogeneity p-value [c][e]	0.2410	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.6 (77.9, 99.5)	87.5 (70.0, 95.1)
6 months	96.6 (77.9, 99.5)	74.6 (55.6, 86.4)
12 months	96.6 (77.9, 99.5)	59.5 (39.5, 74.9)
18 months	96.6 (77.9, 99.5)	59.5 (39.5, 74.9)
24 months	96.6 (77.9, 99.5)	59.5 (39.5, 74.9)
30 months	96.6 (77.9, 99.5)	59.5 (39.5, 74.9)
36 months	96.6 (77.9, 99.5)	59.5 (39.5, 74.9)
42 months	96.6 (77.9, 99.5)	59.5 (39.5, 74.9)
48 months	NE (NE, NE)	59.5 (39.5, 74.9)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Locoregional recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0132	
HR (95% CI) [c][d]	0.108 (0.013, 0.905)	
Heterogeneity p-value [c][e]	0.8397	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.1 (81.4, 99.6)	93.5 (76.6, 98.3)
6 months	97.1 (81.4, 99.6)	85.5 (65.6, 94.4)
12 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
18 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
24 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
30 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
36 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
42 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
48 months	97.1 (81.4, 99.6)	75.8 (53.1, 88.6)
54 months	97.1 (81.4, 99.6)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	17 (18.9%)
Locoregional recurrence, n (%)	4 (4.4%)	17 (18.9%)
Number of censored participants, n (%)	86 (95.6%)	73 (81.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	34.5 (6.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0014	
HR (95% CI) [c][d]	0.201 (0.068, 0.599)	
Heterogeneity p-value [c][e]	0.8397	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	95.2 (87.6, 98.2)
6 months	98.8 (91.7, 99.8)	88.8 (79.6, 94.0)
12 months	98.8 (91.7, 99.8)	81.5 (70.6, 88.6)
18 months	98.8 (91.7, 99.8)	81.5 (70.6, 88.6)
24 months	94.3 (82.7, 98.2)	76.1 (62.9, 85.1)
30 months	94.3 (82.7, 98.2)	76.1 (62.9, 85.1)
36 months	90.9 (76.3, 96.7)	70.6 (53.4, 82.5)
42 months	90.9 (76.3, 96.7)	70.6 (53.4, 82.5)
48 months	90.9 (76.3, 96.7)	70.6 (53.4, 82.5)
54 months	90.9 (76.3, 96.7)	70.6 (53.4, 82.5)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	4 (4.9%)	17 (20.0%)
Locoregional recurrence, n (%)	4 (4.9%)	17 (20.0%)
Number of censored participants, n (%)	78 (95.1%)	68 (80.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (5.0, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0040	
HR (95% CI) [c][d]	0.230 (0.077, 0.684)	
Heterogeneity p-value [c][e]	0.8397	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.0, 99.8)	88.7 (79.4, 94.0)
6 months	98.7 (91.0, 99.8)	82.0 (71.5, 88.9)
12 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
18 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
24 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
30 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
36 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
42 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
48 months	93.4 (83.4, 97.5)	77.5 (66.3, 85.4)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	9 (4.8%)	37 (19.6%)
Locoregional recurrence, n (%)	9 (4.8%)	37 (19.6%)
Number of censored participants, n (%)	180 (95.2%)	152 (80.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	34.5 (7.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.203 (0.097, 0.424)	
Heterogeneity p-value [c][e]	0.9882	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.3 (94.8, 99.4)	91.4 (86.2, 94.8)
6 months	98.3 (94.8, 99.4)	84.7 (78.3, 89.3)
12 months	96.3 (91.9, 98.3)	79.1 (71.9, 84.6)
18 months	96.3 (91.9, 98.3)	79.1 (71.9, 84.6)
24 months	94.1 (88.3, 97.1)	76.6 (68.7, 82.8)
30 months	94.1 (88.3, 97.1)	76.6 (68.7, 82.8)
36 months	92.4 (85.0, 96.2)	73.8 (63.9, 81.3)
42 months	92.4 (85.0, 96.2)	73.8 (63.9, 81.3)
48 months	92.4 (85.0, 96.2)	73.8 (63.9, 81.3)
54 months	92.4 (85.0, 96.2)	73.8 (63.9, 81.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	0	3 (17.6%)
Locoregional recurrence, n (%)	0	3 (17.6%)
Number of censored participants, n (%)	20 (100%)	14 (82.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.2621	
HR (95% CI) [c][d]	NE (NE, NE)	
Heterogeneity p-value [c][e]	0.9882	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	93.8 (63.2, 99.1)
12 months	100 (100, 100)	78.7 (47.0, 92.7)
18 months	100 (100, 100)	78.7 (47.0, 92.7)
24 months	100 (100, 100)	78.7 (47.0, 92.7)
30 months	100 (100, 100)	78.7 (47.0, 92.7)
36 months	100 (100, 100)	78.7 (47.0, 92.7)
42 months	100 (100, 100)	NE (NE, NE)
48 months	100 (100, 100)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	6 (3.6%)	31 (17.5%)
Locoregional recurrence, n (%)	6 (3.6%)	31 (17.5%)
Number of censored participants, n (%)	160 (96.4%)	146 (82.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (10.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.180 (0.075, 0.433)	
Heterogeneity p-value [c][e]	0.7887	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (95.6, 99.9)	92.7 (87.4, 95.8)
6 months	99.4 (95.6, 99.9)	86.8 (80.4, 91.2)
12 months	97.9 (93.6, 99.3)	81.4 (74.1, 86.8)
18 months	97.9 (93.6, 99.3)	81.4 (74.1, 86.8)
24 months	95.3 (88.7, 98.1)	78.6 (70.3, 84.8)
30 months	95.3 (88.7, 98.1)	78.6 (70.3, 84.8)
36 months	93.1 (84.0, 97.1)	75.3 (64.5, 83.3)
42 months	93.1 (84.0, 97.1)	75.3 (64.5, 83.3)
48 months	93.1 (84.0, 97.1)	75.3 (64.5, 83.3)
54 months	93.1 (84.0, 97.1)	75.3 (64.5, 83.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	9 (31.0%)
Locoregional recurrence, n (%)	3 (7.0%)	9 (31.0%)
Number of censored participants, n (%)	40 (93.0%)	20 (69.0%)
Q1 (95% CI), (months)[a]	NR (9.9, NE)	6.4 (2.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (6.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0187	
HR (95% CI) [c][d]	0.235 (0.063, 0.873)	
Heterogeneity p-value [c][e]	0.7887	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.4 (79.6, 98.6)	89.3 (70.4, 96.4)
6 months	94.4 (79.6, 98.6)	78.3 (57.8, 89.6)
12 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
18 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
24 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
30 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
36 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
42 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
48 months	90.7 (73.4, 96.9)	66.3 (45.0, 80.9)
54 months	90.7 (73.4, 96.9)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	7 (5.3%)	21 (16.0%)
Locoregional recurrence, n (%)	7 (5.3%)	21 (16.0%)
Number of censored participants, n (%)	126 (94.7%)	110 (84.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0031	
HR (95% CI) [c][d]	0.293 (0.124, 0.694)	
Heterogeneity p-value [c][e]	0.1130	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.3, 99.9)	96.0 (90.6, 98.3)
6 months	99.2 (94.3, 99.9)	89.9 (82.9, 94.2)
12 months	96.1 (90.0, 98.5)	81.9 (73.2, 88.0)
18 months	96.1 (90.0, 98.5)	81.9 (73.2, 88.0)
24 months	92.8 (84.3, 96.8)	80.2 (71.0, 86.8)
30 months	92.8 (84.3, 96.8)	80.2 (71.0, 86.8)
36 months	89.9 (78.2, 95.5)	80.2 (71.0, 86.8)
42 months	89.9 (78.2, 95.5)	80.2 (71.0, 86.8)
48 months	89.9 (78.2, 95.5)	80.2 (71.0, 86.8)
54 months	89.9 (78.2, 95.5)	80.2 (71.0, 86.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	2 (2.6%)	19 (25.3%)
Locoregional recurrence, n (%)	2 (2.6%)	19 (25.3%)
Number of censored participants, n (%)	74 (97.4%)	56 (74.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.7 (2.9, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.083 (0.019, 0.361)	
Heterogeneity p-value [c][e]	0.1130	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.2 (89.2, 99.3)	85.4 (74.5, 91.9)
6 months	97.2 (89.2, 99.3)	77.6 (65.5, 85.9)
12 months	97.2 (89.2, 99.3)	74.0 (61.4, 83.0)
18 months	97.2 (89.2, 99.3)	74.0 (61.4, 83.0)
24 months	97.2 (89.2, 99.3)	70.3 (55.9, 80.8)
30 months	97.2 (89.2, 99.3)	70.3 (55.9, 80.8)
36 months	97.2 (89.2, 99.3)	63.3 (43.7, 77.7)
42 months	97.2 (89.2, 99.3)	63.3 (43.7, 77.7)
48 months	97.2 (89.2, 99.3)	63.3 (43.7, 77.7)
54 months	97.2 (89.2, 99.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	6 (4.8%)	17 (14.5%)
Locoregional recurrence, n (%)	6 (4.8%)	17 (14.5%)
Number of censored participants, n (%)	119 (95.2%)	100 (85.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0084	
HR (95% CI) [c][d]	0.304 (0.119, 0.776)	
Heterogeneity p-value [c][e]	0.1840	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.4 (92.0, 99.1)	95.4 (89.4, 98.1)
6 months	97.4 (92.0, 99.1)	88.6 (80.8, 93.4)
12 months	96.3 (90.5, 98.6)	82.9 (73.9, 89.1)
18 months	96.3 (90.5, 98.6)	82.9 (73.9, 89.1)
24 months	94.7 (87.4, 97.8)	82.9 (73.9, 89.1)
30 months	94.7 (87.4, 97.8)	82.9 (73.9, 89.1)
36 months	91.5 (79.4, 96.6)	82.9 (73.9, 89.1)
42 months	91.5 (79.4, 96.6)	82.9 (73.9, 89.1)
48 months	91.5 (79.4, 96.6)	82.9 (73.9, 89.1)
54 months	91.5 (79.4, 96.6)	82.9 (73.9, 89.1)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	3 (3.6%)	23 (25.8%)
Locoregional recurrence, n (%)	3 (3.6%)	23 (25.8%)
Number of censored participants, n (%)	81 (96.4%)	66 (74.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	10.8 (3.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.109 (0.033, 0.368)	
Heterogeneity p-value [c][e]	0.1840	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	87.9 (78.7, 93.3)
6 months	100 (100, 100)	81.4 (71.1, 88.4)
12 months	96.9 (88.2, 99.2)	73.9 (62.4, 82.4)
18 months	96.9 (88.2, 99.2)	73.9 (62.4, 82.4)
24 months	94.4 (83.2, 98.2)	68.1 (54.5, 78.5)
30 months	94.4 (83.2, 98.2)	68.1 (54.5, 78.5)
36 months	94.4 (83.2, 98.2)	62.0 (44.1, 75.6)
42 months	94.4 (83.2, 98.2)	62.0 (44.1, 75.6)
48 months	94.4 (83.2, 98.2)	62.0 (44.1, 75.6)
54 months	94.4 (83.2, 98.2)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	2 (3.6%)	15 (23.1%)
Locoregional recurrence, n (%)	2 (3.6%)	15 (23.1%)
Number of censored participants, n (%)	54 (96.4%)	50 (76.9%)
Proportionality Test p-value[a][b]	0.9918	
Hazard ratio(interaction)	0.988 (0.104, 9.356)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	7 (4.6%)	25 (17.7%)
Locoregional recurrence, n (%)	7 (4.6%)	25 (17.7%)
Number of censored participants, n (%)	146 (95.4%)	116 (82.3%)
Proportionality Test p-value[a][b]	0.1442	
Hazard ratio(interaction)	0.513 (0.210, 1.257)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	2 (3.6%)	15 (23.1%)
Locoregional recurrence, n (%)	2 (3.6%)	15 (23.1%)
Number of censored participants, n (%)	54 (96.4%)	50 (76.9%)
Proportionality Test p-value[a][b]	0.9918	
Hazard ratio(interaction)	0.988 (0.104, 9.356)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	4 (5.0%)	11 (15.9%)
Locoregional recurrence, n (%)	4 (5.0%)	11 (15.9%)
Number of censored participants, n (%)	76 (95.0%)	58 (84.1%)
Proportionality Test p-value[a][b]	0.7125	
Hazard ratio(interaction)	1.246 (0.387, 4.017)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	14 (19.4%)
Locoregional recurrence, n (%)	3 (4.1%)	14 (19.4%)
Number of censored participants, n (%)	70 (95.9%)	58 (80.6%)
Proportionality Test p-value[a][b]	0.6124	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	8 (4.6%)	28 (16.1%)
Locoregional recurrence, n (%)	8 (4.6%)	28 (16.1%)
Number of censored participants, n (%)	166 (95.4%)	146 (83.9%)
Proportionality Test p-value[a][b]	0.1608	
Hazard ratio(interaction)	0.538 (0.226, 1.280)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	1 (2.9%)	12 (37.5%)
Locoregional recurrence, n (%)	1 (2.9%)	12 (37.5%)
Number of censored participants, n (%)	34 (97.1%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.4621	
Hazard ratio(interaction)	82.350 (0.001, 1.05E7)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Locoregional recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.6199	
Hazard ratio(interaction)	1.569 (0.264, 9.314)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	17 (18.9%)
Locoregional recurrence, n (%)	4 (4.4%)	17 (18.9%)
Number of censored participants, n (%)	86 (95.6%)	73 (81.1%)
Proportionality Test p-value[a][b]	0.3320	
Hazard ratio(interaction)	0.547 (0.162, 1.851)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	4 (4.9%)	17 (20.0%)
Locoregional recurrence, n (%)	4 (4.9%)	17 (20.0%)
Number of censored participants, n (%)	78 (95.1%)	68 (80.0%)
Proportionality Test p-value[a][b]	0.1613	
Hazard ratio(interaction)	0.192 (0.019, 1.933)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	9 (4.8%)	37 (19.6%)
Locoregional recurrence, n (%)	9 (4.8%)	37 (19.6%)
Number of censored participants, n (%)	180 (95.2%)	152 (80.4%)
Proportionality Test p-value[a][b]	0.1818	
Hazard ratio(interaction)	0.571 (0.251, 1.300)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	0	3 (17.6%)
Locoregional recurrence, n (%)	0	3 (17.6%)
Number of censored participants, n (%)	20 (100%)	14 (82.4%)
Proportionality Test p-value[a][b]	>0.95	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	6 (3.6%)	31 (17.5%)
Locoregional recurrence, n (%)	6 (3.6%)	31 (17.5%)
Number of censored participants, n (%)	160 (96.4%)	146 (82.5%)
Proportionality Test p-value[a][b]	0.1454	
Hazard ratio(interaction)	0.468 (0.169, 1.300)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	9 (31.0%)
Locoregional recurrence, n (%)	3 (7.0%)	9 (31.0%)
Number of censored participants, n (%)	40 (93.0%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.7502	
Hazard ratio(interaction)	1.432 (0.157, 13.050)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	7 (5.3%)	21 (16.0%)
Locoregional recurrence, n (%)	7 (5.3%)	21 (16.0%)
Number of censored participants, n (%)	126 (94.7%)	110 (84.0%)
Proportionality Test p-value[a][b]	0.0338	
Hazard ratio(interaction)	0.205 (0.048, 0.886)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	2 (2.6%)	19 (25.3%)
Locoregional recurrence, n (%)	2 (2.6%)	19 (25.3%)
Number of censored participants, n (%)	74 (97.4%)	56 (74.7%)
Proportionality Test p-value[a][b]	0.1816	
Hazard ratio(interaction)	3.046 (0.594, 15.616)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	6 (4.8%)	17 (14.5%)
Locoregional recurrence, n (%)	6 (4.8%)	17 (14.5%)
Number of censored participants, n (%)	119 (95.2%)	100 (85.5%)
Proportionality Test p-value[a][b]	0.5946	
Hazard ratio(interaction)	0.721 (0.216, 2.405)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

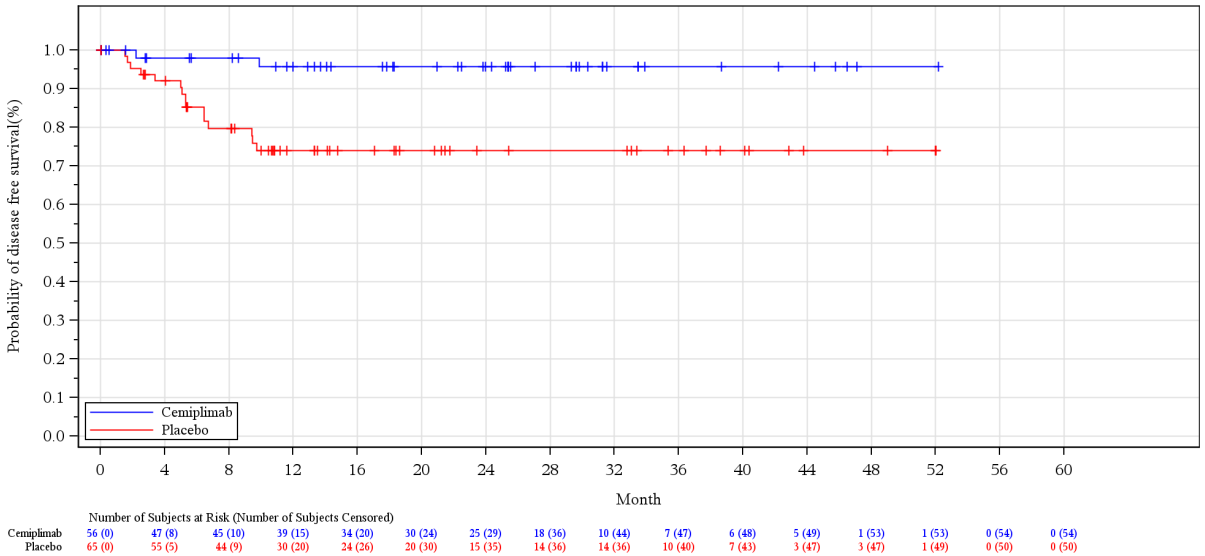
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	3 (3.6%)	23 (25.8%)
Locoregional recurrence, n (%)	3 (3.6%)	23 (25.8%)
Number of censored participants, n (%)	81 (96.4%)	66 (74.2%)
Proportionality Test p-value[a][b]	0.2495	
Hazard ratio(interaction)	0.426 (0.100, 1.819)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	47 (8)	45 (10)	39 (15)	34 (20)	30 (24)	25 (29)	18 (36)	10 (44)	7 (47)	6 (48)	5 (49)	1 (53)	1 (53)	0 (54)	0 (54)
Placebo	65 (0)	55 (5)	44 (9)	30 (20)	24 (26)	20 (30)	15 (35)	14 (36)	14 (36)	10 (40)	7 (43)	3 (47)	3 (47)	1 (49)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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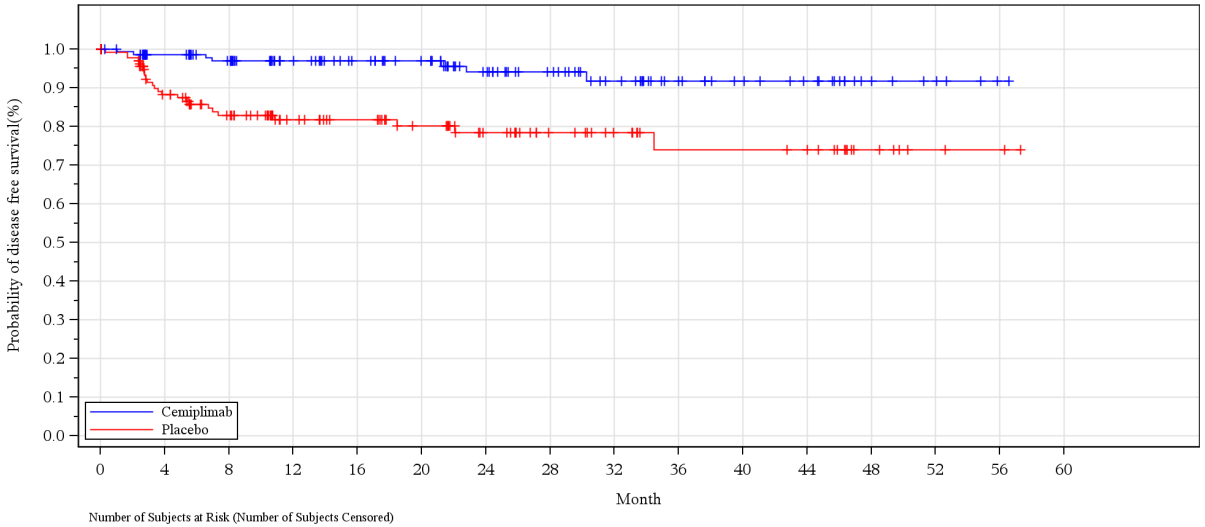
Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65



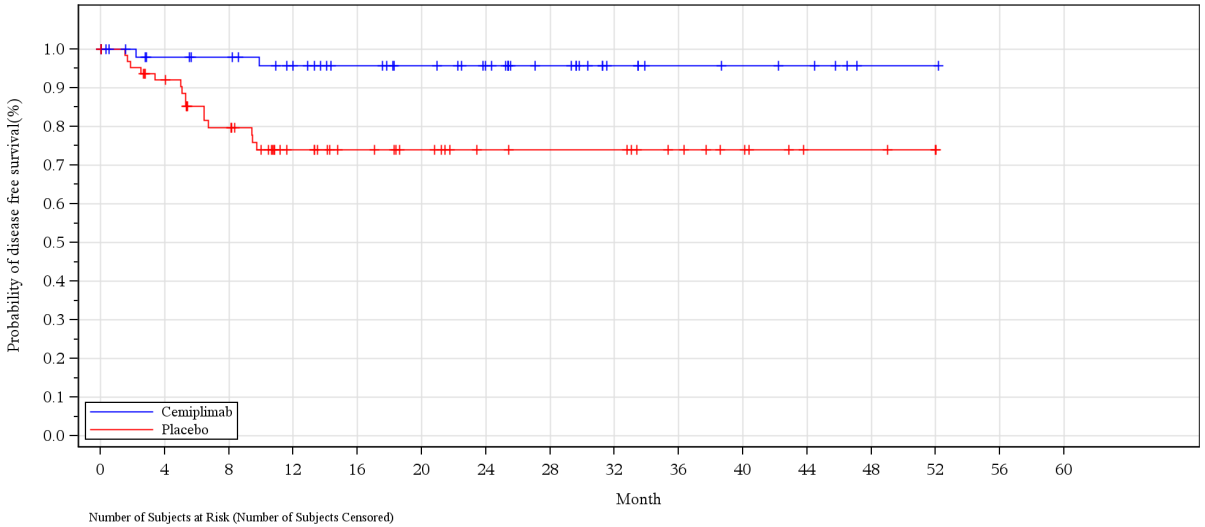
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	127 (24)	115 (34)	96 (53)	85 (64)	77 (72)	60 (87)	49 (98)	38 (108)	26 (120)	21 (125)	17 (129)	8 (139)	5 (141)	1 (145)	0 (146)
Placebo	141 (0)	108 (18)	88 (32)	67 (52)	60 (59)	50 (68)	39 (78)	29 (88)	23 (94)	17 (99)	17 (99)	15 (101)	7 (109)	3 (113)	2 (114)	0 (116)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65



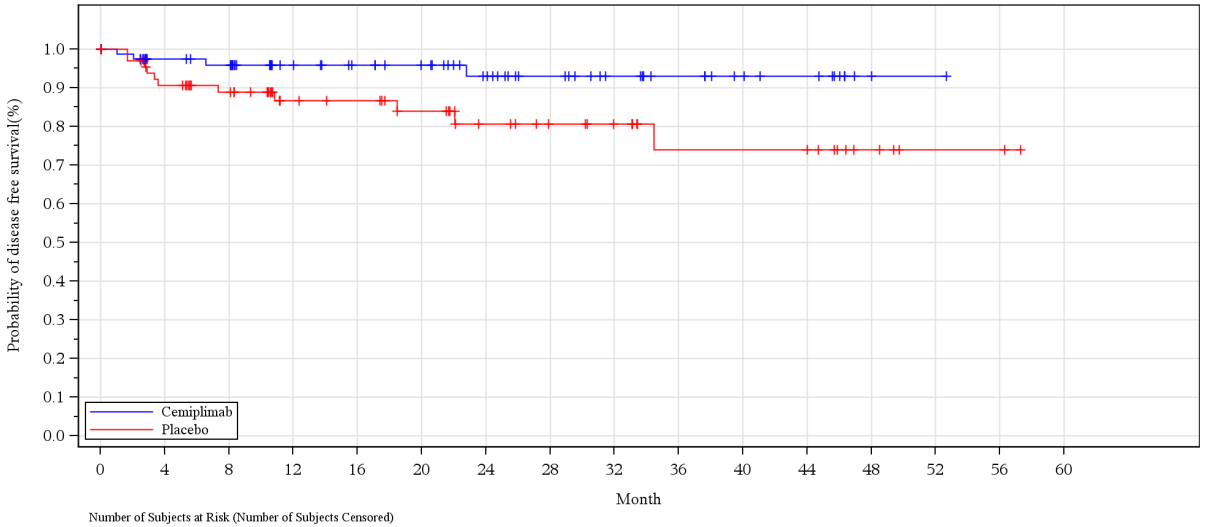
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	47 (8)	45 (10)	39 (15)	34 (20)	30 (24)	25 (29)	18 (36)	10 (44)	7 (47)	6 (48)	5 (49)	1 (53)	1 (53)	0 (54)	0 (54)
Placebo	65 (0)	55 (5)	44 (9)	30 (20)	24 (26)	20 (30)	15 (35)	14 (36)	14 (36)	10 (40)	7 (43)	3 (47)	3 (47)	1 (49)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



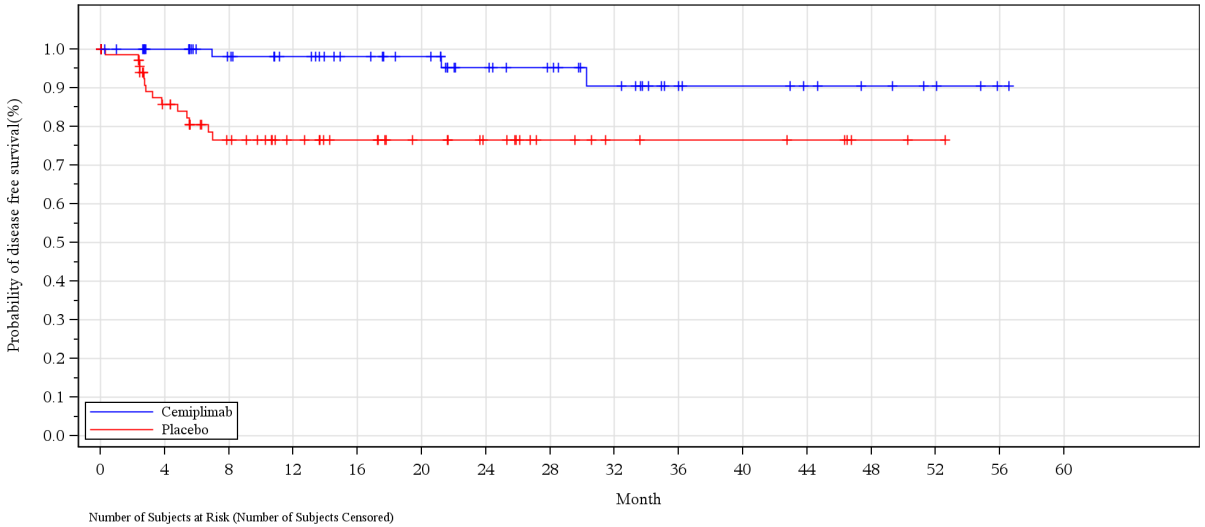
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	66 (12)	63 (14)	49 (28)	44 (33)	40 (37)	32 (44)	25 (51)	19 (57)	15 (61)	11 (65)	9 (67)	2 (75)	1 (75)	0 (76)	0 (76)
Placebo	69 (0)	57 (6)	50 (12)	37 (24)	35 (26)	30 (30)	23 (36)	19 (40)	16 (43)	11 (47)	11 (47)	10 (48)	5 (53)	2 (56)	2 (56)	0 (58)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75



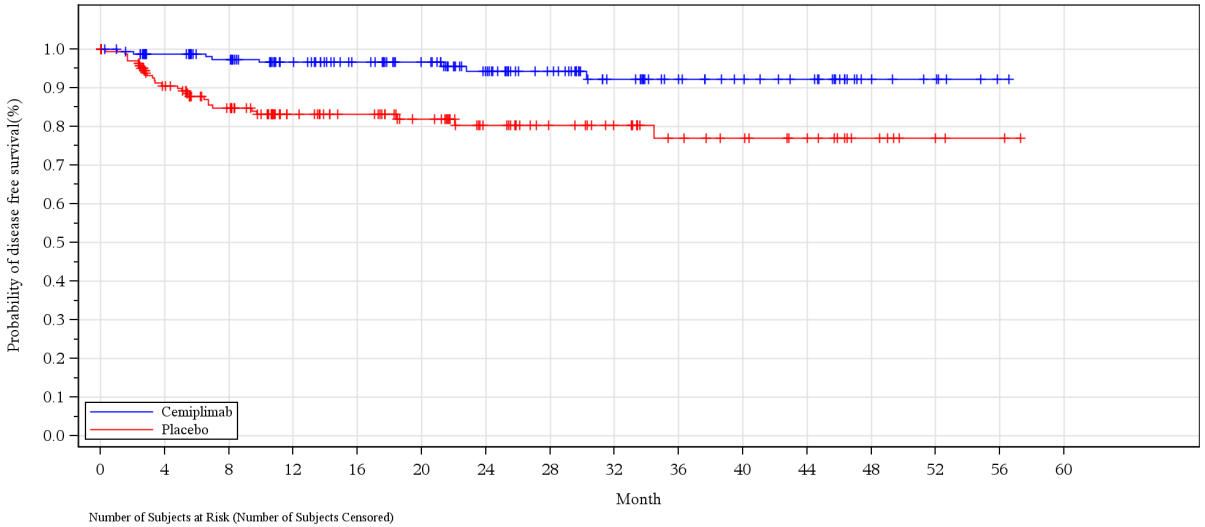
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	61 (12)	52 (20)	47 (25)	41 (31)	37 (35)	28 (43)	24 (47)	19 (51)	11 (59)	10 (60)	8 (62)	6 (64)	4 (66)	1 (69)	0 (70)
Placebo	72 (0)	51 (12)	38 (20)	30 (28)	25 (33)	20 (38)	16 (42)	10 (48)	7 (51)	6 (52)	6 (52)	5 (53)	2 (56)	1 (57)	0 (58)	0 (58)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male



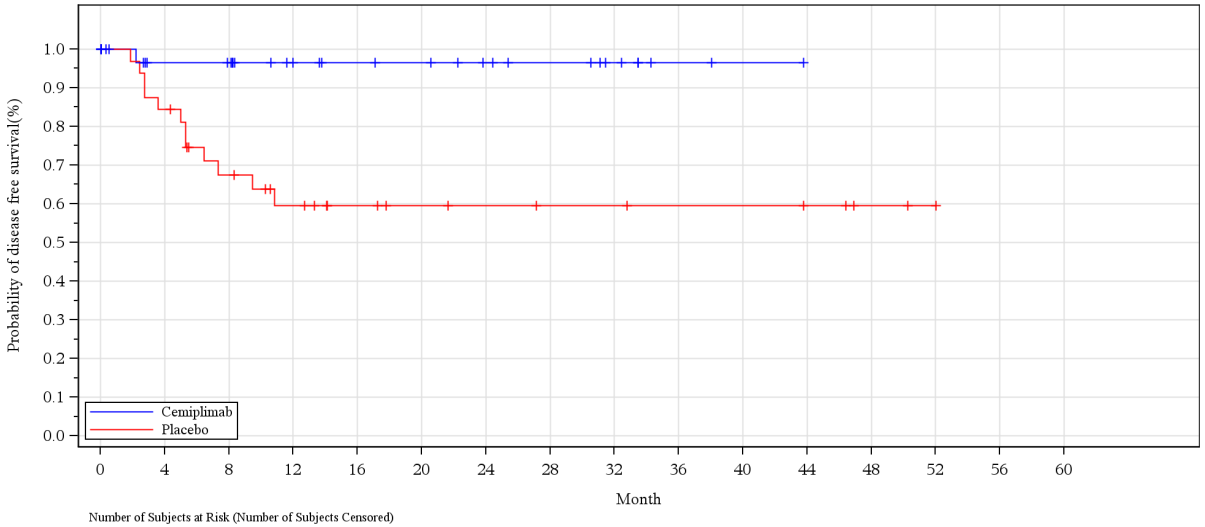
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	149 (23)	136 (34)	118 (51)	104 (65)	93 (76)	74 (93)	58 (109)	42 (124)	31 (135)	26 (140)	22 (144)	9 (158)	6 (160)	1 (165)	0 (166)
Placebo	174 (0)	136 (23)	113 (38)	83 (66)	74 (75)	62 (86)	47 (100)	37 (110)	31 (116)	22 (124)	19 (127)	14 (132)	8 (138)	3 (143)	2 (144)	0 (146)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	25 (9)	24 (10)	17 (17)	15 (19)	14 (20)	11 (23)	9 (25)	6 (28)	2 (32)	1 (33)	0 (34)	0 (34)	0 (34)	0 (34)	0 (34)
Placebo	32 (0)	27 (0)	19 (3)	14 (6)	10 (10)	8 (12)	7 (13)	6 (14)	6 (14)	5 (15)	5 (15)	4 (16)	2 (18)	1 (19)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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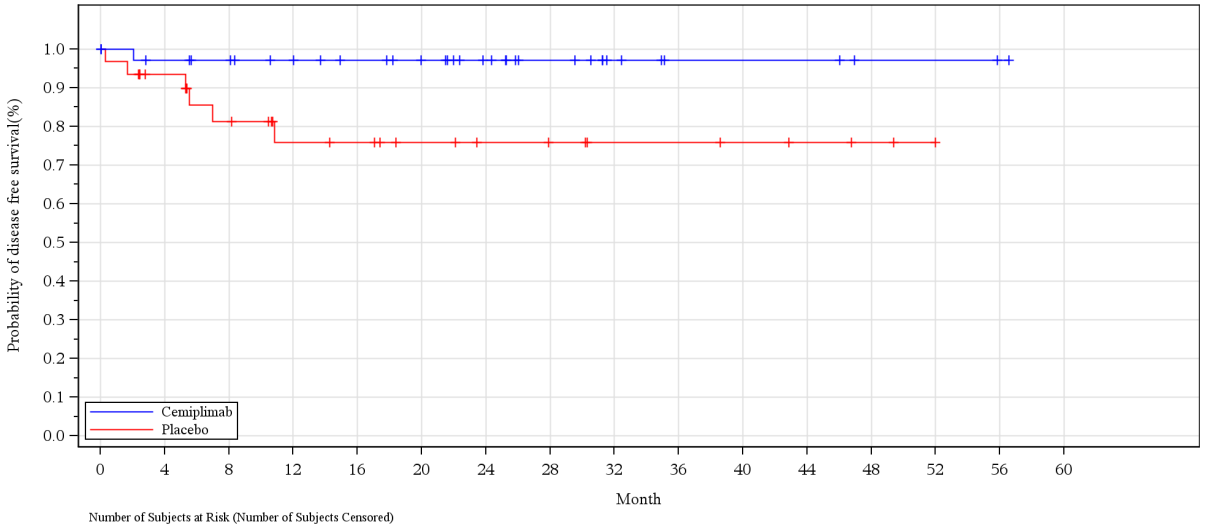
Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	33 (3)	31 (5)	28 (8)	25 (11)	22 (14)	17 (19)	12 (24)	7 (29)	4 (32)	4 (32)	4 (32)	2 (34)	2 (34)	1 (35)	0 (36)
Placebo	31 (0)	25 (4)	19 (7)	14 (11)	13 (12)	10 (15)	8 (17)	7 (18)	5 (20)	5 (20)	4 (21)	3 (22)	2 (23)	0 (25)	0 (25)	0 (25)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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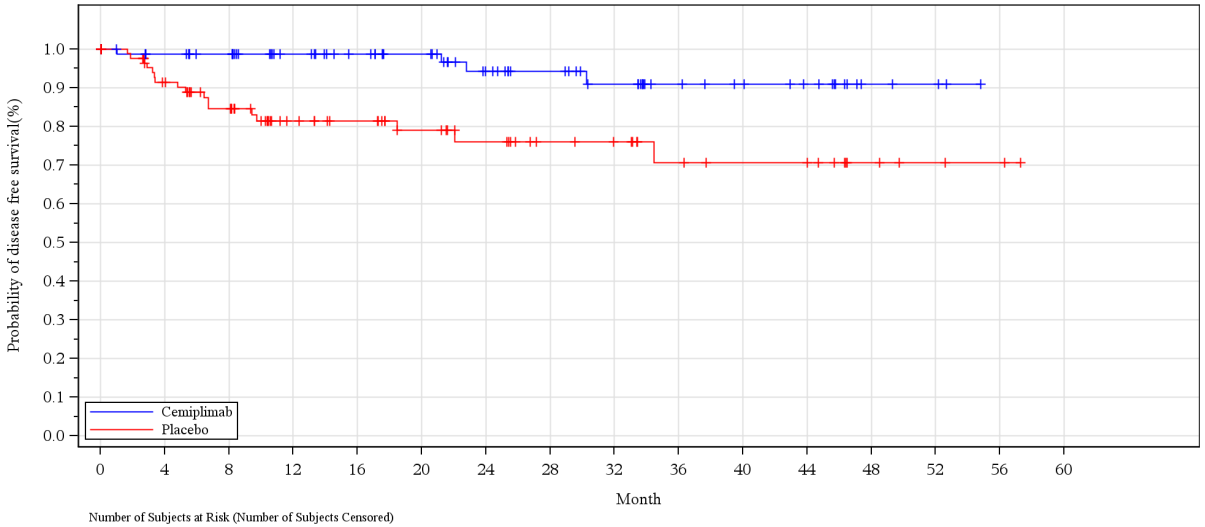
Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



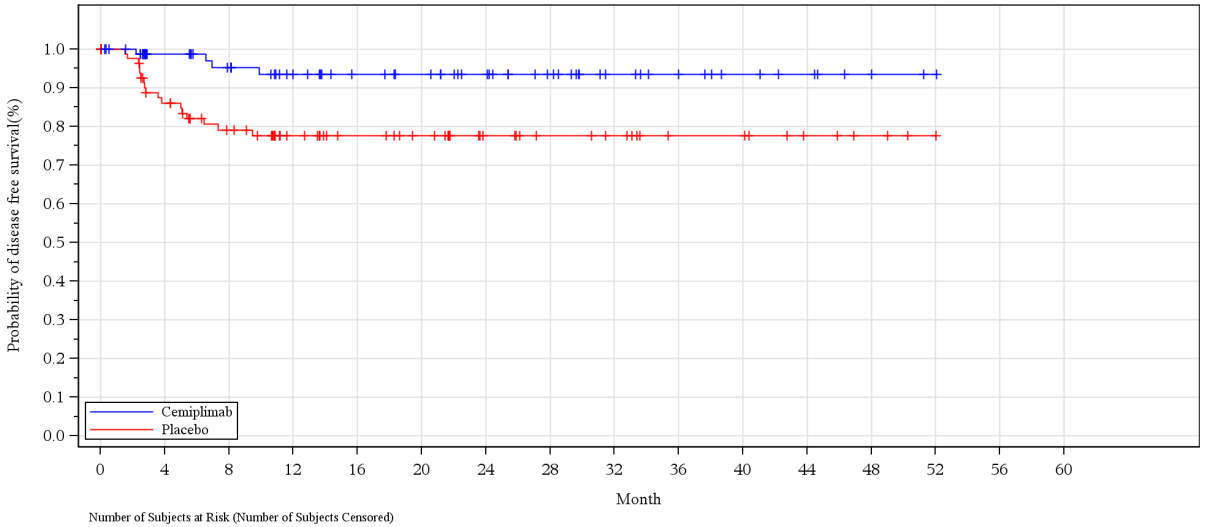
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	79 (10)	74 (15)	62 (27)	55 (34)	49 (40)	38 (49)	32 (55)	26 (60)	18 (68)	15 (71)	12 (74)	4 (82)	3 (83)	0 (86)	0 (86)
Placebo	90 (0)	72 (11)	60 (18)	43 (33)	38 (38)	31 (44)	26 (48)	20 (54)	18 (56)	13 (60)	11 (62)	10 (63)	5 (68)	3 (70)	2 (71)	0 (73)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	62 (19)	55 (24)	45 (33)	39 (39)	36 (42)	30 (48)	23 (55)	15 (63)	11 (67)	8 (70)	6 (72)	3 (76)	1 (77)	0 (78)	0 (78)
Placebo	85 (0)	66 (8)	53 (16)	40 (28)	33 (35)	29 (39)	20 (48)	16 (52)	14 (54)	9 (59)	9 (59)	5 (63)	3 (65)	1 (67)	0 (68)	0 (68)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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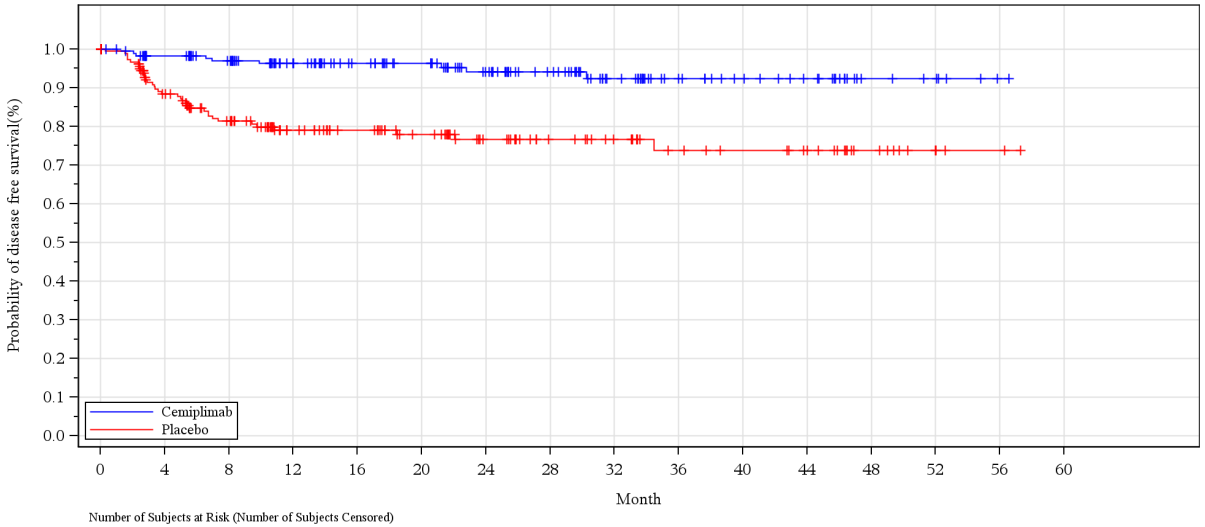
Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	161 (25)	147 (37)	123 (60)	108 (75)	99 (84)	82 (99)	65 (116)	46 (134)	31 (149)	25 (155)	20 (160)	8 (172)	6 (174)	1 (179)	0 (180)
Placebo	189 (0)	146 (23)	120 (38)	90 (65)	79 (76)	67 (87)	51 (102)	40 (113)	34 (119)	25 (127)	22 (130)	18 (134)	10 (142)	4 (148)	2 (150)	0 (152)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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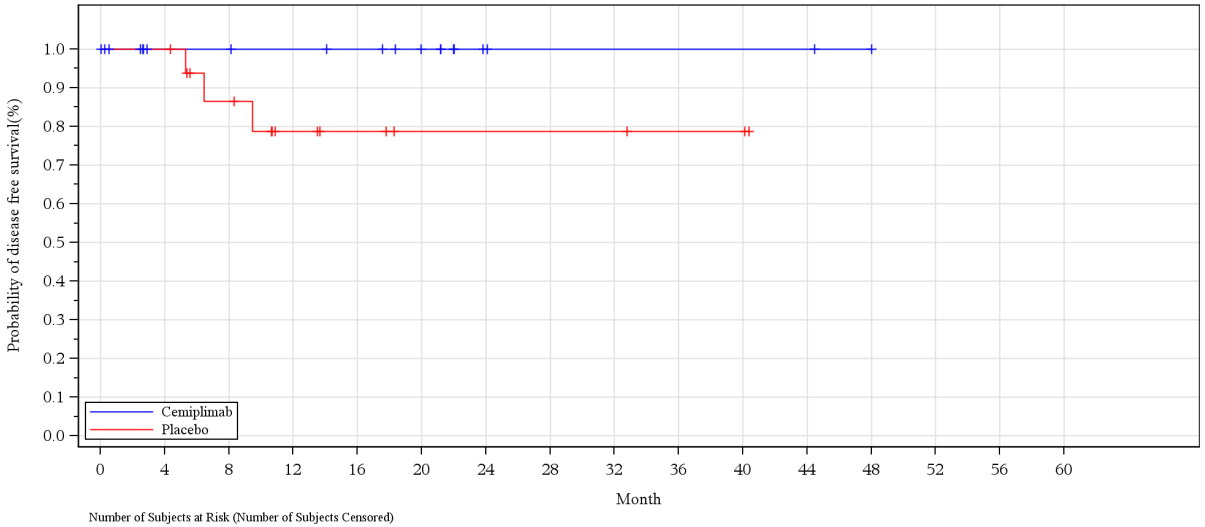
Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white



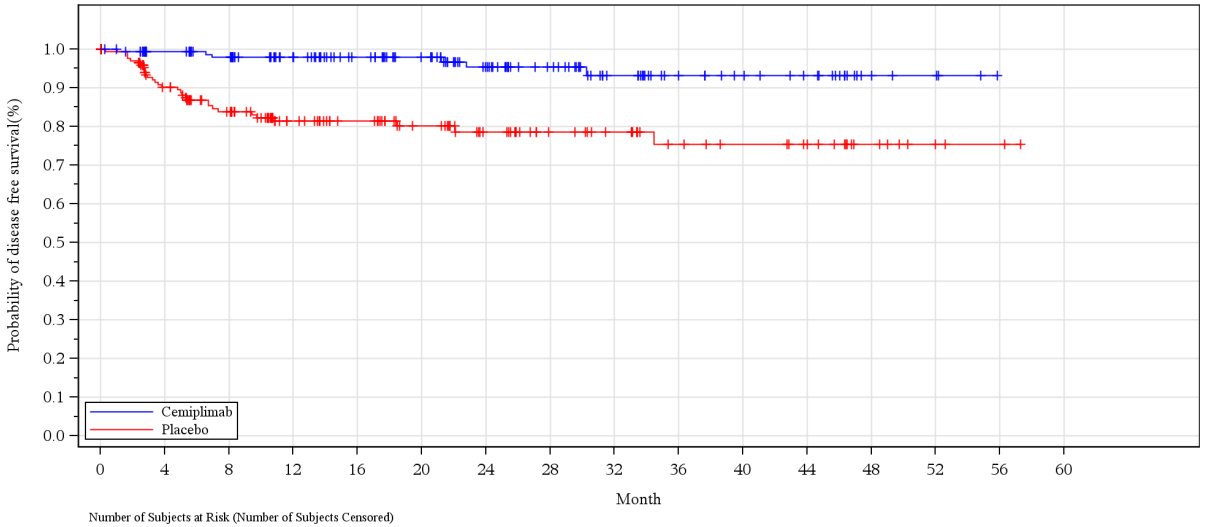
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	13 (7)	13 (7)	12 (8)	11 (9)	8 (12)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (20)	0 (20)	0 (20)	0 (20)
Placebo	17 (0)	17 (0)	12 (3)	7 (7)	5 (9)	3 (11)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



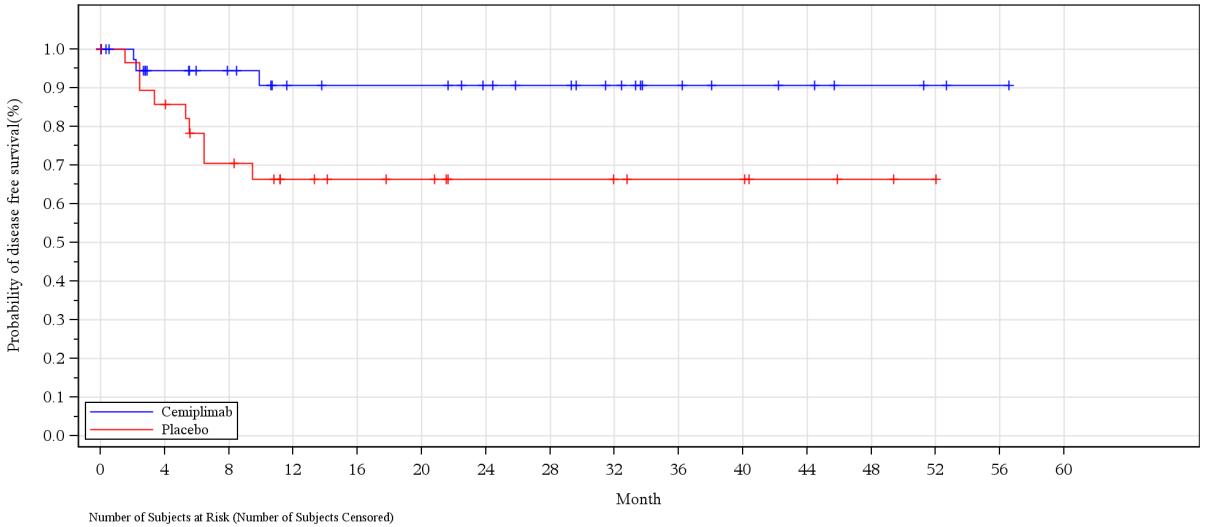
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	144 (21)	134 (29)	114 (49)	99 (64)	87 (76)	68 (93)	52 (109)	36 (124)	25 (135)	21 (139)	17 (143)	6 (155)	4 (156)	0 (160)	0 (160)
Placebo	177 (0)	139 (22)	114 (38)	84 (65)	73 (76)	60 (88)	47 (100)	36 (111)	31 (116)	22 (124)	19 (127)	15 (131)	8 (138)	3 (143)	2 (144)	0 (146)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



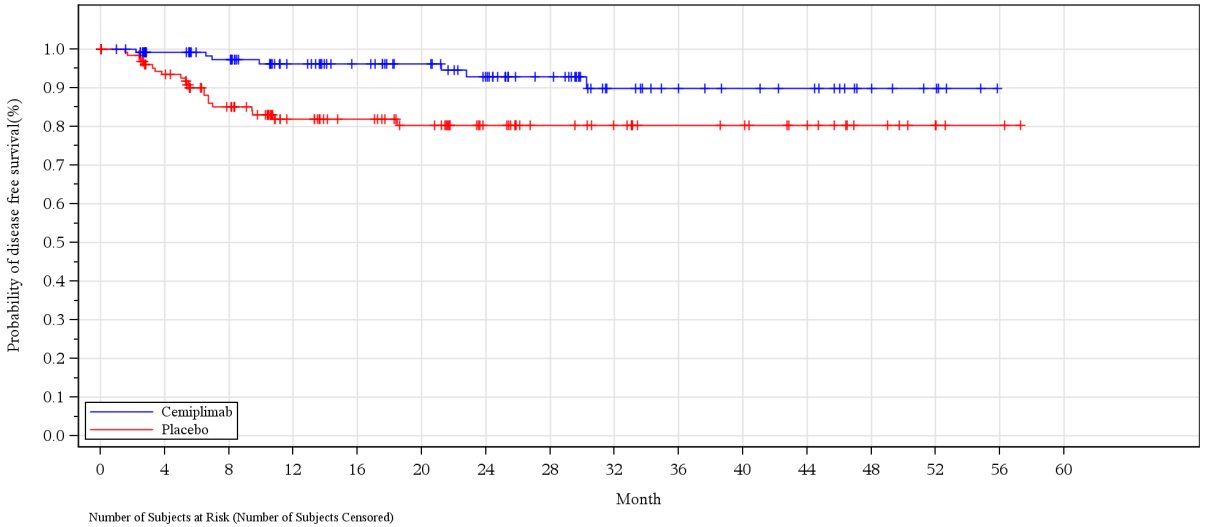
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	30 (11)	26 (15)	21 (19)	20 (20)	20 (20)	17 (23)	15 (25)	12 (28)	8 (32)	6 (34)	5 (35)	3 (37)	2 (38)	1 (39)	0 (40)
Placebo	29 (0)	24 (1)	18 (3)	13 (7)	11 (9)	10 (10)	7 (13)	7 (13)	6 (14)	5 (15)	5 (15)	3 (17)	2 (18)	1 (19)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0



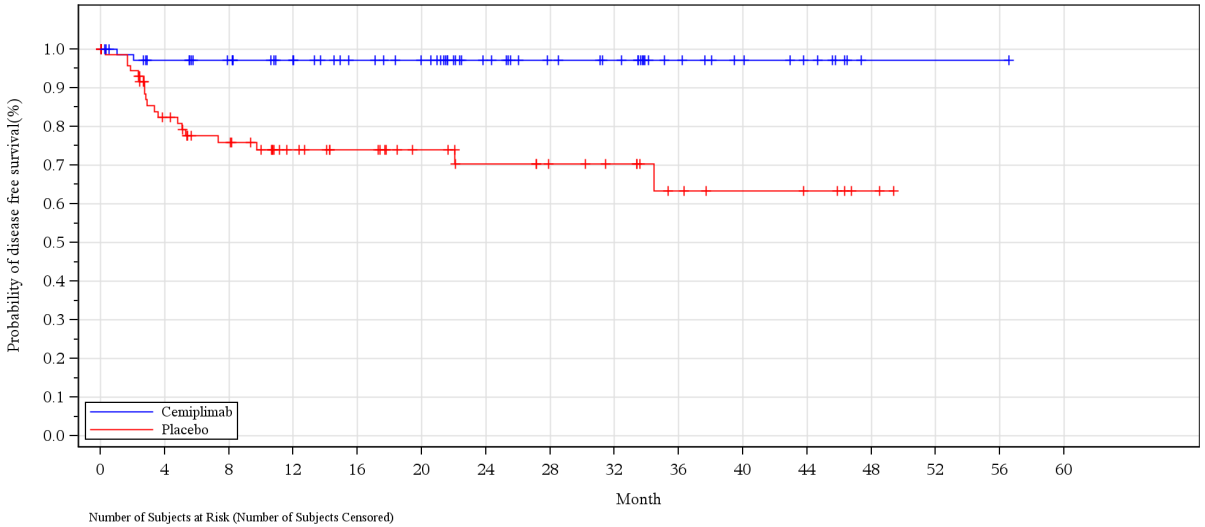
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	108 (24)	99 (31)	81 (48)	71 (58)	63 (66)	53 (74)	41 (86)	25 (101)	19 (107)	17 (109)	15 (111)	8 (119)	5 (121)	0 (126)	0 (126)
Placebo	131 (0)	110 (13)	88 (26)	64 (47)	56 (55)	48 (62)	36 (74)	28 (82)	24 (86)	19 (91)	18 (92)	13 (97)	8 (102)	4 (106)	2 (108)	0 (110)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1



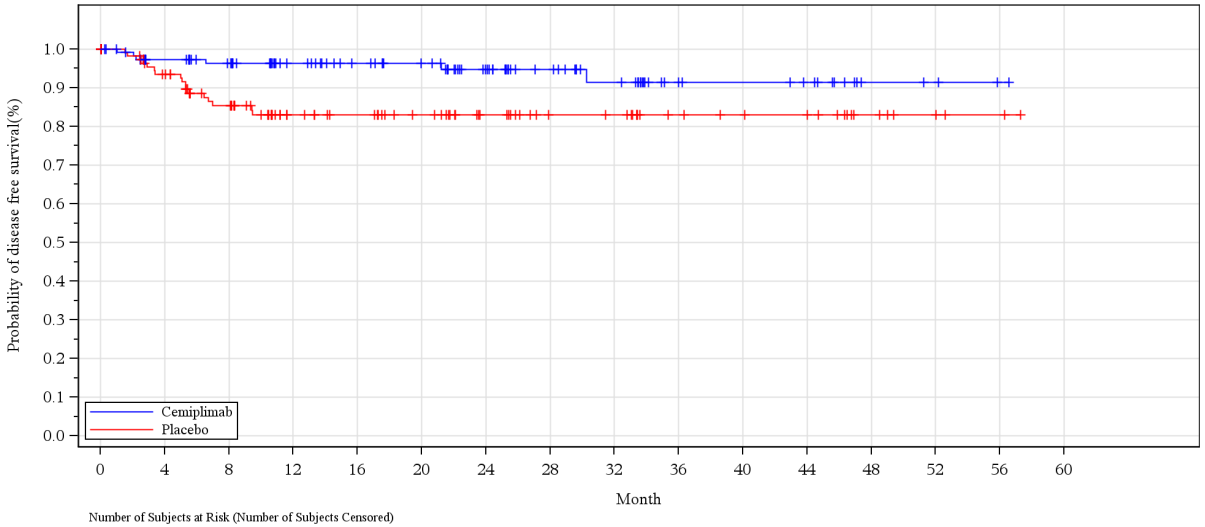
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	66 (8)	61 (13)	54 (20)	48 (26)	44 (30)	32 (42)	26 (48)	23 (51)	14 (60)	10 (64)	7 (67)	1 (73)	1 (73)	1 (73)	0 (74)
Placebo	75 (0)	53 (10)	44 (15)	33 (25)	28 (30)	22 (36)	18 (39)	15 (42)	13 (44)	8 (48)	6 (50)	5 (51)	2 (54)	0 (56)	0 (56)	0 (56)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal



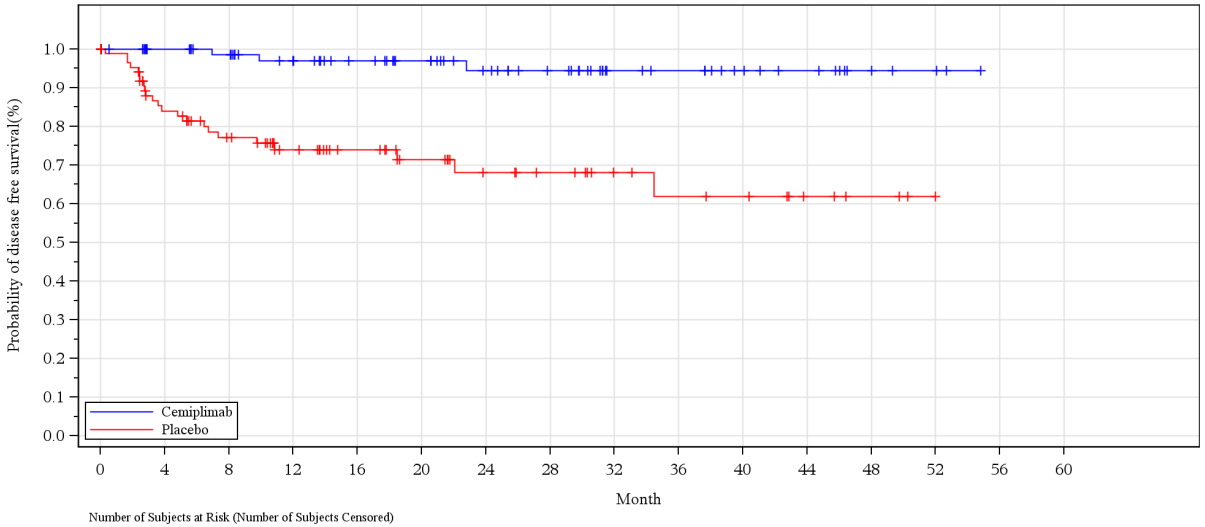
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	102 (20)	93 (28)	77 (44)	68 (53)	62 (59)	48 (72)	36 (84)	28 (91)	15 (104)	14 (105)	12 (107)	4 (115)	3 (116)	1 (118)	0 (119)
Placebo	117 (0)	98 (12)	79 (23)	56 (44)	51 (49)	44 (56)	34 (66)	26 (74)	25 (75)	17 (83)	15 (85)	13 (87)	7 (93)	4 (96)	2 (98)	0 (100)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	72 (12)	67 (16)	58 (24)	51 (31)	45 (37)	37 (44)	31 (50)	20 (61)	18 (63)	13 (68)	10 (71)	5 (77)	3 (78)	0 (81)	0 (81)
Placebo	89 (0)	65 (11)	53 (18)	41 (28)	33 (36)	26 (42)	20 (47)	17 (50)	12 (55)	10 (56)	9 (57)	5 (61)	3 (63)	0 (66)	0 (66)	0 (66)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:15 SAS Linux 9.4)

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Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	16 (24.6%)
Odds ratio (95% CI)	0.160 (0.043, 0.593)	
P-value for Odds Ratio	0.0061	
Relative Risk (95% CI)	0.22 (0.07, 0.71)	
P-value for Relative Risk	0.0110	
Heterogeneity p-value of RR	0.7552	
Risk difference (95% CI)	-17.69 (-36.63, 1.24)	
P-value for Risk Difference	0.0670	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	26 (18.4%)
Odds ratio (95% CI)	0.235 (0.101, 0.546)	
P-value for Odds Ratio	0.0008	
Relative Risk (95% CI)	0.27 (0.13, 0.59)	
P-value for Relative Risk	0.0009	
Heterogeneity p-value of RR	0.7552	
Risk difference (95% CI)	-13.10 (-20.47, -5.72)	
P-value for Risk Difference	0.0005	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	16 (24.6%)
Odds ratio (95% CI)	0.160 (0.043, 0.593)	
P-value for Odds Ratio	0.0061	
Relative Risk (95% CI)	0.22 (0.07, 0.71)	
P-value for Relative Risk	0.0110	
Heterogeneity p-value of RR	0.6726	
Risk difference (95% CI)	-17.69 (-36.63, 1.24)	
P-value for Risk Difference	0.0670	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	11 (15.9%)
Odds ratio (95% CI)	0.357 (0.116, 1.104)	
P-value for Odds Ratio	0.0737	
Relative Risk (95% CI)	0.40 (0.14, 1.10)	
P-value for Relative Risk	0.0770	
Heterogeneity p-value of RR	0.6726	
Risk difference (95% CI)	-9.57 (-19.86, 0.72)	
P-value for Risk Difference	0.0682	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	15 (20.8%)
Odds ratio (95% CI)	0.148 (0.039, 0.563)	
P-value for Odds Ratio	0.0050	
Relative Risk (95% CI)	0.17 (0.05, 0.58)	
P-value for Relative Risk	0.0045	
Heterogeneity p-value of RR	0.6726	
Risk difference (95% CI)	-16.49 (-28.42, -4.55)	
P-value for Risk Difference	0.0068	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	10 (5.7%)	30 (17.2%)
Odds ratio (95% CI)	0.285 (0.134, 0.608)	
P-value for Odds Ratio	0.0012	
Relative Risk (95% CI)	0.33 (0.17, 0.65)	
P-value for Relative Risk	0.0015	
Heterogeneity p-value of RR	0.1006	
Risk difference (95% CI)	-11.55 (-18.33, -4.77)	
P-value for Risk Difference	0.0008	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	1 (2.9%)	12 (37.5%)
Odds ratio (95% CI)	0.042 (0.005, 0.371)	
P-value for Odds Ratio	0.0043	
Relative Risk (95% CI)	0.07 (0.01, 0.51)	
P-value for Relative Risk	0.0086	
Heterogeneity p-value of RR	0.1006	
Risk difference (95% CI)	-35.06 (-62.54, -7.58)	
P-value for Risk Difference	0.0124	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Odds ratio (95% CI)	0.064 (0.005, 0.829)	
P-value for Odds Ratio	0.0355	
Relative Risk (95% CI)	0.40 (0.40, 0.40)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.7092	
Risk difference (95% CI)	-16.29 (-32.47, -0.11)	
P-value for Risk Difference	0.0484	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	17 (18.9%)
Odds ratio (95% CI)	0.196 (0.063, 0.610)	
P-value for Odds Ratio	0.0049	
Relative Risk (95% CI)	0.23 (0.08, 0.66)	
P-value for Relative Risk	0.0060	
Heterogeneity p-value of RR	0.7092	
Risk difference (95% CI)	-15.19 (-25.11, -5.28)	
P-value for Risk Difference	0.0027	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	6 (7.3%)	19 (22.4%)
Odds ratio (95% CI)	0.266 (0.099, 0.710)	
P-value for Odds Ratio	0.0082	
Relative Risk (95% CI)	0.32 (0.13, 0.76)	
P-value for Relative Risk	0.0100	
Heterogeneity p-value of RR	0.7092	
Risk difference (95% CI)	-15.13 (-25.59, -4.66)	
P-value for Risk Difference	0.0046	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	10 (5.3%)	38 (20.1%)
Odds ratio (95% CI)	0.203 (0.096, 0.429)	
P-value for Odds Ratio	<0.0001	
Relative Risk (95% CI)	0.25 (0.13, 0.48)	
P-value for Relative Risk	<0.0001	
Heterogeneity p-value of RR	0.9846	
Risk difference (95% CI)	-14.92 (-21.64, -8.20)	
P-value for Risk Difference	<0.0001	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	4 (23.5%)
Odds ratio (95% CI)	0.177 (0.016, 1.915)	
P-value for Odds Ratio	0.1540	
Relative Risk (95% CI)	0.21 (0.03, 1.78)	
P-value for Relative Risk	0.1543	
Heterogeneity p-value of RR	0.9846	
Risk difference (95% CI)	-18.53 (-18.53, -18.53)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	8 (4.8%)	33 (18.6%)
Odds ratio (95% CI)	0.224 (0.100, 0.501)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	0.26 (0.13, 0.55)	
P-value for Relative Risk	0.0004	
Heterogeneity p-value of RR	0.8553	
Risk difference (95% CI)	-13.89 (-21.29, -6.48)	
P-value for Risk Difference	0.0002	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	9 (31.0%)
Odds ratio (95% CI)	0.147 (0.034, 0.640)	
P-value for Odds Ratio	0.0106	
Relative Risk (95% CI)	0.22 (0.07, 0.74)	
P-value for Relative Risk	0.0145	
Heterogeneity p-value of RR	0.8553	
Risk difference (95% CI)	-25.34 (-47.04, -3.64)	
P-value for Risk Difference	0.0221	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	9 (6.8%)	22 (16.8%)
Odds ratio (95% CI)	0.339 (0.148, 0.777)	
P-value for Odds Ratio	0.0105	
Relative Risk (95% CI)	0.38 (0.18, 0.79)	
P-value for Relative Risk	0.0098	
Heterogeneity p-value of RR	0.0595	
Risk difference (95% CI)	-10.38 (-18.75, -2.00)	
P-value for Risk Difference	0.0151	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	2 (2.6%)	20 (26.7%)
Odds ratio (95% CI)	0.070 (0.015, 0.321)	
P-value for Odds Ratio	0.0006	
Relative Risk (95% CI)	0.10 (0.02, 0.41)	
P-value for Relative Risk	0.0013	
Heterogeneity p-value of RR	0.0595	
Risk difference (95% CI)	-22.45 (-37.66, -7.24)	
P-value for Risk Difference	0.0038	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	7 (5.6%)	18 (15.4%)
Odds ratio (95% CI)	0.293 (0.115, 0.744)	
P-value for Odds Ratio	0.0098	
Relative Risk (95% CI)	0.33 (0.14, 0.76)	
P-value for Relative Risk	0.0095	
Heterogeneity p-value of RR	0.3101	
Risk difference (95% CI)	-9.27 (-17.06, -1.47)	
P-value for Risk Difference	0.0198	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1a Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	4 (4.8%)	24 (27.0%)
Odds ratio (95% CI)	0.132 (0.043, 0.401)	
P-value for Odds Ratio	0.0004	
Relative Risk (95% CI)	0.18 (0.06, 0.48)	
P-value for Relative Risk	0.0008	
Heterogeneity p-value of RR	0.3101	
Risk difference (95% CI)	-21.24 (-33.96, -8.53)	
P-value for Risk Difference	0.0011	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	16 (24.6%)
Locoregional recurrence, n (%)	3 (5.4%)	16 (24.6%)
Number of censored participants, n (%)	53 (94.6%)	49 (75.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	27.1 (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0064	
HR (95% CI) [c][d]	0.207 (0.059, 0.721)	
Heterogeneity p-value [c][e]	0.7591	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.1 (87.1, 99.7)	93.8 (84.2, 97.6)
6 months	98.1 (87.1, 99.7)	85.8 (74.5, 92.3)
12 months	96.0 (85.0, 99.0)	75.9 (63.2, 84.7)
18 months	96.0 (85.0, 99.0)	75.9 (63.2, 84.7)
24 months	93.1 (79.7, 97.8)	75.9 (63.2, 84.7)
30 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
36 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
42 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
48 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
54 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	26 (18.4%)
Locoregional recurrence, n (%)	8 (5.2%)	26 (18.4%)
Number of censored participants, n (%)	145 (94.8%)	115 (81.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (11.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0002	
HR (95% CI) [c][d]	0.247 (0.111, 0.551)	
Heterogeneity p-value [c][e]	0.7591	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (94.7, 99.7)	92.0 (86.0, 95.5)
6 months	98.7 (94.7, 99.7)	86.8 (79.8, 91.5)
12 months	97.3 (92.9, 99.0)	82.5 (74.7, 88.0)
18 months	97.3 (92.9, 99.0)	82.5 (74.7, 88.0)
24 months	95.0 (88.9, 97.8)	79.6 (70.9, 85.9)
30 months	95.0 (88.9, 97.8)	79.6 (70.9, 85.9)
36 months	91.5 (82.9, 95.9)	76.4 (65.4, 84.3)
42 months	91.5 (82.9, 95.9)	76.4 (65.4, 84.3)
48 months	91.5 (82.9, 95.9)	76.4 (65.4, 84.3)
54 months	91.5 (82.9, 95.9)	76.4 (65.4, 84.3)
60 months	91.5 (82.9, 95.9)	76.4 (65.4, 84.3)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	16 (24.6%)
Locoregional recurrence, n (%)	3 (5.4%)	16 (24.6%)
Number of censored participants, n (%)	53 (94.6%)	49 (75.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	27.1 (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0064	
HR (95% CI) [c][d]	0.207 (0.059, 0.721)	
Heterogeneity p-value [c][e]	0.5917	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.1 (87.1, 99.7)	93.8 (84.2, 97.6)
6 months	98.1 (87.1, 99.7)	85.8 (74.5, 92.3)
12 months	96.0 (85.0, 99.0)	75.9 (63.2, 84.7)
18 months	96.0 (85.0, 99.0)	75.9 (63.2, 84.7)
24 months	93.1 (79.7, 97.8)	75.9 (63.2, 84.7)
30 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
36 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
42 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
48 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
54 months	93.1 (79.7, 97.8)	71.7 (56.5, 82.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	11 (15.9%)
Locoregional recurrence, n (%)	5 (6.3%)	11 (15.9%)
Number of censored participants, n (%)	75 (93.8%)	58 (84.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (18.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0591	
HR (95% CI) [c][d]	0.369 (0.126, 1.081)	
Heterogeneity p-value [c][e]	0.5917	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (90.3, 99.4)	94.1 (85.1, 97.8)
6 months	97.5 (90.3, 99.4)	91.2 (81.4, 95.9)
12 months	96.1 (88.4, 98.7)	87.8 (77.1, 93.7)
18 months	96.1 (88.4, 98.7)	87.8 (77.1, 93.7)
24 months	93.8 (83.8, 97.7)	82.7 (69.5, 90.5)
30 months	93.8 (83.8, 97.7)	82.7 (69.5, 90.5)
36 months	90.2 (76.0, 96.2)	78.1 (61.5, 88.1)
42 months	90.2 (76.0, 96.2)	78.1 (61.5, 88.1)
48 months	90.2 (76.0, 96.2)	78.1 (61.5, 88.1)
54 months	90.2 (76.0, 96.2)	78.1 (61.5, 88.1)
60 months	NE (NE, NE)	78.1 (61.5, 88.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	15 (20.8%)
Locoregional recurrence, n (%)	3 (4.1%)	15 (20.8%)
Number of censored participants, n (%)	70 (95.9%)	57 (79.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (4.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0020	
HR (95% CI) [c][d]	0.170 (0.048, 0.599)	
Heterogeneity p-value [c][e]	0.5917	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	89.9 (80.0, 95.1)
6 months	100 (100, 100)	82.3 (70.9, 89.6)
12 months	98.6 (90.2, 99.8)	76.9 (64.4, 85.5)
18 months	98.6 (90.2, 99.8)	76.9 (64.4, 85.5)
24 months	96.4 (86.0, 99.1)	76.9 (64.4, 85.5)
30 months	96.4 (86.0, 99.1)	76.9 (64.4, 85.5)
36 months	93.0 (78.4, 97.8)	76.9 (64.4, 85.5)
42 months	93.0 (78.4, 97.8)	76.9 (64.4, 85.5)
48 months	93.0 (78.4, 97.8)	76.9 (64.4, 85.5)
54 months	93.0 (78.4, 97.8)	76.9 (64.4, 85.5)
60 months	93.0 (78.4, 97.8)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	10 (5.7%)	30 (17.2%)
Locoregional recurrence, n (%)	10 (5.7%)	30 (17.2%)
Number of censored participants, n (%)	164 (94.3%)	144 (82.8%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (22.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0004	
HR (95% CI) [c][d]	0.293 (0.143, 0.602)	
Heterogeneity p-value [c][e]	0.1690	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (95.4, 99.7)	93.5 (88.6, 96.4)
6 months	98.8 (95.4, 99.7)	88.7 (82.8, 92.6)
12 months	96.9 (92.8, 98.7)	83.9 (77.3, 88.8)
18 months	96.9 (92.8, 98.7)	83.9 (77.3, 88.8)
24 months	94.1 (88.4, 97.1)	81.6 (74.2, 87.1)
30 months	94.1 (88.4, 97.1)	80.1 (72.1, 86.0)
36 months	91.3 (83.8, 95.4)	77.7 (68.2, 84.7)
42 months	91.3 (83.8, 95.4)	77.7 (68.2, 84.7)
48 months	91.3 (83.8, 95.4)	77.7 (68.2, 84.7)
54 months	91.3 (83.8, 95.4)	77.7 (68.2, 84.7)
60 months	91.3 (83.8, 95.4)	77.7 (68.2, 84.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	1 (2.9%)	12 (37.5%)
Locoregional recurrence, n (%)	1 (2.9%)	12 (37.5%)
Number of censored participants, n (%)	34 (97.1%)	20 (62.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	5.3 (2.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0027	
HR (95% CI) [c][d]	0.082 (0.010, 0.640)	
Heterogeneity p-value [c][e]	0.1690	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.9 (79.8, 99.6)	87.5 (70.0, 95.1)
6 months	96.9 (79.8, 99.6)	74.6 (55.6, 86.4)
12 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
18 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
24 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
30 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
36 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
42 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
48 months	96.9 (79.8, 99.6)	61.3 (42.0, 75.9)
54 months	NE (NE, NE)	61.3 (42.0, 75.9)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Locoregional recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (5.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0140	
HR (95% CI) [c][d]	0.109 (0.013, 0.919)	
Heterogeneity p-value [c][e]	0.6751	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.2 (81.9, 99.6)	93.5 (76.6, 98.3)
6 months	97.2 (81.9, 99.6)	86.5 (67.8, 94.7)
12 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
18 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
24 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
30 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
36 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
42 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
48 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
54 months	97.2 (81.9, 99.6)	78.5 (58.0, 89.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	17 (18.9%)
Locoregional recurrence, n (%)	4 (4.4%)	17 (18.9%)
Number of censored participants, n (%)	86 (95.6%)	73 (81.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	34.5 (9.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0012	
HR (95% CI) [c][d]	0.197 (0.066, 0.586)	
Heterogeneity p-value [c][e]	0.6751	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (92.0, 99.8)	95.4 (88.2, 98.3)
6 months	98.8 (92.0, 99.8)	89.6 (80.9, 94.4)
12 months	98.8 (92.0, 99.8)	83.1 (73.1, 89.6)
18 months	98.8 (92.0, 99.8)	83.1 (73.1, 89.6)
24 months	95.2 (85.6, 98.5)	78.8 (67.1, 86.7)
30 months	95.2 (85.6, 98.5)	78.8 (67.1, 86.7)
36 months	92.5 (80.4, 97.3)	74.6 (60.1, 84.5)
42 months	92.5 (80.4, 97.3)	74.6 (60.1, 84.5)
48 months	92.5 (80.4, 97.3)	74.6 (60.1, 84.5)
54 months	92.5 (80.4, 97.3)	74.6 (60.1, 84.5)
60 months	92.5 (80.4, 97.3)	74.6 (60.1, 84.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	6 (7.3%)	19 (22.4%)
Locoregional recurrence, n (%)	6 (7.3%)	19 (22.4%)
Number of censored participants, n (%)	76 (92.7%)	66 (77.6%)
Q1 (95% CI), (months)[a]	NR (30.8, NE)	27.1 (5.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0055	
HR (95% CI) [c][d]	0.293 (0.117, 0.735)	
Heterogeneity p-value [c][e]	0.6751	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.4, 99.8)	89.3 (80.4, 94.3)
6 months	98.7 (91.4, 99.8)	83.2 (73.3, 89.7)
12 months	94.4 (85.8, 97.9)	77.8 (67.0, 85.4)
18 months	94.4 (85.8, 97.9)	77.8 (67.0, 85.4)
24 months	92.0 (81.2, 96.7)	77.8 (67.0, 85.4)
30 months	92.0 (81.2, 96.7)	74.9 (62.7, 83.6)
36 months	88.5 (74.4, 95.1)	74.9 (62.7, 83.6)
42 months	88.5 (74.4, 95.1)	74.9 (62.7, 83.6)
48 months	88.5 (74.4, 95.1)	74.9 (62.7, 83.6)
54 months	88.5 (74.4, 95.1)	74.9 (62.7, 83.6)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	10 (5.3%)	38 (20.1%)
Locoregional recurrence, n (%)	10 (5.3%)	38 (20.1%)
Number of censored participants, n (%)	179 (94.7%)	151 (79.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (10.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.221 (0.109, 0.446)	
Heterogeneity p-value [c][e]	0.9569	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.4 (95.0, 99.5)	91.9 (86.9, 95.0)
6 months	98.4 (95.0, 99.5)	85.8 (79.8, 90.1)
12 months	96.6 (92.6, 98.5)	80.9 (74.3, 86.0)
18 months	96.6 (92.6, 98.5)	80.9 (74.3, 86.0)
24 months	93.9 (88.4, 96.9)	78.8 (71.7, 84.4)
30 months	93.9 (88.4, 96.9)	77.5 (69.9, 83.4)
36 months	92.7 (86.4, 96.1)	75.3 (66.5, 82.1)
42 months	92.7 (86.4, 96.1)	75.3 (66.5, 82.1)
48 months	92.7 (86.4, 96.1)	75.3 (66.5, 82.1)
54 months	92.7 (86.4, 96.1)	75.3 (66.5, 82.1)
60 months	92.7 (86.4, 96.1)	75.3 (66.5, 82.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	4 (23.5%)
Locoregional recurrence, n (%)	1 (5.0%)	4 (23.5%)
Number of censored participants, n (%)	19 (95.0%)	13 (76.5%)
Q1 (95% CI), (months)[a]	30.8 (30.8, NE)	11.5 (5.3, NE)
Median (95% CI), (months)[a]	NR (30.8, NE)	NR (11.5, NE)
Q3 (95% CI), (months)[a]	NR (30.8, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.1295	
HR (95% CI) [c][d]	NE (NE, NE)	
Heterogeneity p-value [c][e]	0.9569	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	93.8 (63.2, 99.1)
12 months	100 (100, 100)	73.4 (43.5, 89.2)
18 months	100 (100, 100)	73.4 (43.5, 89.2)
24 months	100 (100, 100)	73.4 (43.5, 89.2)
30 months	100 (100, 100)	73.4 (43.5, 89.2)
36 months	66.7 (5.4, 94.5)	73.4 (43.5, 89.2)
42 months	66.7 (5.4, 94.5)	73.4 (43.5, 89.2)
48 months	66.7 (5.4, 94.5)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	8 (4.8%)	33 (18.6%)
Locoregional recurrence, n (%)	8 (4.8%)	33 (18.6%)
Number of censored participants, n (%)	158 (95.2%)	144 (81.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (18.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.221 (0.102, 0.480)	
Heterogeneity p-value [c][e]	0.9660	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (95.7, 99.9)	93.0 (88.1, 96.0)
6 months	99.4 (95.7, 99.9)	87.7 (81.7, 91.8)
12 months	98.1 (94.3, 99.4)	82.3 (75.5, 87.4)
18 months	98.1 (94.3, 99.4)	82.3 (75.5, 87.4)
24 months	95.1 (89.2, 97.8)	79.9 (72.4, 85.6)
30 months	95.1 (89.2, 97.8)	78.5 (70.4, 84.6)
36 months	91.9 (83.7, 96.1)	76.0 (66.5, 83.2)
42 months	91.9 (83.7, 96.1)	76.0 (66.5, 83.2)
48 months	91.9 (83.7, 96.1)	76.0 (66.5, 83.2)
54 months	91.9 (83.7, 96.1)	76.0 (66.5, 83.2)
60 months	91.9 (83.7, 96.1)	76.0 (66.5, 83.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	9 (31.0%)
Locoregional recurrence, n (%)	3 (7.0%)	9 (31.0%)
Number of censored participants, n (%)	40 (93.0%)	20 (69.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	6.4 (2.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0148	
HR (95% CI) [c][d]	0.224 (0.060, 0.834)	
Heterogeneity p-value [c][e]	0.9660	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	95.0 (81.5, 98.7)	89.7 (71.3, 96.5)
6 months	95.0 (81.5, 98.7)	79.3 (59.6, 90.1)
12 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
18 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
24 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
30 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
36 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
42 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
48 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
54 months	91.8 (76.6, 97.3)	68.5 (48.1, 82.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	9 (6.8%)	22 (16.8%)
Locoregional recurrence, n (%)	9 (6.8%)	22 (16.8%)
Number of censored participants, n (%)	124 (93.2%)	109 (83.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (18.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0061	
HR (95% CI) [c][d]	0.352 (0.161, 0.767)	
Heterogeneity p-value [c][e]	0.0531	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.6, 99.9)	96.2 (91.1, 98.4)
6 months	99.2 (94.6, 99.9)	90.8 (84.3, 94.6)
12 months	96.7 (91.3, 98.7)	84.0 (76.2, 89.4)
18 months	96.7 (91.3, 98.7)	84.0 (76.2, 89.4)
24 months	92.5 (84.5, 96.5)	82.6 (74.3, 88.4)
30 months	92.5 (84.5, 96.5)	80.6 (71.5, 87.1)
36 months	88.5 (78.1, 94.1)	80.6 (71.5, 87.1)
42 months	88.5 (78.1, 94.1)	80.6 (71.5, 87.1)
48 months	88.5 (78.1, 94.1)	80.6 (71.5, 87.1)
54 months	88.5 (78.1, 94.1)	80.6 (71.5, 87.1)
60 months	88.5 (78.1, 94.1)	80.6 (71.5, 87.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	2 (2.6%)	20 (26.7%)
Locoregional recurrence, n (%)	2 (2.6%)	20 (26.7%)
Number of censored participants, n (%)	74 (97.4%)	55 (73.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	11.5 (3.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.074 (0.017, 0.321)	
Heterogeneity p-value [c][e]	0.0531	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.3 (89.5, 99.3)	85.8 (75.2, 92.1)
6 months	97.3 (89.5, 99.3)	78.4 (66.7, 86.4)
12 months	97.3 (89.5, 99.3)	73.4 (61.0, 82.4)
18 months	97.3 (89.5, 99.3)	73.4 (61.0, 82.4)
24 months	97.3 (89.5, 99.3)	70.5 (57.2, 80.4)
30 months	97.3 (89.5, 99.3)	70.5 (57.2, 80.4)
36 months	97.3 (89.5, 99.3)	65.5 (49.2, 77.7)
42 months	97.3 (89.5, 99.3)	65.5 (49.2, 77.7)
48 months	97.3 (89.5, 99.3)	65.5 (49.2, 77.7)
54 months	97.3 (89.5, 99.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	7 (5.6%)	18 (15.4%)
Locoregional recurrence, n (%)	7 (5.6%)	18 (15.4%)
Number of censored participants, n (%)	118 (94.4%)	99 (84.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (11.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0083	
HR (95% CI) [c][d]	0.325 (0.135, 0.782)	
Heterogeneity p-value [c][e]	0.2182	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (92.5, 99.2)	95.6 (89.8, 98.2)
6 months	97.5 (92.5, 99.2)	89.3 (81.9, 93.8)
12 months	96.6 (91.3, 98.7)	83.3 (74.8, 89.2)
18 months	96.6 (91.3, 98.7)	83.3 (74.8, 89.2)
24 months	95.3 (88.8, 98.1)	83.3 (74.8, 89.2)
30 months	95.3 (88.8, 98.1)	83.3 (74.8, 89.2)
36 months	90.8 (80.2, 95.9)	83.3 (74.8, 89.2)
42 months	90.8 (80.2, 95.9)	83.3 (74.8, 89.2)
48 months	90.8 (80.2, 95.9)	83.3 (74.8, 89.2)
54 months	90.8 (80.2, 95.9)	83.3 (74.8, 89.2)
60 months	NE (NE, NE)	83.3 (74.8, 89.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	4 (4.8%)	24 (27.0%)
Locoregional recurrence, n (%)	4 (4.8%)	24 (27.0%)
Number of censored participants, n (%)	80 (95.2%)	65 (73.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	18.5 (4.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (34.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.137 (0.047, 0.400)	
Heterogeneity p-value [c][e]	0.2182	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.7.1 Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	88.5 (79.6, 93.6)
6 months	100 (100, 100)	82.6 (72.9, 89.2)
12 months	97.4 (89.9, 99.3)	76.2 (65.5, 83.9)
18 months	97.4 (89.9, 99.3)	76.2 (65.5, 83.9)
24 months	93.4 (83.0, 97.5)	71.4 (59.1, 80.6)
30 months	93.4 (83.0, 97.5)	68.3 (54.9, 78.5)
36 months	93.4 (83.0, 97.5)	63.1 (46.5, 75.8)
42 months	93.4 (83.0, 97.5)	63.1 (46.5, 75.8)
48 months	93.4 (83.0, 97.5)	63.1 (46.5, 75.8)
54 months	93.4 (83.0, 97.5)	63.1 (46.5, 75.8)
60 months	93.4 (83.0, 97.5)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	16 (24.6%)
Locoregional recurrence, n (%)	3 (5.4%)	16 (24.6%)
Number of censored participants, n (%)	53 (94.6%)	49 (75.4%)
Proportionality Test p-value[a][b]	0.4208	
Hazard ratio(interaction)	0.515 (0.102, 2.590)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	26 (18.4%)
Locoregional recurrence, n (%)	8 (5.2%)	26 (18.4%)
Number of censored participants, n (%)	145 (94.8%)	115 (81.6%)
Proportionality Test p-value[a][b]	0.0859	
Hazard ratio(interaction)	0.472 (0.200, 1.112)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	16 (24.6%)
Locoregional recurrence, n (%)	3 (5.4%)	16 (24.6%)
Number of censored participants, n (%)	53 (94.6%)	49 (75.4%)
Proportionality Test p-value[a][b]	0.4208	
Hazard ratio(interaction)	0.515 (0.102, 2.590)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	11 (15.9%)
Locoregional recurrence, n (%)	5 (6.3%)	11 (15.9%)
Number of censored participants, n (%)	75 (93.8%)	58 (84.1%)
Proportionality Test p-value[a][b]	0.9042	
Hazard ratio(interaction)	0.942 (0.357, 2.489)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	15 (20.8%)
Locoregional recurrence, n (%)	3 (4.1%)	15 (20.8%)
Number of censored participants, n (%)	70 (95.9%)	57 (79.2%)
Proportionality Test p-value[a][b]	0.1037	
Hazard ratio(interaction)	0.027 (0.000, 2.090)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	10 (5.7%)	30 (17.2%)
Locoregional recurrence, n (%)	10 (5.7%)	30 (17.2%)
Number of censored participants, n (%)	164 (94.3%)	144 (82.8%)
Proportionality Test p-value[a][b]	0.0813	
Hazard ratio(interaction)	0.496 (0.226, 1.091)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	1 (2.9%)	12 (37.5%)
Locoregional recurrence, n (%)	1 (2.9%)	12 (37.5%)
Number of censored participants, n (%)	34 (97.1%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.4464	
Hazard ratio(interaction)	92.257 (0.001, 1.06E7)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Locoregional recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.6407	
Hazard ratio(interaction)	1.531 (0.256, 9.152)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	17 (18.9%)
Locoregional recurrence, n (%)	4 (4.4%)	17 (18.9%)
Number of censored participants, n (%)	86 (95.6%)	73 (81.1%)
Proportionality Test p-value[a][b]	0.3469	
Hazard ratio(interaction)	0.557 (0.165, 1.885)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	6 (7.3%)	19 (22.4%)
Locoregional recurrence, n (%)	6 (7.3%)	19 (22.4%)
Number of censored participants, n (%)	76 (92.7%)	66 (77.6%)
Proportionality Test p-value[a][b]	0.0683	
Hazard ratio(interaction)	0.309 (0.087, 1.092)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	10 (5.3%)	38 (20.1%)
Locoregional recurrence, n (%)	10 (5.3%)	38 (20.1%)
Number of censored participants, n (%)	179 (94.7%)	151 (79.9%)
Proportionality Test p-value[a][b]	0.1234	
Hazard ratio(interaction)	0.547 (0.254, 1.178)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	4 (23.5%)
Locoregional recurrence, n (%)	1 (5.0%)	4 (23.5%)
Number of censored participants, n (%)	19 (95.0%)	13 (76.5%)
Proportionality Test p-value[a][b]	1.0000	
Hazard ratio(interaction)	1.208 (0.000, NE)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	8 (4.8%)	33 (18.6%)
Locoregional recurrence, n (%)	8 (4.8%)	33 (18.6%)
Number of censored participants, n (%)	158 (95.2%)	144 (81.4%)
Proportionality Test p-value[a][b]	0.0549	
Hazard ratio(interaction)	0.399 (0.156, 1.019)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	9 (31.0%)
Locoregional recurrence, n (%)	3 (7.0%)	9 (31.0%)
Number of censored participants, n (%)	40 (93.0%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.7536	
Hazard ratio(interaction)	1.429 (0.154, 13.241)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	9 (6.8%)	22 (16.8%)
Locoregional recurrence, n (%)	9 (6.8%)	22 (16.8%)
Number of censored participants, n (%)	124 (93.2%)	109 (83.2%)
Proportionality Test p-value[a][b]	0.0182	
Hazard ratio(interaction)	0.233 (0.070, 0.781)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	2 (2.6%)	20 (26.7%)
Locoregional recurrence, n (%)	2 (2.6%)	20 (26.7%)
Number of censored participants, n (%)	74 (97.4%)	55 (73.3%)
Proportionality Test p-value[a][b]	0.1546	
Hazard ratio(interaction)	3.248 (0.641, 16.446)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	7 (5.6%)	18 (15.4%)
Locoregional recurrence, n (%)	7 (5.6%)	18 (15.4%)
Number of censored participants, n (%)	118 (94.4%)	99 (84.6%)
Proportionality Test p-value[a][b]	0.3187	
Hazard ratio(interaction)	0.586 (0.205, 1.676)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.8.1 Test of Proportional Hazards Assumption for Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

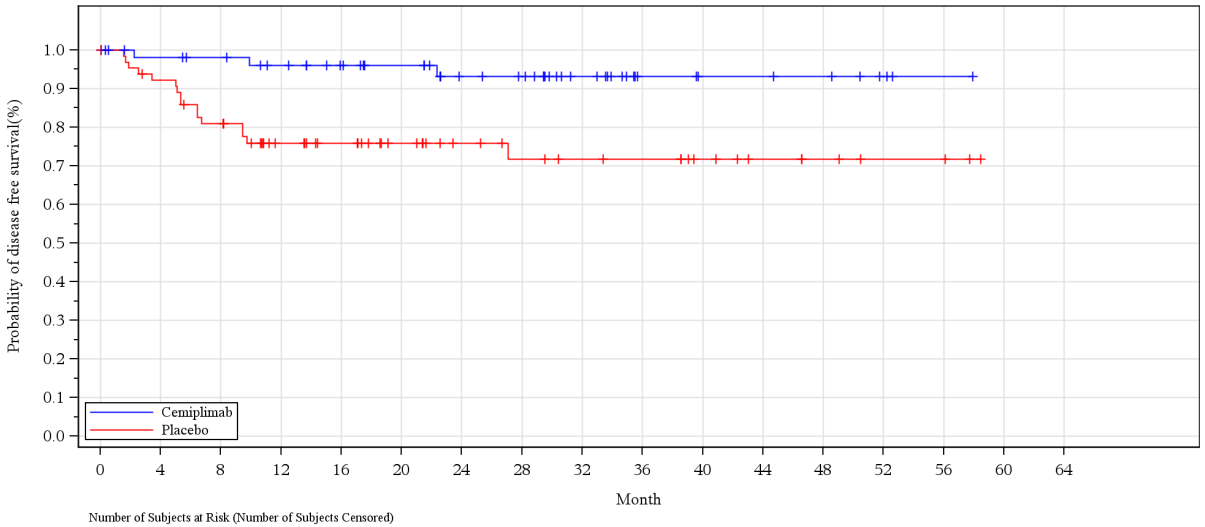
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	4 (4.8%)	24 (27.0%)
Locoregional recurrence, n (%)	4 (4.8%)	24 (27.0%)
Number of censored participants, n (%)	80 (95.2%)	65 (73.0%)
Proportionality Test p-value[a][b]	0.1775	
Hazard ratio(interaction)	0.395 (0.103, 1.523)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65



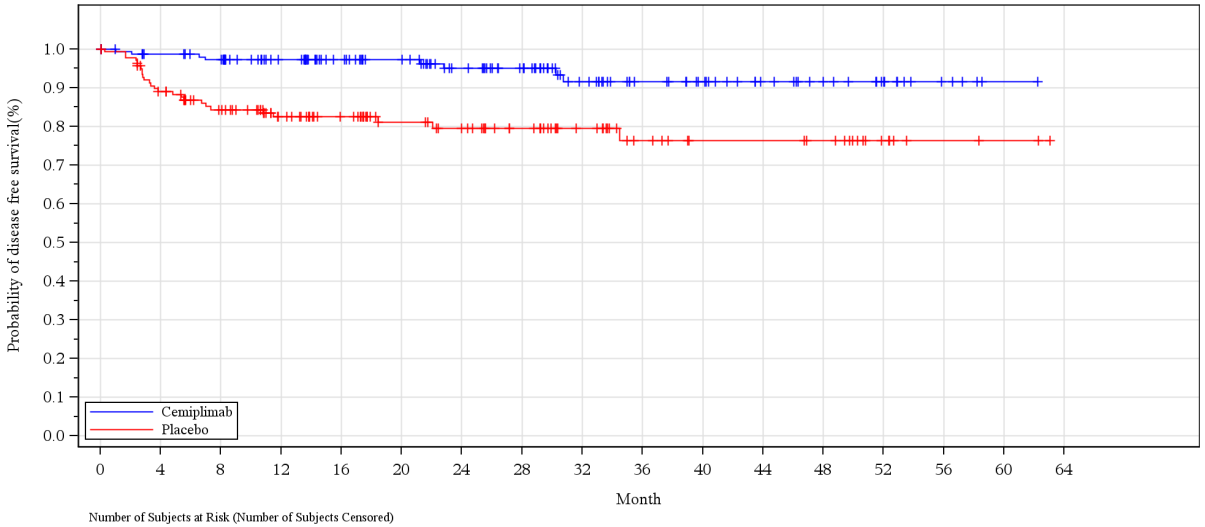
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	51 (4)	49 (6)	45 (9)	40 (14)	36 (18)	29 (24)	27 (26)	18 (35)	9 (44)	7 (46)	7 (46)	6 (47)	3 (50)	1 (52)	0 (53)	0 (53)
Placebo	65 (0)	58 (2)	50 (3)	38 (12)	33 (17)	26 (24)	20 (30)	17 (32)	15 (34)	14 (35)	10 (39)	7 (42)	5 (44)	3 (46)	3 (46)	0 (49)	0 (49)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65



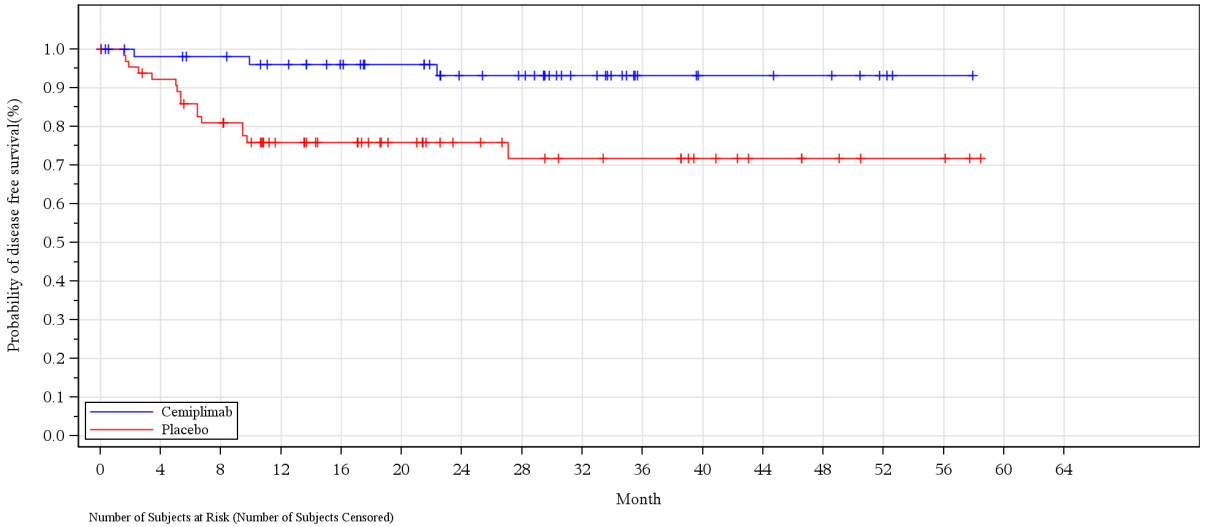
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	144 (7)	139 (10)	119 (30)	102 (47)	93 (56)	78 (69)	68 (79)	50 (95)	38 (107)	32 (113)	23 (122)	18 (128)	12 (133)	5 (140)	1 (144)	0 (145)
Placebo	141 (0)	120 (6)	103 (17)	83 (35)	71 (47)	57 (60)	51 (65)	42 (74)	32 (84)	22 (93)	17 (98)	17 (98)	15 (100)	7 (108)	3 (112)	2 (113)	0 (115)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65



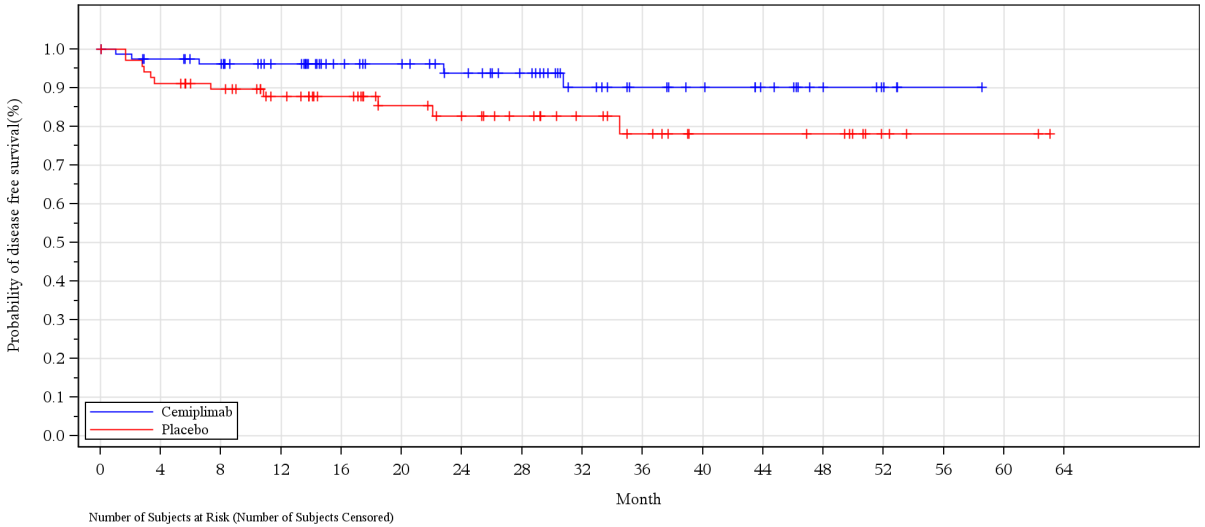
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	51 (4)	49 (6)	45 (9)	40 (14)	36 (18)	29 (24)	27 (26)	18 (35)	9 (44)	7 (46)	7 (46)	6 (47)	3 (50)	1 (52)	0 (53)	0 (53)
Placebo	65 (0)	58 (2)	50 (3)	38 (12)	33 (17)	26 (24)	20 (30)	17 (32)	15 (34)	14 (35)	10 (39)	7 (42)	5 (44)	3 (46)	3 (46)	0 (49)	0 (49)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



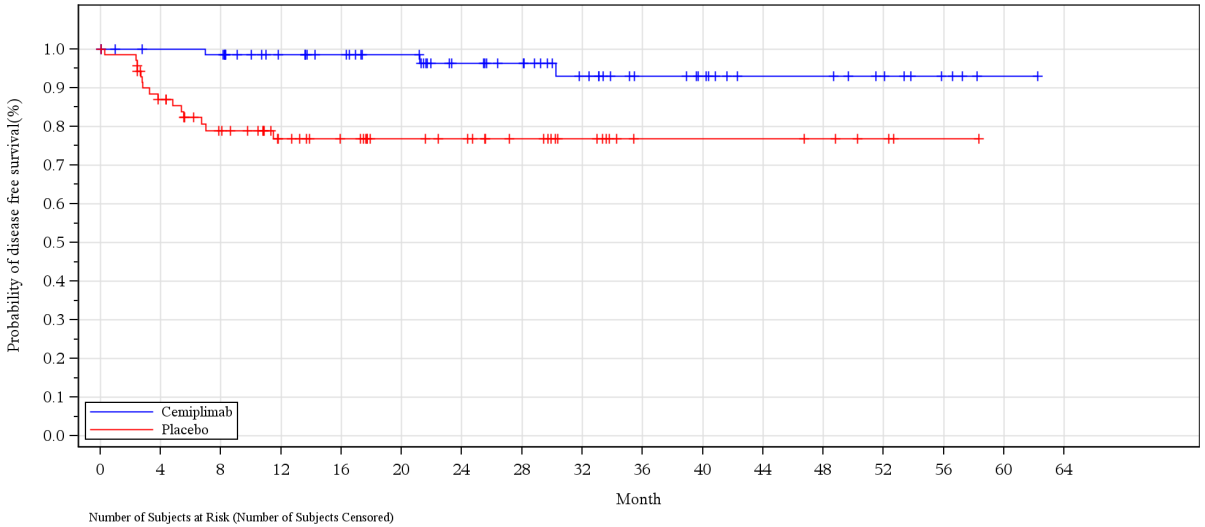
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	75 (3)	71 (6)	62 (15)	50 (27)	46 (31)	40 (36)	34 (42)	24 (51)	19 (56)	16 (59)	12 (63)	7 (69)	4 (71)	1 (74)	0 (75)	0 (75)
Placebo	69 (0)	62 (1)	57 (5)	48 (13)	41 (20)	33 (27)	29 (30)	25 (34)	20 (39)	16 (42)	11 (47)	11 (47)	10 (48)	4 (54)	2 (56)	2 (56)	0 (58)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75



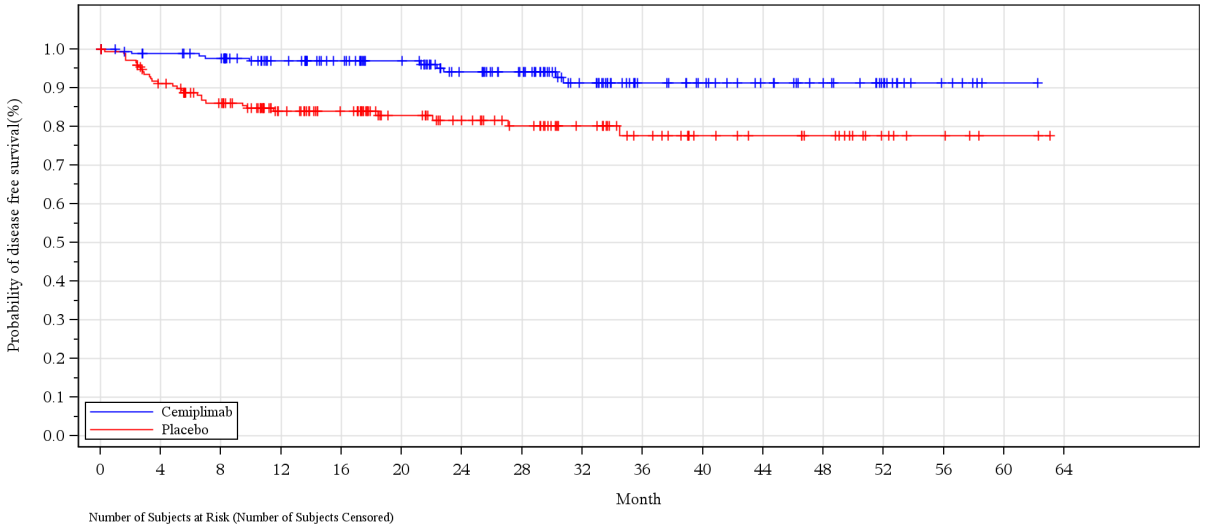
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	69 (4)	68 (4)	57 (15)	52 (20)	47 (25)	38 (33)	34 (37)	26 (44)	19 (51)	16 (54)	11 (59)	11 (59)	8 (62)	4 (66)	1 (69)	0 (70)
Placebo	72 (0)	58 (5)	46 (12)	35 (22)	30 (27)	24 (33)	22 (35)	17 (40)	12 (45)	6 (51)	6 (51)	6 (51)	5 (52)	3 (54)	1 (56)	0 (57)	0 (57)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male



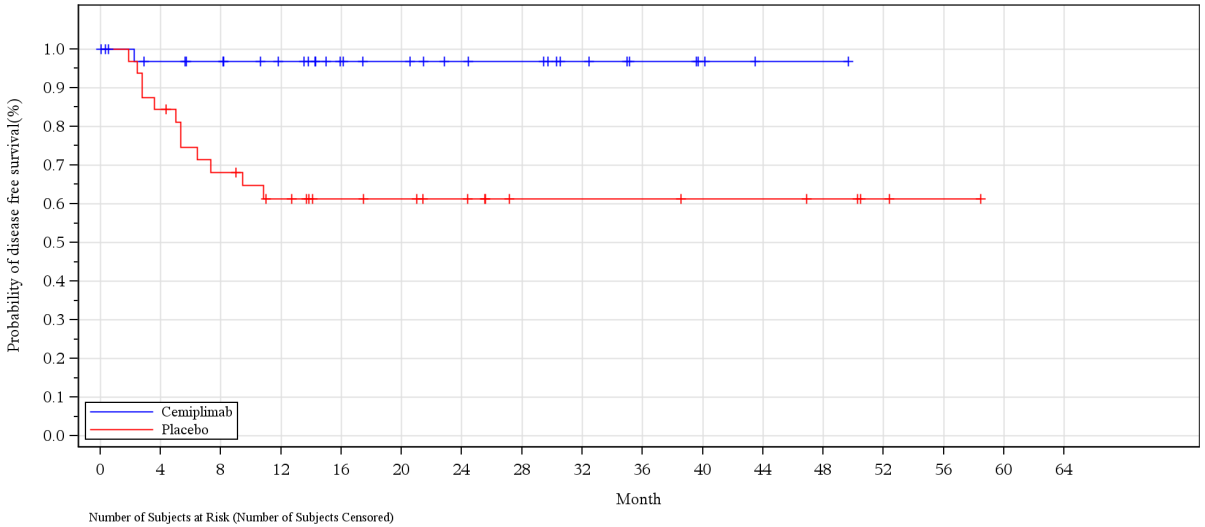
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	165 (7)	160 (10)	140 (29)	124 (45)	113 (56)	94 (72)	83 (83)	60 (104)	42 (122)	36 (128)	29 (135)	23 (142)	15 (149)	6 (158)	1 (163)	0 (164)
Placebo	174 (0)	151 (8)	132 (19)	104 (44)	91 (57)	71 (76)	61 (85)	53 (92)	41 (104)	30 (114)	22 (122)	19 (125)	16 (128)	8 (136)	5 (139)	2 (142)	0 (144)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female



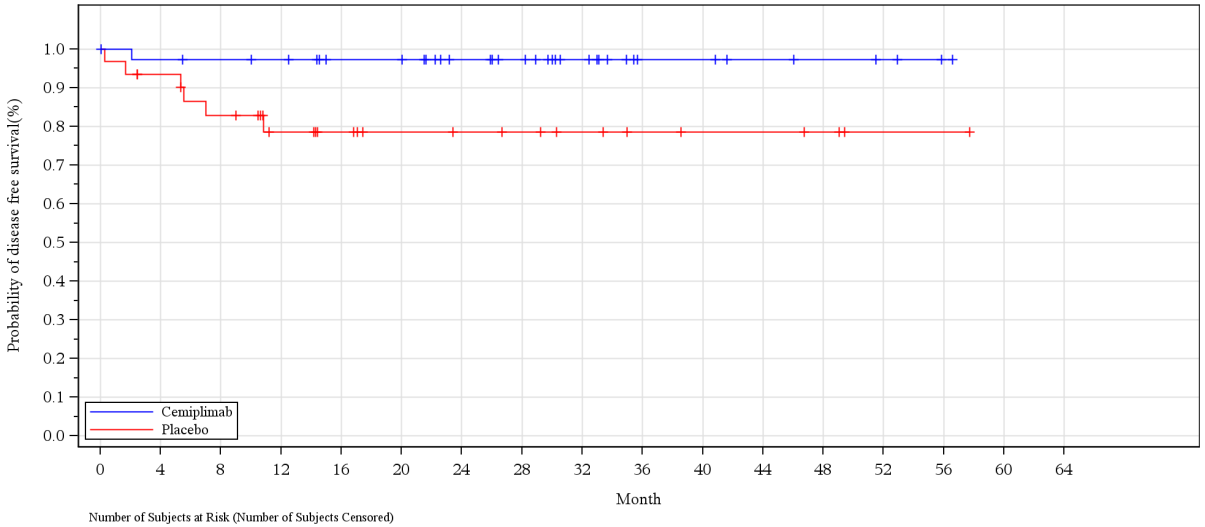
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	30 (4)	28 (6)	24 (10)	18 (16)	16 (18)	13 (21)	12 (22)	8 (26)	5 (29)	3 (31)	1 (33)	1 (33)	0 (34)	0 (34)	0 (34)	0 (34)
Placebo	32 (0)	27 (0)	21 (1)	17 (3)	13 (7)	12 (8)	10 (10)	6 (14)	6 (14)	6 (14)	5 (15)	5 (15)	4 (16)	2 (18)	1 (19)	0 (20)	0 (20)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



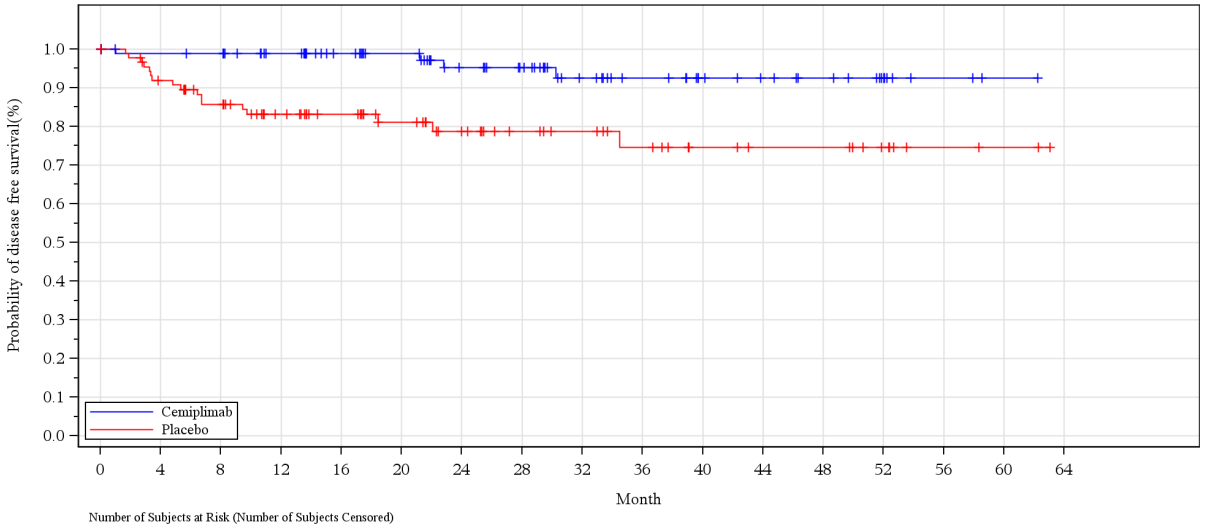
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	35 (1)	34 (2)	33 (3)	29 (7)	29 (7)	23 (13)	20 (16)	14 (22)	7 (29)	7 (29)	5 (31)	4 (32)	3 (33)	1 (35)	0 (36)	0 (36)
Placebo	31 (0)	27 (2)	23 (3)	17 (8)	14 (11)	11 (14)	10 (15)	9 (16)	7 (18)	5 (20)	4 (21)	4 (21)	3 (22)	1 (24)	1 (24)	0 (25)	0 (25)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



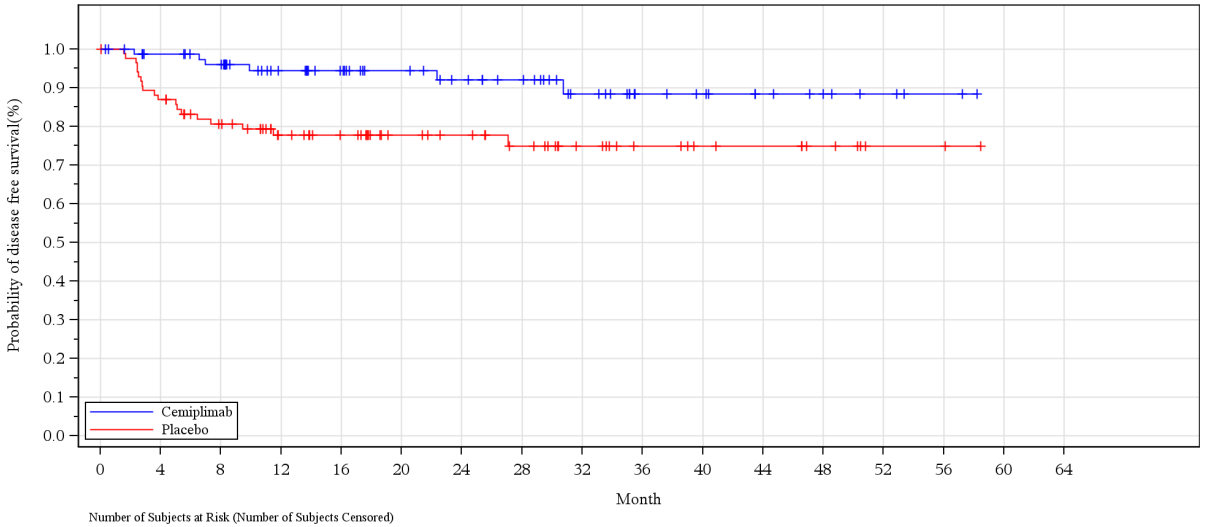
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	85 (4)	84 (5)	76 (13)	65 (24)	59 (30)	48 (39)	43 (44)	31 (55)	25 (61)	19 (67)	16 (70)	13 (73)	8 (78)	3 (83)	1 (85)	0 (86)
Placebo	90 (0)	78 (5)	68 (10)	55 (21)	47 (29)	39 (36)	31 (43)	25 (49)	22 (52)	18 (55)	13 (60)	11 (62)	11 (62)	7 (66)	3 (70)	2 (71)	0 (73)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



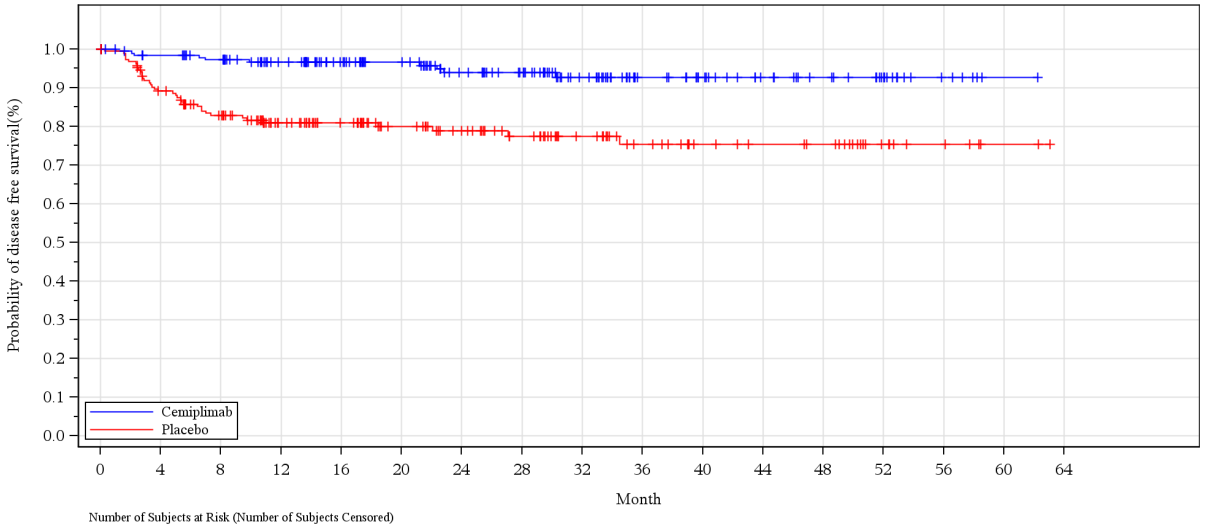
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	75 (6)	70 (9)	55 (23)	48 (30)	41 (37)	36 (41)	32 (45)	23 (53)	15 (61)	13 (63)	9 (67)	7 (70)	4 (72)	2 (74)	0 (76)	0 (76)
Placebo	85 (0)	73 (1)	62 (7)	49 (18)	43 (24)	33 (34)	30 (37)	25 (41)	18 (48)	13 (53)	10 (56)	9 (57)	6 (60)	2 (64)	2 (64)	0 (66)	0 (66)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: White



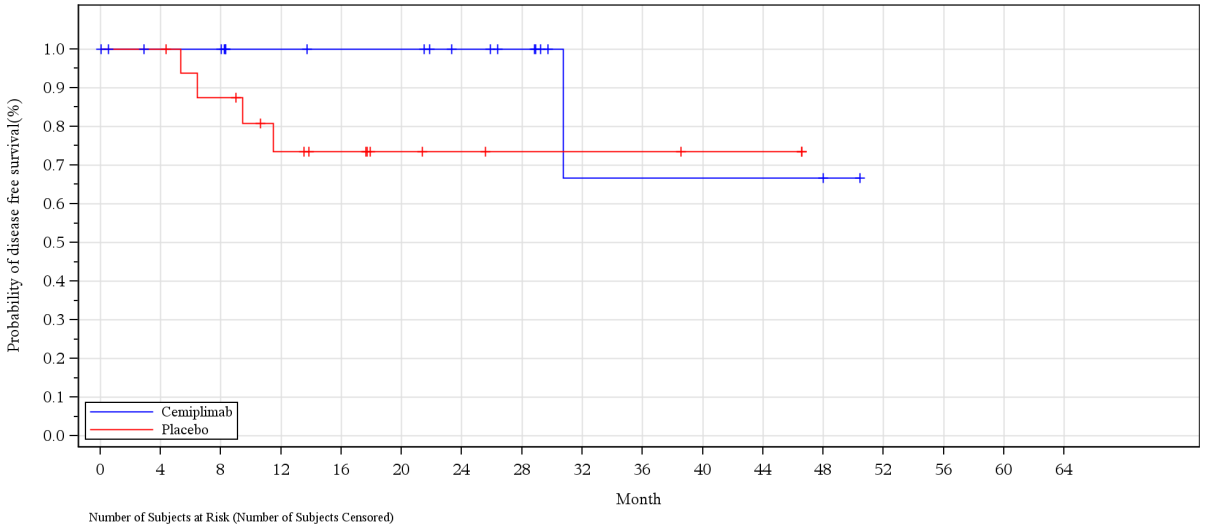
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	178 (8)	171 (13)	151 (32)	130 (53)	117 (66)	98 (82)	88 (92)	66 (113)	45 (134)	37 (142)	28 (151)	22 (157)	15 (164)	6 (173)	1 (178)	0 (179)
Placebo	189 (0)	161 (8)	139 (19)	111 (44)	96 (59)	78 (76)	67 (86)	56 (96)	44 (108)	33 (118)	25 (126)	22 (129)	20 (131)	10 (141)	6 (145)	2 (149)	0 (151)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white



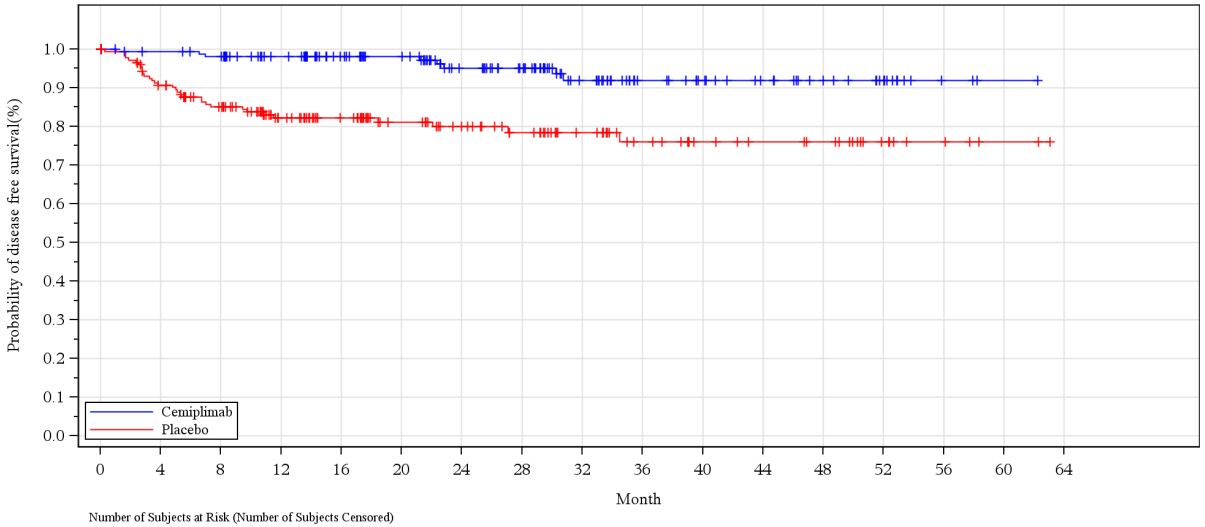
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	17 (3)	17 (3)	13 (7)	12 (8)	12 (8)	9 (11)	7 (13)	2 (17)	2 (17)	2 (17)	2 (17)	2 (18)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	17 (0)	17 (0)	14 (1)	10 (3)	8 (5)	5 (8)	4 (9)	3 (10)	3 (10)	3 (10)	2 (11)	2 (11)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



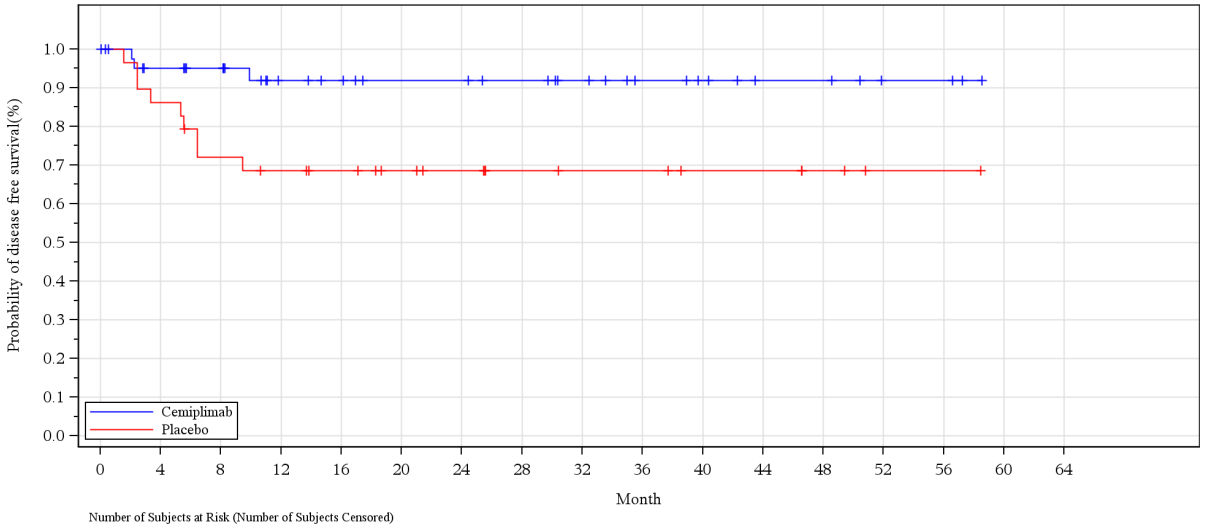
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	159 (6)	155 (8)	139 (24)	119 (44)	109 (54)	87 (73)	77 (83)	53 (105)	36 (122)	30 (128)	24 (134)	18 (141)	12 (146)	3 (155)	1 (157)	0 (158)
Placebo	177 (0)	153 (8)	133 (19)	103 (45)	88 (60)	70 (77)	60 (86)	51 (94)	40 (105)	29 (115)	22 (122)	19 (125)	17 (127)	9 (135)	5 (139)	2 (142)	0 (144)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



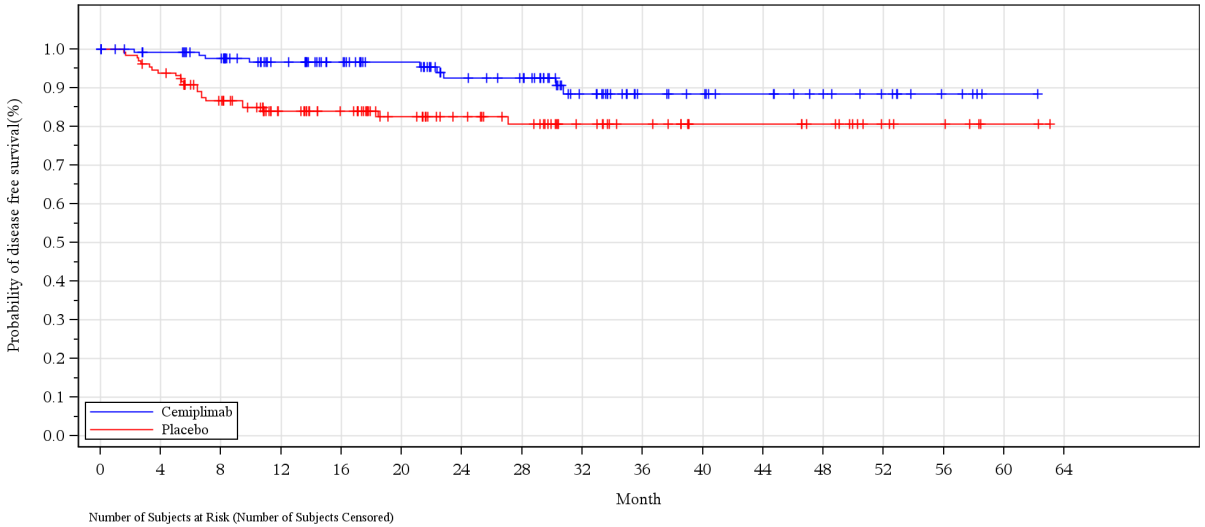
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	36 (5)	33 (8)	25 (15)	23 (17)	20 (20)	20 (20)	18 (22)	15 (25)	11 (29)	9 (31)	6 (34)	6 (34)	3 (37)	3 (37)	0 (40)	0 (40)
Placebo	29 (0)	25 (0)	20 (1)	18 (2)	16 (4)	13 (7)	11 (9)	8 (12)	7 (13)	7 (13)	5 (15)	5 (15)	3 (17)	1 (19)	1 (19)	0 (20)	0 (20)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0



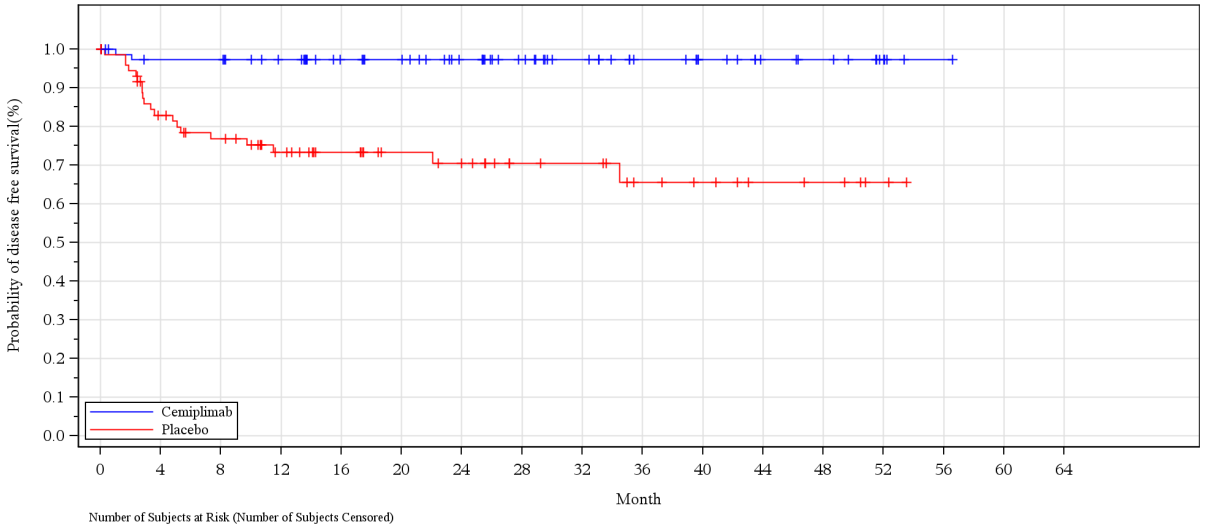
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	125 (7)	118 (12)	100 (29)	87 (42)	77 (52)	63 (63)	59 (67)	39 (85)	25 (99)	22 (102)	18 (106)	14 (111)	10 (114)	5 (119)	1 (123)	0 (124)
Placebo	131 (0)	122 (1)	104 (10)	82 (29)	72 (39)	57 (53)	48 (62)	42 (67)	31 (78)	25 (84)	18 (91)	18 (91)	15 (94)	8 (101)	6 (103)	2 (107)	0 (109)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1



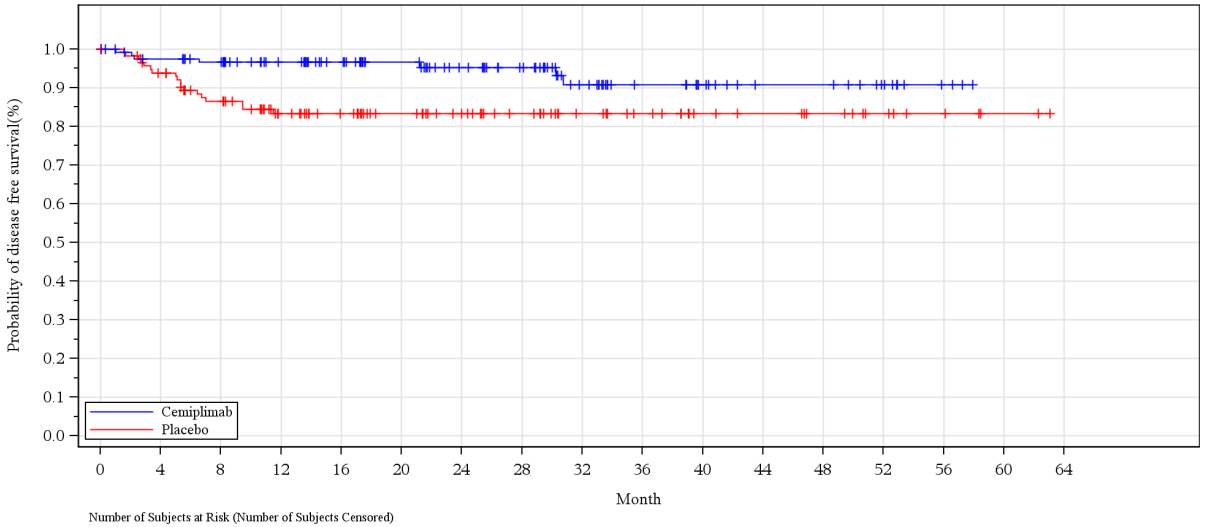
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	70 (4)	70 (4)	64 (10)	55 (19)	52 (22)	44 (30)	36 (38)	29 (45)	22 (52)	17 (57)	12 (62)	10 (64)	5 (69)	1 (73)	0 (74)	0 (74)
Placebo	75 (0)	56 (7)	49 (10)	39 (18)	32 (25)	26 (31)	23 (33)	17 (39)	16 (40)	11 (44)	9 (46)	6 (49)	5 (50)	2 (53)	0 (55)	0 (55)	0 (55)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal



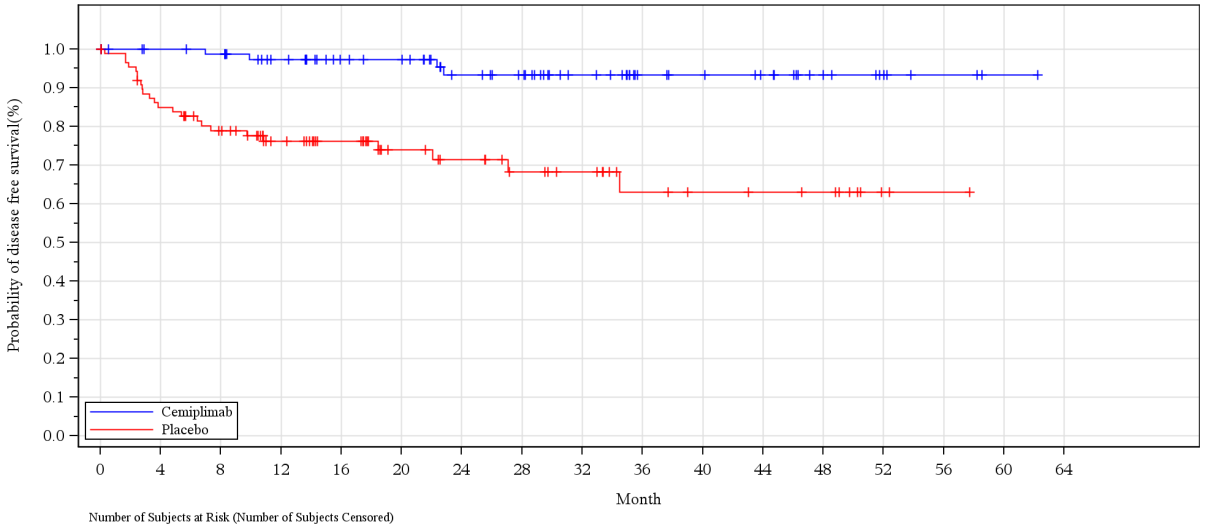
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	116 (6)	111 (10)	96 (25)	84 (37)	73 (48)	62 (58)	54 (66)	37 (81)	26 (92)	20 (98)	14 (104)	14 (104)	9 (109)	3 (115)	0 (118)	0 (118)
Placebo	117 (0)	105 (5)	90 (12)	72 (27)	63 (36)	53 (46)	45 (54)	38 (61)	29 (70)	24 (75)	17 (82)	15 (84)	12 (87)	8 (91)	5 (94)	2 (97)	0 (99)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

Figure 14.2.2.2.1 Kaplan-Meier Curve of Freedom from Locoregional Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	79 (5)	77 (6)	68 (14)	58 (24)	56 (26)	45 (35)	41 (39)	31 (49)	21 (59)	19 (61)	16 (64)	10 (71)	6 (74)	3 (77)	1 (79)	0 (80)
Placebo	89 (0)	73 (3)	63 (8)	49 (20)	41 (28)	30 (38)	26 (41)	21 (45)	18 (48)	12 (53)	10 (55)	9 (56)	8 (57)	2 (63)	1 (64)	0 (65)	0 (65)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-fflrr-sub.sas' (wenju.shi 04DEC2025 7:21 SAS Linux 9.4)

2.4 Freiheit von Fernrezidiven

2.4.1 1. Datenschnitt

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	10 (15.4%)
Odds ratio (95% CI)	0.422 (0.123, 1.442)	
P-value for Odds Ratio	0.1688	
Relative Risk (95% CI)	0.46 (0.15, 1.39)	
P-value for Relative Risk	0.1698	
Heterogeneity p-value of RR	0.6784	
Risk difference (95% CI)	-8.72 (-22.00, 4.57)	
P-value for Risk Difference	0.1983	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	6 (3.9%)	16 (11.3%)
Odds ratio (95% CI)	0.318 (0.119, 0.846)	
P-value for Odds Ratio	0.0217	
Relative Risk (95% CI)	0.34 (0.14, 0.85)	
P-value for Relative Risk	0.0213	
Heterogeneity p-value of RR	0.6784	
Risk difference (95% CI)	-7.65 (-13.93, -1.36)	
P-value for Risk Difference	0.0171	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	10 (15.4%)
Odds ratio (95% CI)	0.422 (0.123, 1.442)	
P-value for Odds Ratio	0.1688	
Relative Risk (95% CI)	0.46 (0.15, 1.39)	
P-value for Relative Risk	0.1698	
Heterogeneity p-value of RR	0.8625	
Risk difference (95% CI)	-8.72 (-22.00, 4.57)	
P-value for Risk Difference	0.1983	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	3 (3.8%)	9 (13.0%)
Odds ratio (95% CI)	0.260 (0.066, 1.021)	
P-value for Odds Ratio	0.0536	
Relative Risk (95% CI)	0.29 (0.08, 1.02)	
P-value for Relative Risk	0.0538	
Heterogeneity p-value of RR	0.8625	
Risk difference (95% CI)	-9.02 (-19.29, 1.25)	
P-value for Risk Difference	0.0851	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	7 (9.7%)
Odds ratio (95% CI)	0.365 (0.088, 1.526)	
P-value for Odds Ratio	0.1674	
Relative Risk (95% CI)	0.70 (0.70, 0.70)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.8625	
Risk difference (95% CI)	-7.81 (-18.08, 2.46)	
P-value for Risk Difference	0.1361	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	8 (4.6%)	22 (12.6%)
Odds ratio (95% CI)	0.333 (0.143, 0.774)	
P-value for Odds Ratio	0.0106	
Relative Risk (95% CI)	0.36 (0.17, 0.79)	
P-value for Relative Risk	0.0109	
Heterogeneity p-value of RR	0.8026	
Risk difference (95% CI)	-7.09 (-13.38, -0.81)	
P-value for Risk Difference	0.0269	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	4 (12.5%)
Odds ratio (95% CI)	0.331 (0.048, 2.276)	
P-value for Odds Ratio	0.2612	
Relative Risk (95% CI)	0.39 (0.07, 2.08)	
P-value for Relative Risk	0.2721	
Heterogeneity p-value of RR	0.8026	
Risk difference (95% CI)	-5.44 (-32.88, 22.00)	
P-value for Risk Difference	0.6976	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Odds ratio (95% CI)	0.124 (0.014, 1.099)	
P-value for Odds Ratio	0.0608	
Relative Risk (95% CI)	0.15 (0.02, 1.18)	
P-value for Relative Risk	0.0716	
Heterogeneity p-value of RR	0.2671	
Risk difference (95% CI)	-15.04 (-33.49, 3.41)	
P-value for Risk Difference	0.1101	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	13 (14.4%)
Odds ratio (95% CI)	0.275 (0.086, 0.880)	
P-value for Odds Ratio	0.0296	
Relative Risk (95% CI)	0.31 (0.10, 0.91)	
P-value for Relative Risk	0.0327	
Heterogeneity p-value of RR	0.2671	
Risk difference (95% CI)	-10.22 (-18.64, -1.80)	
P-value for Risk Difference	0.0173	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(wenju.shi 22AUG2025 07:22 SAS Linux 9.4)

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	5 (6.1%)	7 (8.2%)
Odds ratio (95% CI)	0.724 (0.219, 2.396)	
P-value for Odds Ratio	0.5967	
Relative Risk (95% CI)	0.74 (0.24, 2.25)	
P-value for Relative Risk	0.5969	
Heterogeneity p-value of RR	0.2671	
Risk difference (95% CI)	-2.19 (-10.27, 5.88)	
P-value for Risk Difference	0.5950	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	9 (4.8%)	23 (12.2%)
Odds ratio (95% CI)	0.359 (0.161, 0.804)	
P-value for Odds Ratio	0.0128	
Relative Risk (95% CI)	0.39 (0.18, 0.82)	
P-value for Relative Risk	0.0131	
Heterogeneity p-value of RR	0.6680	
Risk difference (95% CI)	-7.43 (-13.24, -1.62)	
P-value for Risk Difference	0.0122	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	3 (17.6%)
Odds ratio (95% CI)	0.214 (0.018, 2.492)	
P-value for Odds Ratio	0.2183	
Relative Risk (95% CI)	0.25 (0.03, 2.20)	
P-value for Relative Risk	0.2125	
Heterogeneity p-value of RR	0.6680	
Risk difference (95% CI)	-13.35 (-47.25, 20.54)	
P-value for Risk Difference	0.4401	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	7 (4.2%)	24 (13.6%)
Odds ratio (95% CI)	0.274 (0.115, 0.657)	
P-value for Odds Ratio	0.0037	
Relative Risk (95% CI)	0.30 (0.13, 0.69)	
P-value for Relative Risk	0.0041	
Heterogeneity p-value of RR	0.2203	
Risk difference (95% CI)	-9.12 (-15.16, -3.09)	
P-value for Risk Difference	0.0031	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(wenju.shi 22AUG2025 07:22 SAS Linux 9.4)

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	2 (6.9%)
Odds ratio (95% CI)	1.069 (0.166, 6.884)	
P-value for Odds Ratio	0.9442	
Relative Risk (95% CI)	1.06 (0.19, 5.91)	
P-value for Relative Risk	0.9479	
Heterogeneity p-value of RR	0.2203	
Risk difference (95% CI)	0.49 (-15.85, 16.82)	
P-value for Risk Difference	0.9532	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	4 (3.0%)	13 (9.9%)
Odds ratio (95% CI)	0.264 (0.083, 0.844)	
P-value for Odds Ratio	0.0246	
Relative Risk (95% CI)	0.29 (0.10, 0.86)	
P-value for Relative Risk	0.0259	
Heterogeneity p-value of RR	0.5881	
Risk difference (95% CI)	-6.72 (-14.46, 1.01)	
P-value for Risk Difference	0.0886	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	6 (7.9%)	13 (17.3%)
Odds ratio (95% CI)	0.413 (0.146, 1.166)	
P-value for Odds Ratio	0.0950	
Relative Risk (95% CI)	0.46 (0.18, 1.13)	
P-value for Relative Risk	0.0893	
Heterogeneity p-value of RR	0.5881	
Risk difference (95% CI)	-7.48 (-18.71, 3.76)	
P-value for Risk Difference	0.1921	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	8 (6.4%)	19 (16.2%)
Odds ratio (95% CI)	0.348 (0.145, 0.837)	
P-value for Odds Ratio	0.0183	
Relative Risk (95% CI)	0.39 (0.18, 0.86)	
P-value for Relative Risk	0.0189	
Heterogeneity p-value of RR	0.7485	
Risk difference (95% CI)	-9.97 (-18.05, -1.89)	
P-value for Risk Difference	0.0156	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	2 (2.4%)	7 (7.9%)
Odds ratio (95% CI)	0.294 (0.059, 1.465)	
P-value for Odds Ratio	0.1352	
Relative Risk (95% CI)	0.31 (0.07, 1.46)	
P-value for Relative Risk	0.1390	
Heterogeneity p-value of RR	0.7485	
Risk difference (95% CI)	-4.82 (-18.24, 8.59)	
P-value for Risk Difference	0.4810	

Data cut-off as of October 4, 2024.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	10 (15.4%)
Distant recurrence, n (%)	4 (7.1%)	10 (15.4%)
Number of censored participants, n (%)	52 (92.9%)	55 (84.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0849	
HR (95% CI) [c][d]	0.361 (0.108, 1.203)	
Heterogeneity p-value [c][e]	0.7058	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.2 (85.6, 99.0)	95.2 (85.7, 98.4)
6 months	94.1 (82.9, 98.1)	91.7 (81.1, 96.5)
12 months	94.1 (82.9, 98.1)	80.1 (65.7, 88.9)
18 months	94.1 (82.9, 98.1)	80.1 (65.7, 88.9)
24 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
30 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
36 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
42 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
48 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	6 (3.9%)	16 (11.3%)
Distant recurrence, n (%)	6 (3.9%)	16 (11.3%)
Number of censored participants, n (%)	147 (96.1%)	125 (88.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (27.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0095	
HR (95% CI) [c][d]	0.304 (0.118, 0.786)	
Heterogeneity p-value [c][e]	0.7058	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (94.5, 99.6)	97.7 (93.0, 99.2)
6 months	97.0 (92.3, 98.9)	93.3 (87.0, 96.6)
12 months	97.0 (92.3, 98.9)	89.0 (81.3, 93.6)
18 months	95.8 (90.0, 98.3)	87.5 (79.2, 92.7)
24 months	95.8 (90.0, 98.3)	85.7 (76.4, 91.5)
30 months	95.8 (90.0, 98.3)	83.1 (72.2, 90.0)
36 months	95.8 (90.0, 98.3)	83.1 (72.2, 90.0)
42 months	92.0 (78.5, 97.2)	83.1 (72.2, 90.0)
48 months	92.0 (78.5, 97.2)	83.1 (72.2, 90.0)
54 months	92.0 (78.5, 97.2)	71.2 (41.8, 87.6)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	10 (15.4%)
Distant recurrence, n (%)	4 (7.1%)	10 (15.4%)
Number of censored participants, n (%)	52 (92.9%)	55 (84.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0849	
HR (95% CI) [c][d]	0.361 (0.108, 1.203)	
Heterogeneity p-value [c][e]	0.9271	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.2 (85.6, 99.0)	95.2 (85.7, 98.4)
6 months	94.1 (82.9, 98.1)	91.7 (81.1, 96.5)
12 months	94.1 (82.9, 98.1)	80.1 (65.7, 88.9)
18 months	94.1 (82.9, 98.1)	80.1 (65.7, 88.9)
24 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
30 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
36 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
42 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
48 months	90.5 (75.6, 96.5)	80.1 (65.7, 88.9)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	3 (3.8%)	9 (13.0%)
Distant recurrence, n (%)	3 (3.8%)	9 (13.0%)
Number of censored participants, n (%)	77 (96.3%)	60 (87.0%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	48.5 (21.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0493	
HR (95% CI) [c][d]	0.278 (0.072, 1.078)	
Heterogeneity p-value [c][e]	0.9271	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.1, 99.8)	98.5 (89.7, 99.8)
6 months	97.2 (89.3, 99.3)	95.1 (85.6, 98.4)
12 months	97.2 (89.3, 99.3)	89.1 (77.1, 95.0)
18 months	97.2 (89.3, 99.3)	89.1 (77.1, 95.0)
24 months	97.2 (89.3, 99.3)	86.0 (72.2, 93.3)
30 months	97.2 (89.3, 99.3)	82.1 (65.9, 91.1)
36 months	97.2 (89.3, 99.3)	82.1 (65.9, 91.1)
42 months	90.7 (66.1, 97.7)	82.1 (65.9, 91.1)
48 months	90.7 (66.1, 97.7)	82.1 (65.9, 91.1)
54 months	NE (NE, NE)	65.7 (28.3, 86.9)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	7 (9.7%)
Distant recurrence, n (%)	3 (4.1%)	7 (9.7%)
Number of censored participants, n (%)	70 (95.9%)	65 (90.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (17.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0612	
HR (95% CI) [c][d]	0.245 (0.050, 1.198)	
Heterogeneity p-value [c][e]	0.9271	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.5 (89.9, 99.8)	96.8 (87.8, 99.2)
6 months	96.8 (87.8, 99.2)	91.2 (80.1, 96.3)
12 months	96.8 (87.8, 99.2)	89.0 (77.0, 94.9)
18 months	94.3 (82.9, 98.2)	85.4 (70.8, 93.1)
24 months	94.3 (82.9, 98.2)	85.4 (70.8, 93.1)
30 months	94.3 (82.9, 98.2)	85.4 (70.8, 93.1)
36 months	94.3 (82.9, 98.2)	85.4 (70.8, 93.1)
42 months	94.3 (82.9, 98.2)	85.4 (70.8, 93.1)
48 months	94.3 (82.9, 98.2)	85.4 (70.8, 93.1)
54 months	94.3 (82.9, 98.2)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	8 (4.6%)	22 (12.6%)
Distant recurrence, n (%)	8 (4.6%)	22 (12.6%)
Number of censored participants, n (%)	166 (95.4%)	152 (87.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (21.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0021	
HR (95% CI) [c][d]	0.298 (0.131, 0.675)	
Heterogeneity p-value [c][e]	0.3911	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (94.5, 99.4)	96.2 (91.8, 98.3)
6 months	96.9 (92.6, 98.7)	92.8 (87.3, 95.9)
12 months	96.9 (92.6, 98.7)	85.8 (78.4, 90.7)
18 months	95.9 (90.9, 98.2)	84.6 (76.8, 89.9)
24 months	94.6 (88.7, 97.5)	83.0 (74.7, 88.8)
30 months	94.6 (88.7, 97.5)	83.0 (74.7, 88.8)
36 months	94.6 (88.7, 97.5)	83.0 (74.7, 88.8)
42 months	91.5 (80.6, 96.4)	83.0 (74.7, 88.8)
48 months	91.5 (80.6, 96.4)	83.0 (74.7, 88.8)
54 months	91.5 (80.6, 96.4)	72.6 (47.0, 87.4)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	4 (12.5%)
Distant recurrence, n (%)	2 (5.7%)	4 (12.5%)
Number of censored participants, n (%)	33 (94.3%)	28 (87.5%)
Q1 (95% CI), (months)[a]	NR (4.0, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (27.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.5900	
HR (95% CI) [c][d]	0.618 (0.106, 3.603)	
Heterogeneity p-value [c][e]	0.3911	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.8 (79.2, 99.5)	100 (100, 100)
6 months	92.9 (74.3, 98.2)	93.1 (75.1, 98.2)
12 months	92.9 (74.3, 98.2)	88.4 (67.9, 96.2)
18 months	92.9 (74.3, 98.2)	88.4 (67.9, 96.2)
24 months	92.9 (74.3, 98.2)	88.4 (67.9, 96.2)
30 months	92.9 (74.3, 98.2)	77.4 (44.1, 92.3)
36 months	92.9 (74.3, 98.2)	77.4 (44.1, 92.3)
42 months	92.9 (74.3, 98.2)	77.4 (44.1, 92.3)
48 months	NE (NE, NE)	77.4 (44.1, 92.3)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Distant recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (2.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0328	
HR (95% CI) [c][d]	0.139 (0.017, 1.156)	
Heterogeneity p-value [c][e]	0.2401	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.1 (81.4, 99.6)	89.9 (71.8, 96.6)
6 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
12 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
18 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
24 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
30 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
36 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
42 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
48 months	97.1 (81.4, 99.6)	78.5 (58.1, 89.7)
54 months	97.1 (81.4, 99.6)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	13 (14.4%)
Distant recurrence, n (%)	4 (4.4%)	13 (14.4%)
Number of censored participants, n (%)	86 (95.6%)	77 (85.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (10.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0161	
HR (95% CI) [c][d]	0.275 (0.089, 0.846)	
Heterogeneity p-value [c][e]	0.2401	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	96.4 (89.1, 98.8)
6 months	96.2 (88.8, 98.8)	95.0 (87.3, 98.1)
12 months	96.2 (88.8, 98.8)	83.0 (71.2, 90.3)
18 months	96.2 (88.8, 98.8)	80.9 (68.4, 88.8)
24 months	93.9 (83.8, 97.8)	80.9 (68.4, 88.8)
30 months	93.9 (83.8, 97.8)	80.9 (68.4, 88.8)
36 months	93.9 (83.8, 97.8)	80.9 (68.4, 88.8)
42 months	93.9 (83.8, 97.8)	80.9 (68.4, 88.8)
48 months	93.9 (83.8, 97.8)	80.9 (68.4, 88.8)
54 months	93.9 (83.8, 97.8)	64.7 (29.0, 85.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	5 (6.1%)	7 (8.2%)
Distant recurrence, n (%)	5 (6.1%)	7 (8.2%)
Number of censored participants, n (%)	77 (93.9%)	78 (91.8%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	NR (27.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.5126	
HR (95% CI) [c][d]	0.681 (0.215, 2.156)	
Heterogeneity p-value [c][e]	0.2401	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (90.2, 99.4)	100 (100, 100)
6 months	95.9 (87.7, 98.7)	95.8 (87.4, 98.6)
12 months	95.9 (87.7, 98.7)	92.3 (82.4, 96.7)
18 months	93.4 (82.5, 97.6)	92.3 (82.4, 96.7)
24 months	93.4 (82.5, 97.6)	88.8 (75.1, 95.2)
30 months	93.4 (82.5, 97.6)	83.8 (65.7, 92.9)
36 months	93.4 (82.5, 97.6)	83.8 (65.7, 92.9)
42 months	84.9 (57.4, 95.3)	83.8 (65.7, 92.9)
48 months	84.9 (57.4, 95.3)	83.8 (65.7, 92.9)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	9 (4.8%)	23 (12.2%)
Distant recurrence, n (%)	9 (4.8%)	23 (12.2%)
Number of censored participants, n (%)	180 (95.2%)	166 (87.8%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (27.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0052	
HR (95% CI) [c][d]	0.347 (0.160, 0.753)	
Heterogeneity p-value [c][e]	0.8767	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.8 (94.1, 99.2)	96.6 (92.5, 98.4)
6 months	95.9 (91.6, 98.0)	93.3 (88.3, 96.3)
12 months	95.9 (91.6, 98.0)	86.8 (80.0, 91.5)
18 months	95.9 (91.6, 98.0)	85.7 (78.5, 90.7)
24 months	94.8 (89.5, 97.4)	84.3 (76.5, 89.7)
30 months	94.8 (89.5, 97.4)	82.3 (73.5, 88.5)
36 months	94.8 (89.5, 97.4)	82.3 (73.5, 88.5)
42 months	91.6 (81.0, 96.4)	82.3 (73.5, 88.5)
48 months	91.6 (81.0, 96.4)	82.3 (73.5, 88.5)
54 months	91.6 (81.0, 96.4)	74.1 (53.0, 86.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	3 (17.6%)
Distant recurrence, n (%)	1 (5.0%)	3 (17.6%)
Number of censored participants, n (%)	19 (95.0%)	14 (82.4%)
Q1 (95% CI), (months)[a]	NR (17.5, NE)	NR (4.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.2407	
HR (95% CI) [c][d]	0.231 (0.018, 2.959)	
Heterogeneity p-value [c][e]	0.8767	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	88.2 (60.6, 96.9)
12 months	100 (100, 100)	80.2 (49.6, 93.3)
18 months	90.9 (50.8, 98.7)	80.2 (49.6, 93.3)
24 months	90.9 (50.8, 98.7)	80.2 (49.6, 93.3)
30 months	90.9 (50.8, 98.7)	80.2 (49.6, 93.3)
36 months	90.9 (50.8, 98.7)	80.2 (49.6, 93.3)
42 months	90.9 (50.8, 98.7)	NE (NE, NE)
48 months	90.9 (50.8, 98.7)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	7 (4.2%)	24 (13.6%)
Distant recurrence, n (%)	7 (4.2%)	24 (13.6%)
Number of censored participants, n (%)	159 (95.8%)	153 (86.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (21.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0009	
HR (95% CI) [c][d]	0.263 (0.113, 0.613)	
Heterogeneity p-value [c][e]	0.1731	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.1 (94.3, 99.4)	97.0 (92.9, 98.7)
6 months	97.4 (93.3, 99.0)	92.2 (86.6, 95.5)
12 months	97.4 (93.3, 99.0)	85.3 (78.0, 90.3)
18 months	96.4 (91.4, 98.5)	84.1 (76.5, 89.5)
24 months	95.0 (88.8, 97.8)	82.6 (74.4, 88.4)
30 months	95.0 (88.8, 97.8)	80.5 (71.1, 87.1)
36 months	95.0 (88.8, 97.8)	80.5 (71.1, 87.1)
42 months	91.2 (78.1, 96.6)	80.5 (71.1, 87.1)
48 months	91.2 (78.1, 96.6)	80.5 (71.1, 87.1)
54 months	91.2 (78.1, 96.6)	70.5 (45.9, 85.4)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	2 (6.9%)
Distant recurrence, n (%)	3 (7.0%)	2 (6.9%)
Number of censored participants, n (%)	40 (93.0%)	27 (93.1%)
Q1 (95% CI), (months)[a]	NR (5.6, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.7650	
HR (95% CI) [c][d]	1.313 (0.219, 7.870)	
Heterogeneity p-value [c][e]	0.1731	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.4 (82.8, 99.6)	96.4 (77.2, 99.5)
6 months	91.0 (74.4, 97.0)	96.4 (77.2, 99.5)
12 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
18 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
24 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
30 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
36 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
42 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
48 months	91.0 (74.4, 97.0)	91.1 (67.9, 97.8)
54 months	91.0 (74.4, 97.0)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	4 (3.0%)	13 (9.9%)
Distant recurrence, n (%)	4 (3.0%)	13 (9.9%)
Number of censored participants, n (%)	129 (97.0%)	118 (90.1%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	NR (NE, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0186	
HR (95% CI) [c][d]	0.282 (0.092, 0.868)	
Heterogeneity p-value [c][e]	0.6635	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.4, 99.9)	96.8 (91.6, 98.8)
6 months	97.3 (92.0, 99.1)	93.3 (87.0, 96.6)
12 months	97.3 (92.0, 99.1)	88.9 (81.1, 93.6)
18 months	97.3 (92.0, 99.1)	88.9 (81.1, 93.6)
24 months	97.3 (92.0, 99.1)	86.7 (77.4, 92.3)
30 months	97.3 (92.0, 99.1)	86.7 (77.4, 92.3)
36 months	97.3 (92.0, 99.1)	86.7 (77.4, 92.3)
42 months	92.2 (72.9, 97.9)	86.7 (77.4, 92.3)
48 months	92.2 (72.9, 97.9)	86.7 (77.4, 92.3)
54 months	92.2 (72.9, 97.9)	86.7 (77.4, 92.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	6 (7.9%)	13 (17.3%)
Distant recurrence, n (%)	6 (7.9%)	13 (17.3%)
Number of censored participants, n (%)	70 (92.1%)	62 (82.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	27.1 (9.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	48.5 (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Stratified log-rank test p-value [b][c]	0.0459	
HR (95% CI) [c][d]	0.380 (0.142, 1.019)	
Heterogeneity p-value [c][e]	0.6635	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	95.9 (87.7, 98.6)	97.0 (88.5, 99.2)
6 months	94.4 (85.8, 97.9)	91.9 (81.5, 96.5)
12 months	94.4 (85.8, 97.9)	81.1 (67.5, 89.5)
18 months	92.3 (82.2, 96.8)	78.3 (63.8, 87.6)
24 months	89.4 (77.0, 95.3)	78.3 (63.8, 87.6)
30 months	89.4 (77.0, 95.3)	74.2 (57.7, 85.1)
36 months	89.4 (77.0, 95.3)	74.2 (57.7, 85.1)
42 months	89.4 (77.0, 95.3)	74.2 (57.7, 85.1)
48 months	89.4 (77.0, 95.3)	74.2 (57.7, 85.1)
54 months	89.4 (77.0, 95.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	8 (6.4%)	19 (16.2%)
Distant recurrence, n (%)	8 (6.4%)	19 (16.2%)
Number of censored participants, n (%)	117 (93.6%)	98 (83.8%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (11.6, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0288	
HR (95% CI) [c][d]	0.407 (0.177, 0.935)	
Heterogeneity p-value [c][e]	0.5873	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.5 (91.1, 98.7)	95.5 (89.5, 98.1)
6 months	93.7 (87.2, 96.9)	89.8 (82.3, 94.2)
12 months	93.7 (87.2, 96.9)	83.3 (74.0, 89.5)
18 months	93.7 (87.2, 96.9)	81.6 (71.7, 88.3)
24 months	91.8 (83.6, 96.0)	79.5 (68.8, 86.9)
30 months	91.8 (83.6, 96.0)	79.5 (68.8, 86.9)
36 months	91.8 (83.6, 96.0)	79.5 (68.8, 86.9)
42 months	91.8 (83.6, 96.0)	79.5 (68.8, 86.9)
48 months	91.8 (83.6, 96.0)	79.5 (68.8, 86.9)
54 months	91.8 (83.6, 96.0)	68.2 (41.1, 84.8)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	2 (2.4%)	7 (7.9%)
Distant recurrence, n (%)	2 (2.4%)	7 (7.9%)
Number of censored participants, n (%)	82 (97.6%)	82 (92.1%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	NR (27.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0427	
HR (95% CI) [c][d]	0.225 (0.047, 1.089)	
Heterogeneity p-value [c][e]	0.5873	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	98.8 (91.8, 99.8)
6 months	100 (100, 100)	97.3 (89.6, 99.3)
12 months	100 (100, 100)	90.3 (79.5, 95.6)
18 months	98.0 (86.6, 99.7)	90.3 (79.5, 95.6)
24 months	98.0 (86.6, 99.7)	90.3 (79.5, 95.6)
30 months	98.0 (86.6, 99.7)	85.5 (69.1, 93.6)
36 months	98.0 (86.6, 99.7)	85.5 (69.1, 93.6)
42 months	92.6 (69.8, 98.3)	85.5 (69.1, 93.6)
48 months	92.6 (69.8, 98.3)	85.5 (69.1, 93.6)
54 months	92.6 (69.8, 98.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

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Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	10 (15.4%)
Distant recurrence, n (%)	4 (7.1%)	10 (15.4%)
Number of censored participants, n (%)	52 (92.9%)	55 (84.6%)
Proportionality Test p-value[a][b]	0.1291	
Hazard ratio(interaction)	2.285 (0.786, 6.645)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	6 (3.9%)	16 (11.3%)
Distant recurrence, n (%)	6 (3.9%)	16 (11.3%)
Number of censored participants, n (%)	147 (96.1%)	125 (88.7%)
Proportionality Test p-value[a][b]	0.5200	
Hazard ratio(interaction)	1.382 (0.516, 3.703)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	10 (15.4%)
Distant recurrence, n (%)	4 (7.1%)	10 (15.4%)
Number of censored participants, n (%)	52 (92.9%)	55 (84.6%)
Proportionality Test p-value[a][b]	0.1291	
Hazard ratio(interaction)	2.285 (0.786, 6.645)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	3 (3.8%)	9 (13.0%)
Distant recurrence, n (%)	3 (3.8%)	9 (13.0%)
Number of censored participants, n (%)	77 (96.3%)	60 (87.0%)
Proportionality Test p-value[a][b]	0.4048	
Hazard ratio(interaction)	1.767 (0.463, 6.745)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	7 (9.7%)
Distant recurrence, n (%)	3 (4.1%)	7 (9.7%)
Number of censored participants, n (%)	70 (95.9%)	65 (90.3%)
Proportionality Test p-value[a][b]	0.9694	
Hazard ratio(interaction)	1.034 (0.184, 5.816)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	8 (4.6%)	22 (12.6%)
Distant recurrence, n (%)	8 (4.6%)	22 (12.6%)
Number of censored participants, n (%)	166 (95.4%)	152 (87.4%)
Proportionality Test p-value[a][b]	0.5360	
Hazard ratio(interaction)	1.290 (0.576, 2.891)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	4 (12.5%)
Distant recurrence, n (%)	2 (5.7%)	4 (12.5%)
Number of censored participants, n (%)	33 (94.3%)	28 (87.5%)
Proportionality Test p-value[a][b]	0.9970	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Distant recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.9958	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	4 (4.4%)	13 (14.4%)
Distant recurrence, n (%)	4 (4.4%)	13 (14.4%)
Number of censored participants, n (%)	86 (95.6%)	77 (85.6%)
Proportionality Test p-value[a][b]	0.4682	
Hazard ratio(interaction)	1.662 (0.421, 6.558)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	5 (6.1%)	7 (8.2%)
Distant recurrence, n (%)	5 (6.1%)	7 (8.2%)
Number of censored participants, n (%)	77 (93.9%)	78 (91.8%)
Proportionality Test p-value[a][b]	0.3010	
Hazard ratio(interaction)	1.653 (0.638, 4.281)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	9 (4.8%)	23 (12.2%)
Distant recurrence, n (%)	9 (4.8%)	23 (12.2%)
Number of censored participants, n (%)	180 (95.2%)	166 (87.8%)
Proportionality Test p-value[a][b]	0.1533	
Hazard ratio(interaction)	1.757 (0.811, 3.809)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	3 (17.6%)
Distant recurrence, n (%)	1 (5.0%)	3 (17.6%)
Number of censored participants, n (%)	19 (95.0%)	14 (82.4%)
Proportionality Test p-value[a][b]	0.9971	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	7 (4.2%)	24 (13.6%)
Distant recurrence, n (%)	7 (4.2%)	24 (13.6%)
Number of censored participants, n (%)	159 (95.8%)	153 (86.4%)
Proportionality Test p-value[a][b]	0.4984	
Hazard ratio(interaction)	1.333 (0.580, 3.067)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	2 (6.9%)
Distant recurrence, n (%)	3 (7.0%)	2 (6.9%)
Number of censored participants, n (%)	40 (93.0%)	27 (93.1%)
Proportionality Test p-value[a][b]	0.4690	
Hazard ratio(interaction)	3.232 (0.135, 77.314)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	4 (3.0%)	13 (9.9%)
Distant recurrence, n (%)	4 (3.0%)	13 (9.9%)
Number of censored participants, n (%)	129 (97.0%)	118 (90.1%)
Proportionality Test p-value[a][b]	0.9311	
Hazard ratio(interaction)	1.054 (0.320, 3.468)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	6 (7.9%)	13 (17.3%)
Distant recurrence, n (%)	6 (7.9%)	13 (17.3%)
Number of censored participants, n (%)	70 (92.1%)	62 (82.7%)
Proportionality Test p-value[a][b]	0.1195	
Hazard ratio(interaction)	2.198 (0.816, 5.921)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	8 (6.4%)	19 (16.2%)
Distant recurrence, n (%)	8 (6.4%)	19 (16.2%)
Number of censored participants, n (%)	117 (93.6%)	98 (83.8%)
Proportionality Test p-value[a][b]	0.0784	
Hazard ratio(interaction)	2.429 (0.904, 6.524)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

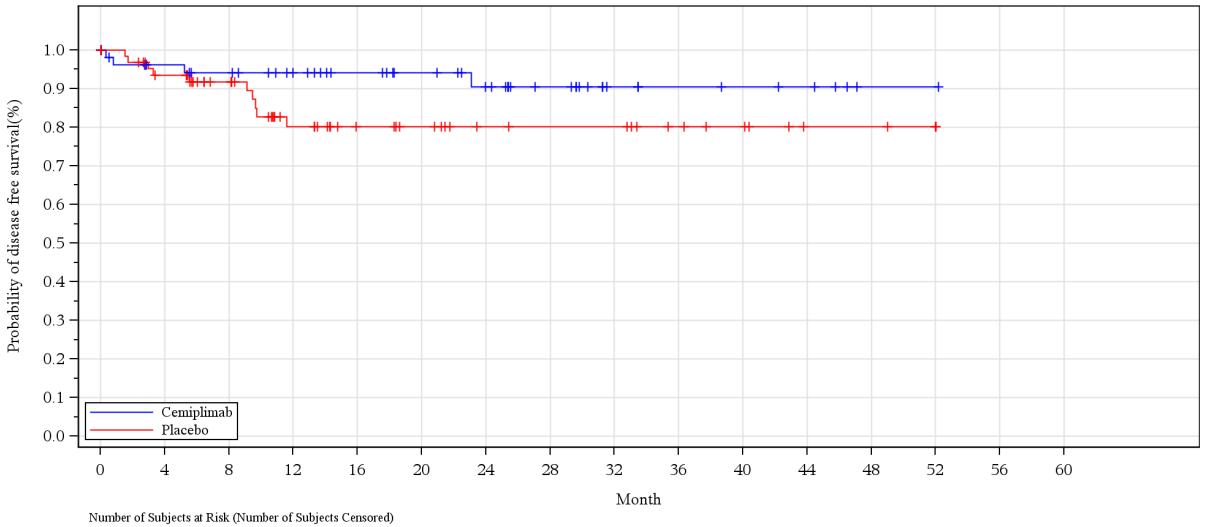
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	2 (2.4%)	7 (7.9%)
Distant recurrence, n (%)	2 (2.4%)	7 (7.9%)
Number of censored participants, n (%)	82 (97.6%)	82 (92.1%)
Proportionality Test p-value[a][b]	0.1586	
Hazard ratio(interaction)	0.046 (0.001, 3.335)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	47 (7)	44 (9)	38 (15)	33 (20)	29 (24)	24 (28)	17 (35)	9 (43)	7 (45)	6 (46)	5 (47)	1 (51)	1 (51)	0 (52)	0 (52)
Placebo	65 (0)	55 (6)	44 (16)	30 (25)	22 (33)	19 (36)	14 (41)	13 (42)	13 (42)	9 (46)	7 (48)	3 (52)	3 (52)	1 (54)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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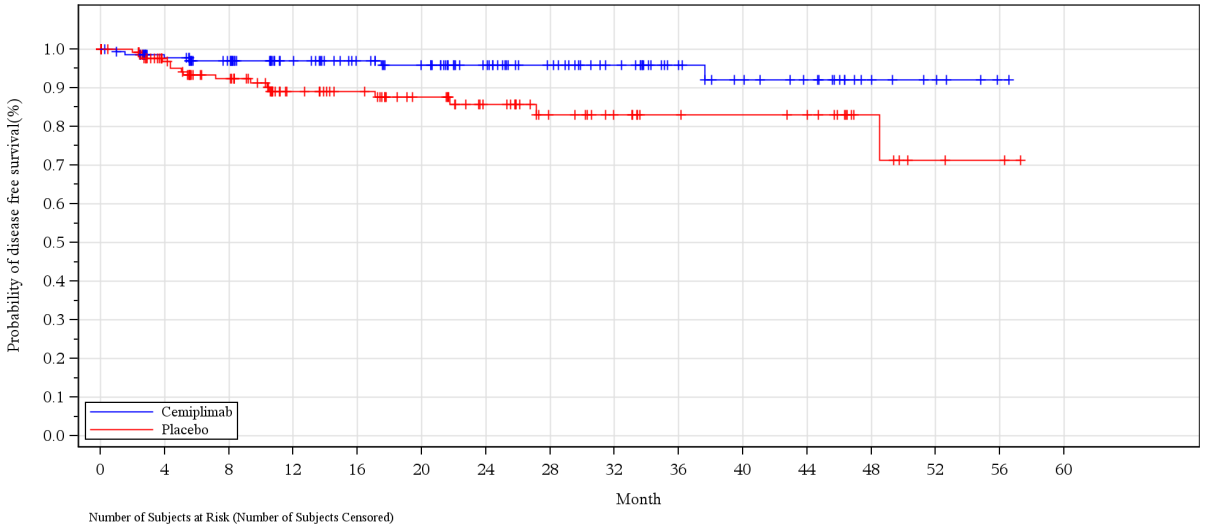
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	126 (24)	114 (35)	95 (54)	83 (66)	75 (73)	61 (87)	49 (99)	39 (109)	26 (122)	21 (126)	17 (130)	8 (140)	5 (142)	1 (146)	0 (147)
Placebo	141 (0)	111 (26)	93 (39)	69 (60)	62 (67)	51 (77)	40 (87)	29 (97)	23 (103)	18 (108)	17 (109)	15 (111)	7 (119)	3 (122)	2 (123)	0 (125)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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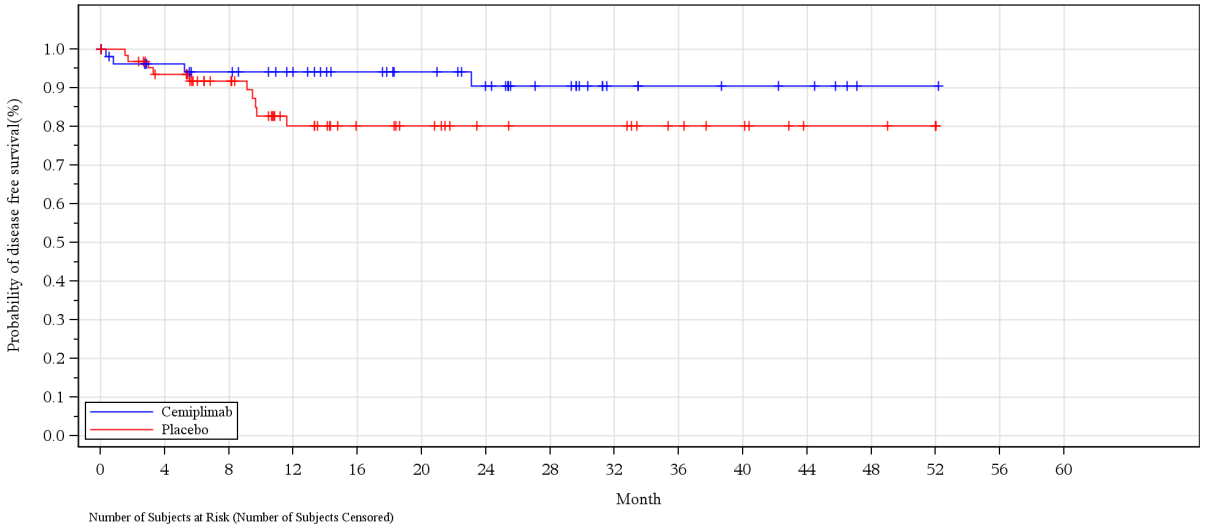
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65



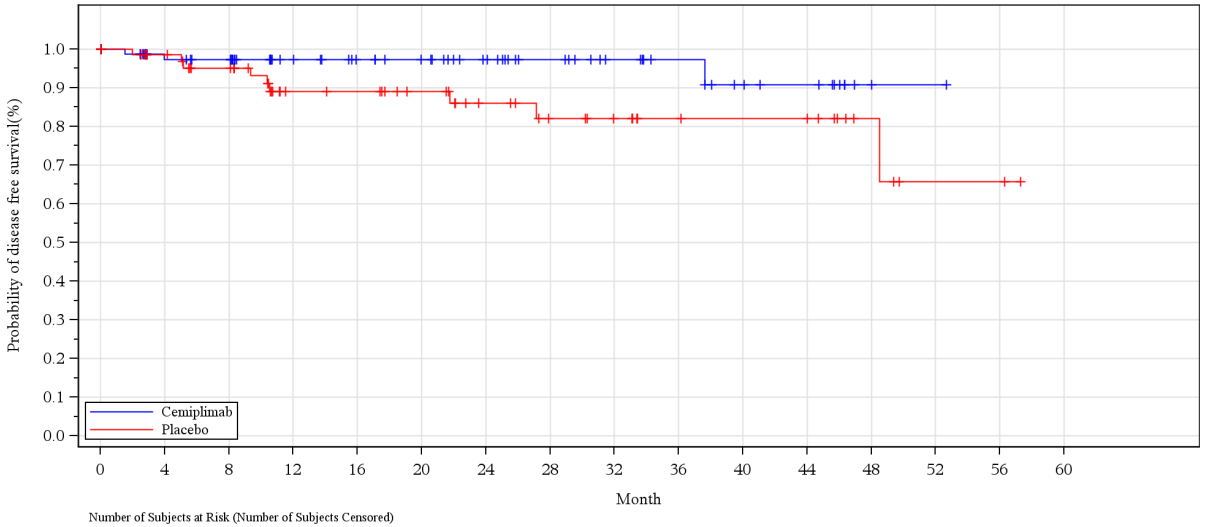
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	47 (7)	44 (9)	38 (15)	33 (20)	29 (24)	24 (28)	17 (35)	9 (43)	7 (45)	6 (46)	5 (47)	1 (51)	1 (51)	0 (52)	0 (52)
Placebo	65 (0)	55 (6)	44 (16)	30 (25)	22 (33)	19 (36)	14 (41)	13 (42)	13 (42)	9 (46)	7 (48)	3 (52)	3 (52)	1 (54)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	66 (12)	63 (15)	49 (29)	43 (35)	39 (39)	32 (46)	25 (53)	19 (59)	15 (63)	11 (66)	9 (68)	2 (76)	1 (76)	0 (77)	0 (77)
Placebo	69 (0)	60 (8)	53 (13)	37 (26)	36 (27)	31 (32)	24 (38)	19 (42)	16 (45)	12 (49)	11 (50)	10 (51)	5 (56)	2 (58)	2 (58)	0 (60)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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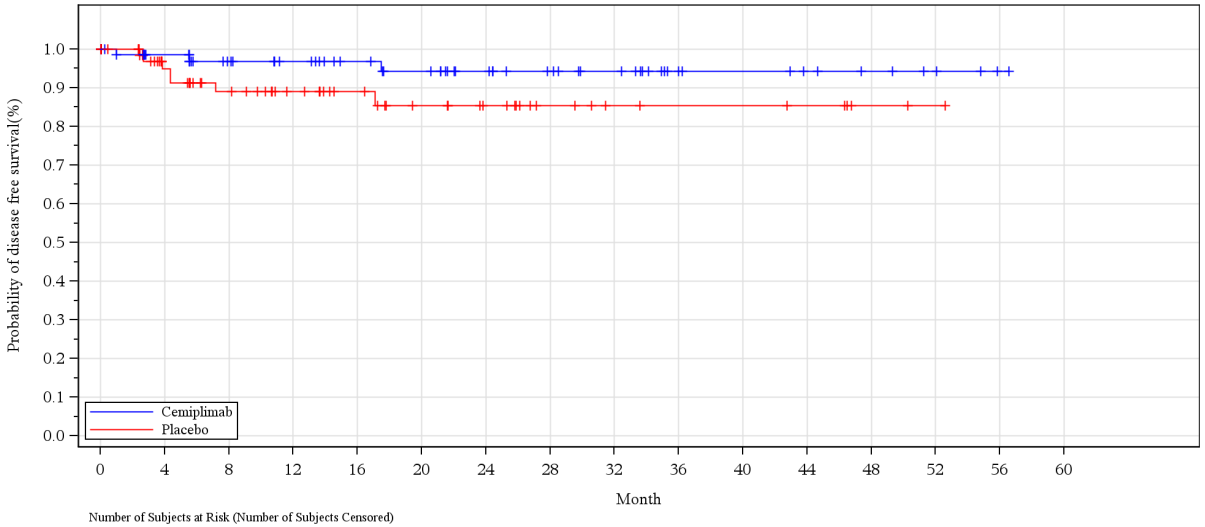
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	60 (12)	51 (20)	46 (25)	40 (31)	36 (34)	29 (41)	24 (46)	20 (50)	11 (59)	10 (60)	8 (62)	6 (64)	4 (66)	1 (69)	0 (70)
Placebo	72 (0)	51 (18)	40 (26)	32 (34)	26 (40)	20 (45)	16 (49)	10 (55)	7 (58)	6 (59)	6 (59)	5 (60)	2 (63)	1 (64)	0 (65)	0 (65)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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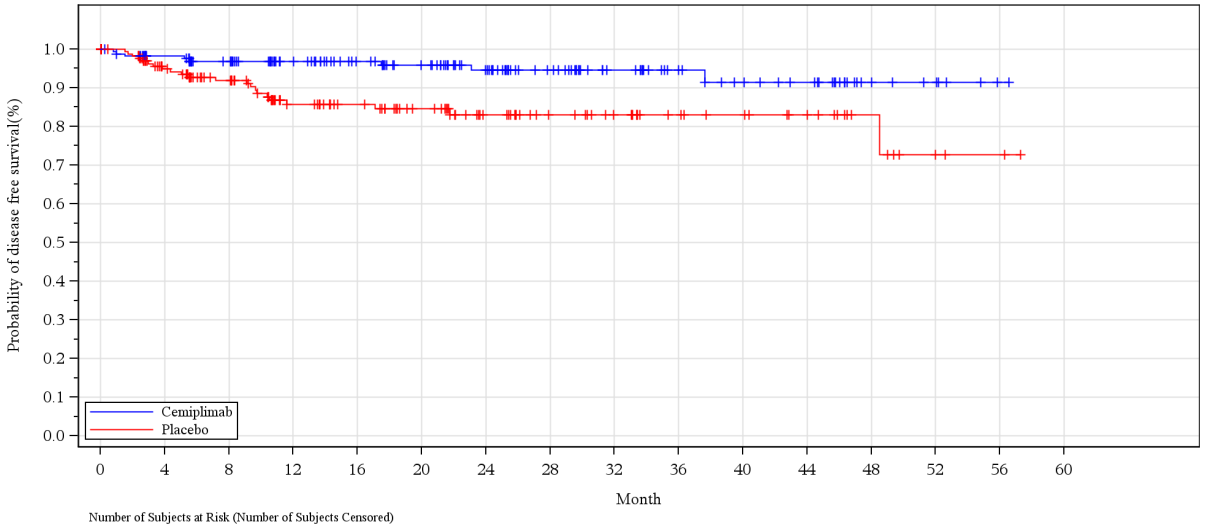
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male



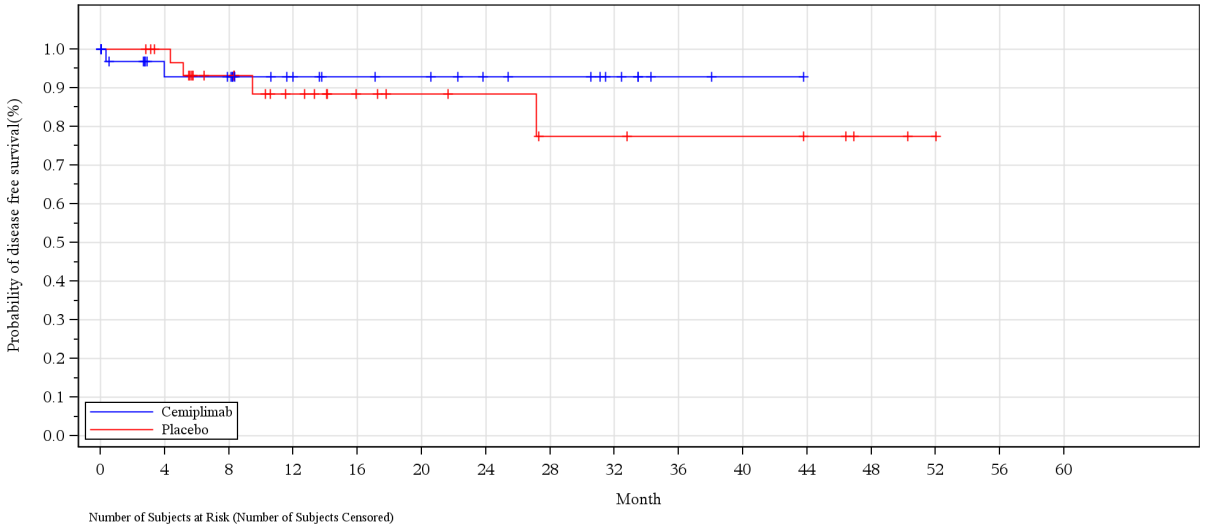
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	149 (22)	135 (34)	117 (52)	102 (67)	91 (77)	75 (92)	57 (110)	42 (125)	31 (136)	26 (140)	22 (144)	9 (158)	6 (160)	1 (165)	0 (166)
Placebo	174 (0)	137 (29)	115 (47)	83 (72)	73 (82)	61 (93)	46 (107)	36 (117)	30 (123)	22 (131)	19 (134)	14 (139)	8 (145)	3 (149)	2 (150)	0 (152)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	24 (9)	23 (10)	16 (17)	14 (19)	13 (20)	10 (23)	9 (24)	6 (27)	2 (31)	1 (32)	0 (33)	0 (33)	0 (33)	0 (33)	0 (33)
Placebo	32 (0)	29 (3)	22 (8)	16 (13)	11 (18)	9 (20)	8 (21)	6 (22)	6 (22)	5 (23)	5 (23)	4 (24)	2 (26)	1 (27)	0 (28)	0 (28)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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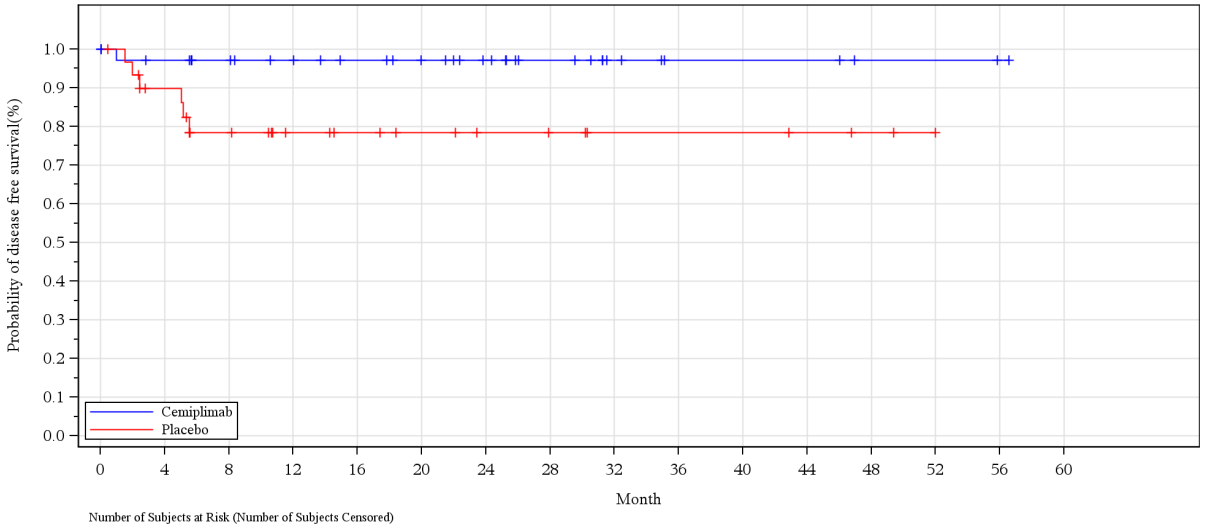
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



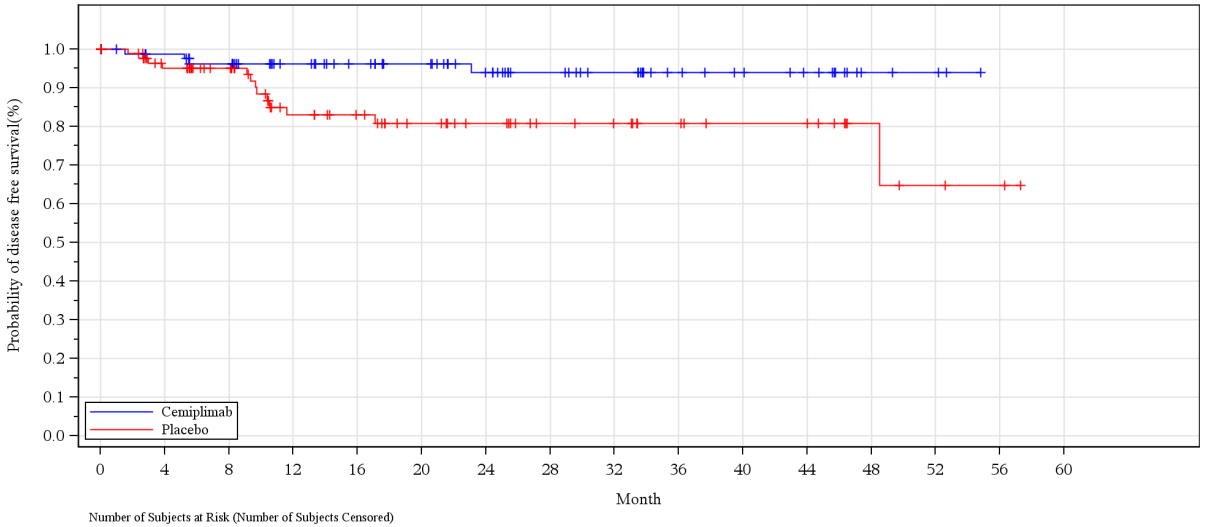
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	33 (3)	30 (6)	27 (9)	24 (12)	21 (15)	17 (19)	12 (24)	7 (29)	4 (32)	4 (32)	4 (32)	2 (34)	2 (34)	1 (35)	0 (36)
Placebo	31 (0)	24 (4)	18 (7)	13 (12)	11 (14)	9 (16)	7 (18)	6 (19)	4 (21)	4 (21)	4 (21)	3 (22)	2 (23)	0 (25)	0 (25)	0 (25)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



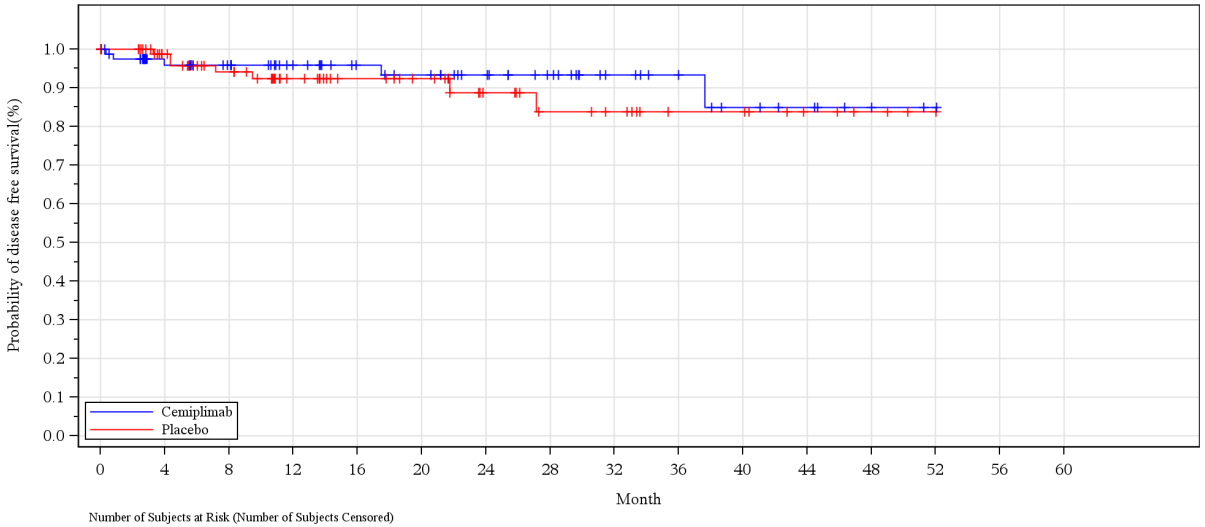
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	79 (10)	73 (14)	61 (26)	54 (33)	48 (39)	39 (47)	31 (55)	26 (60)	18 (68)	15 (71)	12 (74)	4 (82)	3 (83)	0 (86)	0 (86)
Placebo	90 (0)	73 (13)	63 (23)	44 (35)	39 (40)	31 (47)	26 (52)	20 (58)	18 (60)	14 (64)	11 (67)	10 (68)	5 (73)	3 (74)	2 (75)	0 (77)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



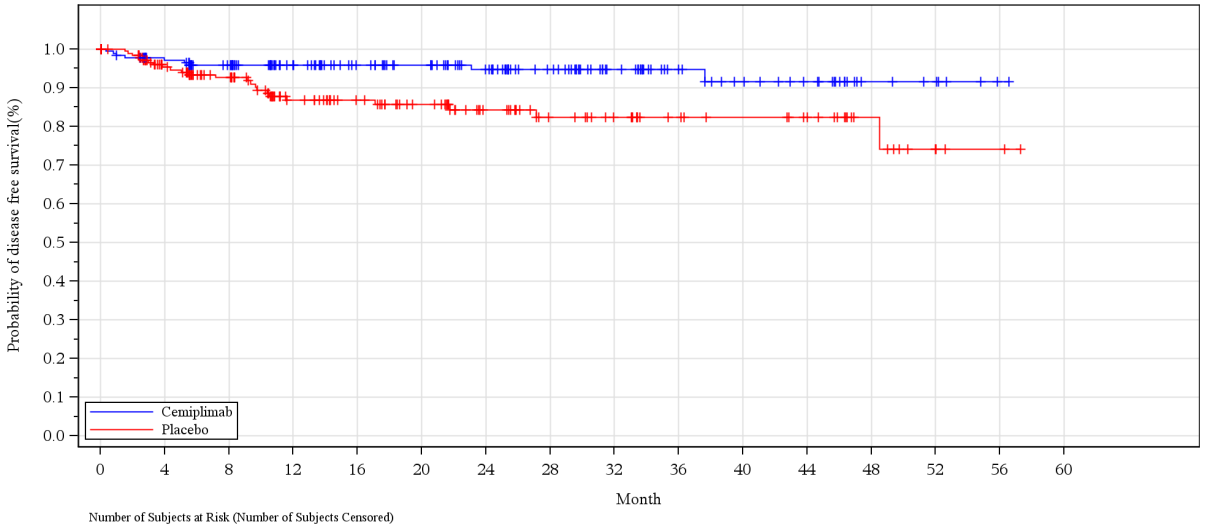
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	61 (18)	55 (24)	45 (34)	38 (41)	35 (43)	29 (49)	23 (55)	15 (63)	11 (67)	8 (69)	6 (71)	3 (75)	1 (76)	0 (77)	0 (77)
Placebo	85 (0)	69 (15)	56 (25)	42 (38)	34 (46)	30 (50)	21 (58)	16 (62)	14 (64)	9 (69)	9 (69)	5 (73)	3 (75)	1 (77)	0 (78)	0 (78)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White



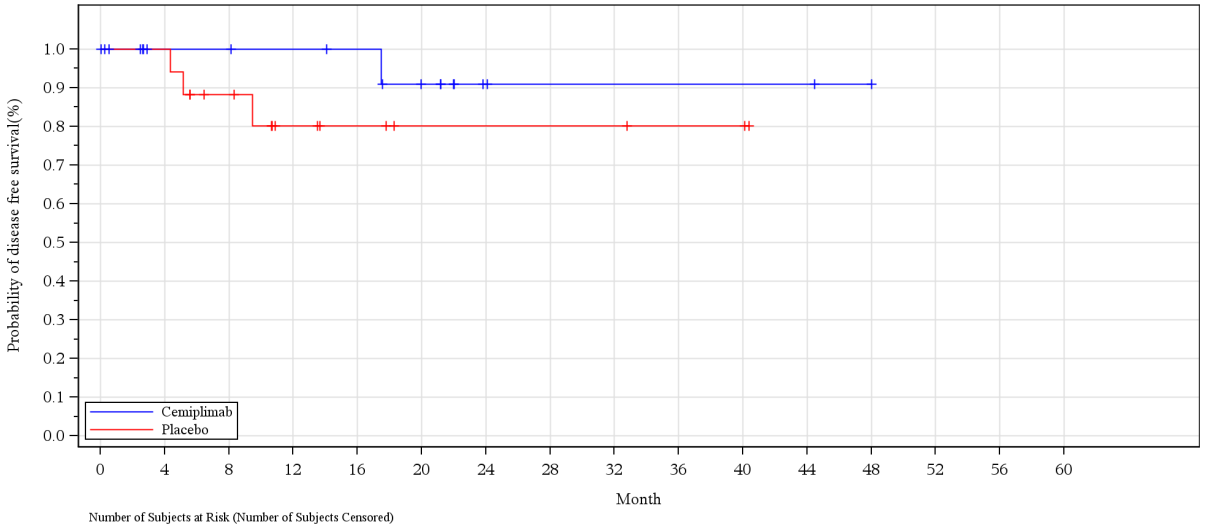
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	160 (24)	145 (37)	121 (61)	105 (77)	96 (86)	82 (99)	64 (117)	46 (135)	31 (150)	25 (155)	20 (160)	8 (172)	6 (174)	1 (179)	0 (180)
Placebo	189 (0)	149 (32)	125 (52)	92 (78)	79 (91)	67 (102)	51 (117)	39 (128)	33 (134)	25 (142)	22 (145)	18 (149)	10 (157)	4 (162)	2 (164)	0 (166)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white



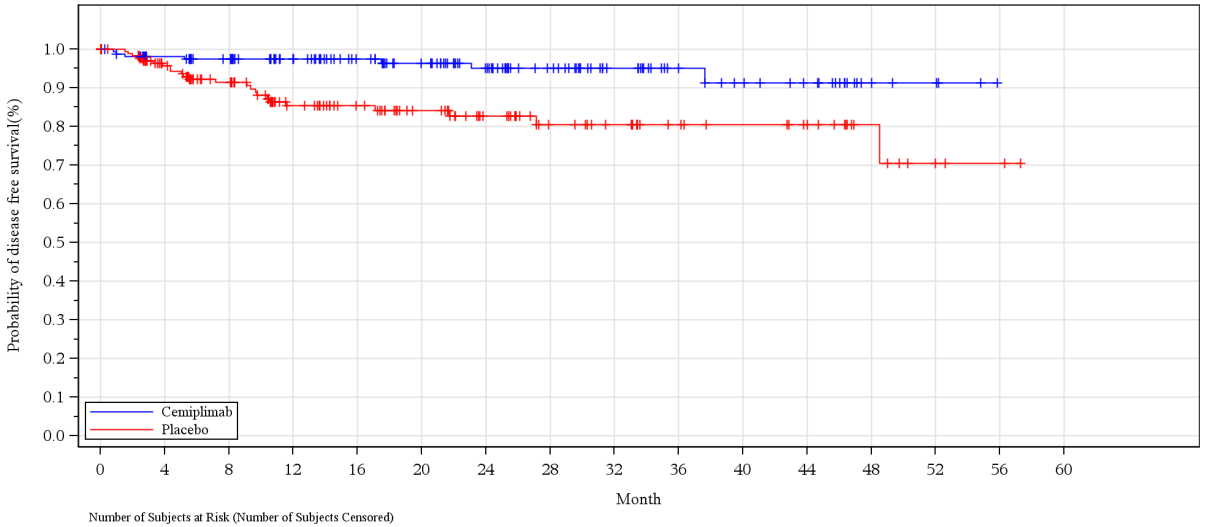
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	13 (7)	13 (7)	12 (8)	11 (9)	8 (11)	3 (16)	2 (17)	2 (17)	2 (17)	2 (17)	2 (17)	1 (19)	0 (19)	0 (19)	0 (19)
Placebo	17 (0)	17 (0)	12 (3)	7 (7)	5 (9)	3 (11)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



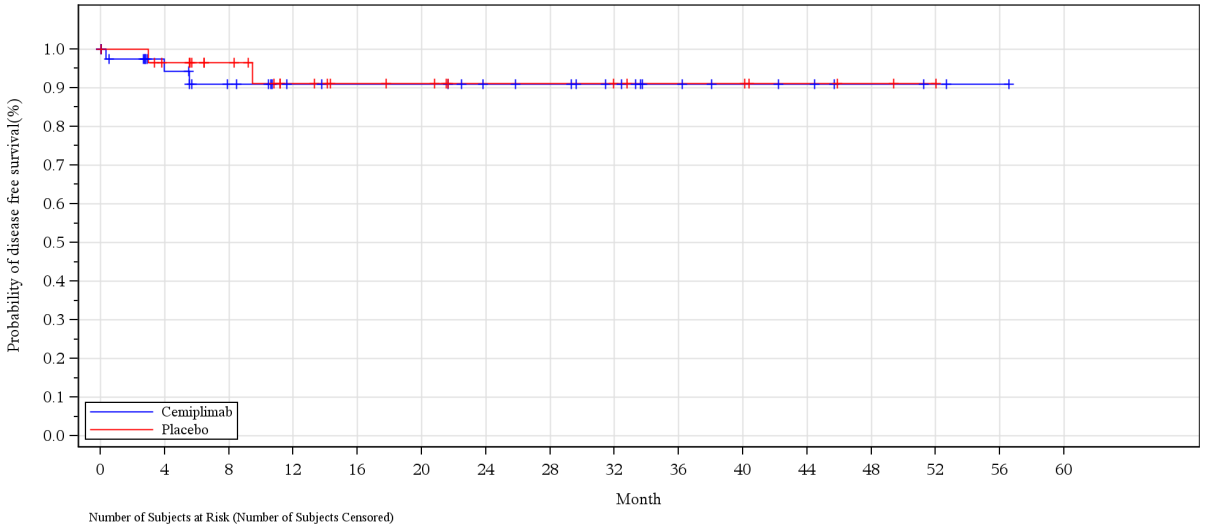
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	143 (20)	133 (29)	113 (49)	97 (65)	85 (76)	69 (91)	51 (109)	36 (124)	25 (135)	21 (138)	17 (142)	6 (154)	4 (155)	0 (159)	0 (159)
Placebo	177 (0)	141 (29)	117 (47)	85 (72)	73 (84)	60 (96)	47 (108)	35 (119)	30 (124)	22 (132)	19 (135)	15 (139)	8 (146)	3 (150)	2 (151)	0 (153)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



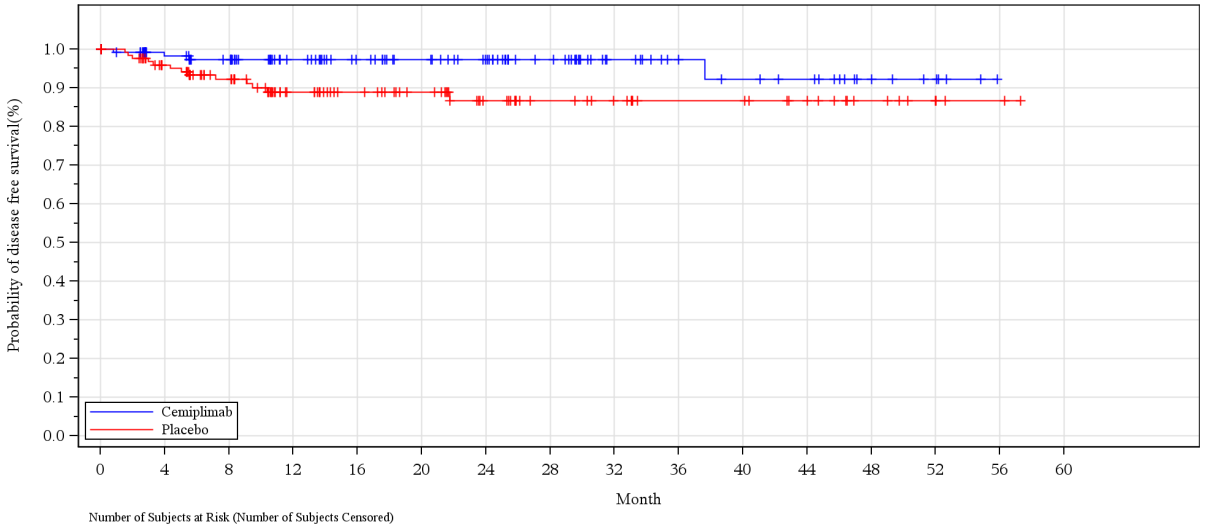
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	30 (11)	25 (15)	20 (20)	19 (21)	19 (21)	16 (24)	15 (25)	12 (28)	8 (32)	6 (34)	5 (35)	3 (37)	2 (38)	1 (39)	0 (40)
Placebo	29 (0)	25 (3)	20 (8)	14 (13)	11 (16)	10 (17)	7 (20)	7 (20)	6 (21)	5 (22)	5 (22)	3 (24)	2 (25)	1 (26)	0 (27)	0 (27)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0



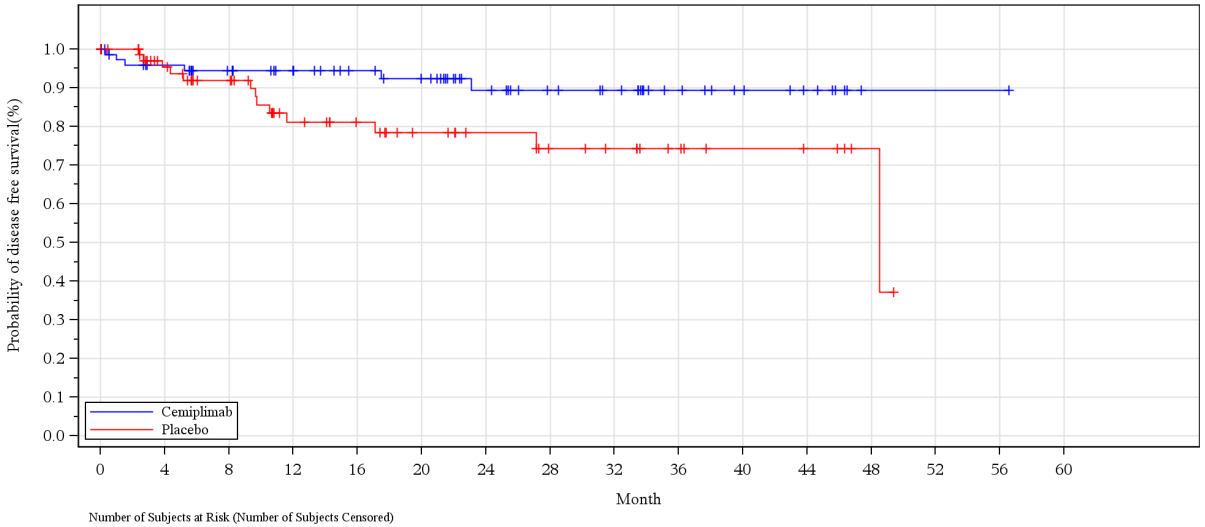
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	107 (24)	99 (31)	81 (49)	70 (60)	62 (68)	54 (76)	41 (89)	26 (104)	19 (111)	17 (112)	15 (114)	8 (122)	5 (124)	0 (129)	0 (129)
Placebo	131 (0)	109 (17)	89 (33)	65 (54)	55 (64)	47 (72)	35 (83)	27 (91)	23 (95)	18 (100)	18 (100)	13 (105)	8 (110)	4 (114)	2 (116)	0 (118)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1



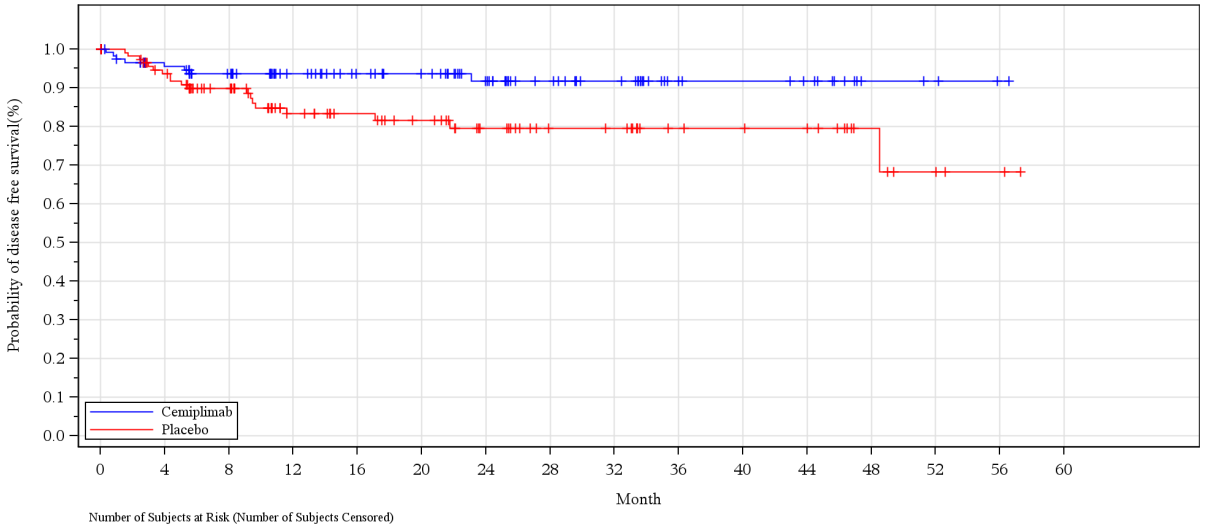
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	66 (7)	59 (13)	52 (20)	46 (26)	42 (29)	31 (39)	25 (45)	22 (48)	14 (56)	10 (60)	7 (63)	1 (69)	1 (69)	1 (69)	0 (70)
Placebo	75 (0)	57 (15)	48 (22)	34 (31)	29 (36)	23 (41)	19 (45)	15 (48)	13 (50)	9 (54)	6 (57)	5 (58)	2 (61)	0 (62)	0 (62)	0 (62)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal



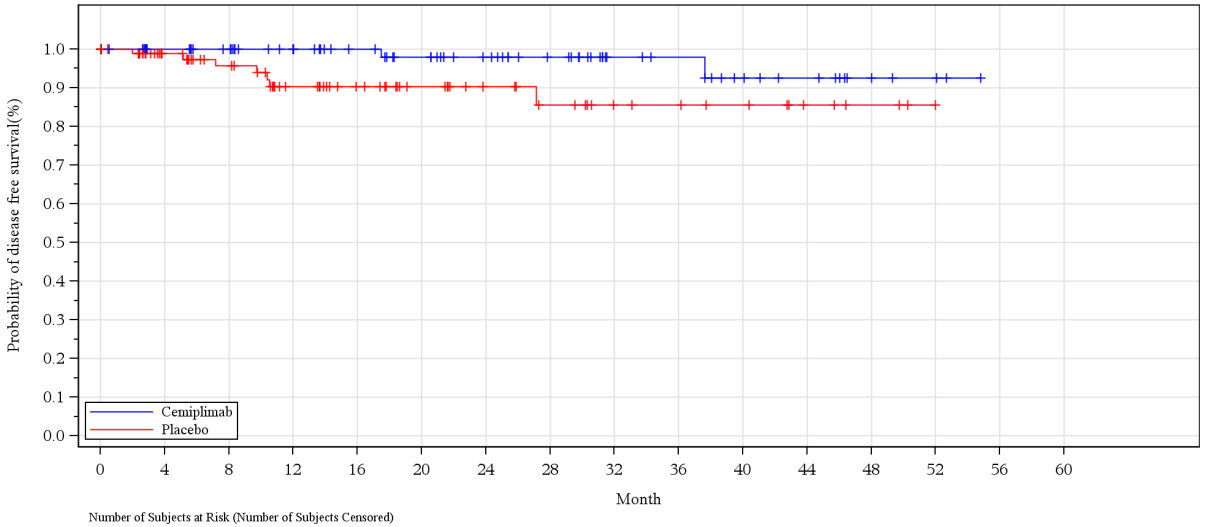
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	101 (19)	91 (27)	75 (43)	65 (53)	59 (59)	47 (70)	35 (82)	28 (89)	15 (102)	14 (103)	12 (105)	4 (113)	3 (114)	1 (116)	0 (117)
Placebo	117 (0)	99 (11)	80 (26)	56 (45)	49 (52)	43 (57)	33 (66)	25 (74)	24 (75)	16 (83)	15 (84)	13 (86)	7 (92)	4 (94)	2 (96)	0 (98)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	72 (12)	67 (17)	58 (26)	51 (33)	45 (38)	38 (45)	31 (52)	20 (63)	18 (65)	13 (69)	10 (72)	5 (78)	3 (79)	0 (82)	0 (82)
Placebo	89 (0)	67 (21)	57 (29)	43 (40)	35 (48)	27 (56)	21 (62)	17 (65)	12 (70)	11 (71)	9 (73)	5 (77)	3 (79)	0 (82)	0 (82)	0 (82)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:14 SAS Linux 9.4)

2.4.2 2. Datenschnitt

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	11 (16.9%)
Odds ratio (95% CI)	0.373 (0.111, 1.255)	
P-value for Odds Ratio	0.1111	
Relative Risk (95% CI)	0.42 (0.14, 1.24)	
P-value for Relative Risk	0.1170	
Heterogeneity p-value of RR	0.9538	
Risk difference (95% CI)	-10.68 (-23.87, 2.51)	
P-value for Risk Difference	0.1126	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	17 (12.1%)
Odds ratio (95% CI)	0.411 (0.170, 0.994)	
P-value for Odds Ratio	0.0485	
Relative Risk (95% CI)	0.44 (0.19, 0.99)	
P-value for Relative Risk	0.0464	
Heterogeneity p-value of RR	0.9538	
Risk difference (95% CI)	-6.49 (-13.41, 0.44)	
P-value for Risk Difference	0.0665	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	11 (16.9%)
Odds ratio (95% CI)	0.373 (0.111, 1.255)	
P-value for Odds Ratio	0.1111	
Relative Risk (95% CI)	0.42 (0.14, 1.24)	
P-value for Relative Risk	0.1170	
Heterogeneity p-value of RR	0.9320	
Risk difference (95% CI)	-10.68 (-23.87, 2.51)	
P-value for Risk Difference	0.1126	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	9 (13.0%)
Odds ratio (95% CI)	0.459 (0.144, 1.468)	
P-value for Odds Ratio	0.1891	
Relative Risk (95% CI)	0.49 (0.17, 1.41)	
P-value for Relative Risk	0.1857	
Heterogeneity p-value of RR	0.9320	
Risk difference (95% CI)	-6.09 (-17.46, 5.28)	
P-value for Risk Difference	0.2939	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	8 (11.1%)
Odds ratio (95% CI)	0.308 (0.075, 1.256)	
P-value for Odds Ratio	0.1005	
Relative Risk (95% CI)	0.69 (0.69, 0.69)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.9320	
Risk difference (95% CI)	-8.15 (-18.59, 2.29)	
P-value for Risk Difference	0.1258	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	9 (5.2%)	24 (13.8%)
Odds ratio (95% CI)	0.345 (0.155, 0.769)	
P-value for Odds Ratio	0.0093	
Relative Risk (95% CI)	0.38 (0.18, 0.79)	
P-value for Relative Risk	0.0096	
Heterogeneity p-value of RR	0.4464	
Risk difference (95% CI)	-7.39 (-13.94, -0.85)	
P-value for Risk Difference	0.0269	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	3 (8.6%)	4 (12.5%)
Odds ratio (95% CI)	0.633 (0.122, 3.269)	
P-value for Odds Ratio	0.5848	
Relative Risk (95% CI)	0.64 (0.15, 2.76)	
P-value for Relative Risk	0.5533	
Heterogeneity p-value of RR	0.4464	
Risk difference (95% CI)	1.02 (-19.63, 21.67)	
P-value for Risk Difference	0.9227	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Odds ratio (95% CI)	0.124 (0.014, 1.099)	
P-value for Odds Ratio	0.0608	
Relative Risk (95% CI)	0.15 (0.02, 1.18)	
P-value for Relative Risk	0.0716	
Heterogeneity p-value of RR	0.2311	
Risk difference (95% CI)	-15.04 (-33.49, 3.41)	
P-value for Risk Difference	0.1101	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	5 (5.6%)	14 (15.6%)
Odds ratio (95% CI)	0.320 (0.110, 0.933)	
P-value for Odds Ratio	0.0369	
Relative Risk (95% CI)	0.36 (0.13, 0.95)	
P-value for Relative Risk	0.0400	
Heterogeneity p-value of RR	0.2311	
Risk difference (95% CI)	-10.08 (-18.99, -1.16)	
P-value for Risk Difference	0.0267	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	6 (7.3%)	8 (9.4%)
Odds ratio (95% CI)	0.775 (0.255, 2.355)	
P-value for Odds Ratio	0.6536	
Relative Risk (95% CI)	0.79 (0.29, 2.19)	
P-value for Relative Risk	0.6509	
Heterogeneity p-value of RR	0.2311	
Risk difference (95% CI)	-1.79 (-10.47, 6.89)	
P-value for Risk Difference	0.6860	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	11 (5.8%)	25 (13.2%)
Odds ratio (95% CI)	0.412 (0.196, 0.870)	
P-value for Odds Ratio	0.0200	
Relative Risk (95% CI)	0.44 (0.22, 0.88)	
P-value for Relative Risk	0.0200	
Heterogeneity p-value of RR	0.5842	
Risk difference (95% CI)	-7.27 (-13.44, -1.10)	
P-value for Risk Difference	0.0209	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	3 (17.6%)
Odds ratio (95% CI)	0.214 (0.018, 2.492)	
P-value for Odds Ratio	0.2183	
Relative Risk (95% CI)	0.25 (0.03, 2.20)	
P-value for Relative Risk	0.2125	
Heterogeneity p-value of RR	0.5842	
Risk difference (95% CI)	-13.35 (-47.25, 20.54)	
P-value for Risk Difference	0.4401	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	9 (5.4%)	26 (14.7%)
Odds ratio (95% CI)	0.329 (0.149, 0.725)	
P-value for Odds Ratio	0.0059	
Relative Risk (95% CI)	0.36 (0.18, 0.75)	
P-value for Relative Risk	0.0064	
Heterogeneity p-value of RR	0.2849	
Risk difference (95% CI)	-8.90 (-15.29, -2.51)	
P-value for Risk Difference	0.0063	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	2 (6.9%)
Odds ratio (95% CI)	1.069 (0.166, 6.884)	
P-value for Odds Ratio	0.9442	
Relative Risk (95% CI)	1.06 (0.19, 5.91)	
P-value for Relative Risk	0.9479	
Heterogeneity p-value of RR	0.2849	
Risk difference (95% CI)	0.49 (-15.85, 16.82)	
P-value for Risk Difference	0.9532	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	5 (3.8%)	15 (11.5%)
Odds ratio (95% CI)	0.295 (0.103, 0.842)	
P-value for Odds Ratio	0.0226	
Relative Risk (95% CI)	0.32 (0.12, 0.86)	
P-value for Relative Risk	0.0238	
Heterogeneity p-value of RR	0.4818	
Risk difference (95% CI)	-8.14 (-16.47, 0.19)	
P-value for Risk Difference	0.0553	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	7 (9.2%)	13 (17.3%)
Odds ratio (95% CI)	0.489 (0.181, 1.325)	
P-value for Odds Ratio	0.1597	
Relative Risk (95% CI)	0.54 (0.23, 1.25)	
P-value for Relative Risk	0.1504	
Heterogeneity p-value of RR	0.4818	
Risk difference (95% CI)	-5.99 (-17.30, 5.32)	
P-value for Risk Difference	0.2995	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	10 (8.0%)	20 (17.1%)
Odds ratio (95% CI)	0.426 (0.189, 0.959)	
P-value for Odds Ratio	0.0392	
Relative Risk (95% CI)	0.47 (0.23, 0.96)	
P-value for Relative Risk	0.0388	
Heterogeneity p-value of RR	0.4771	
Risk difference (95% CI)	-8.80 (-17.40, -0.19)	
P-value for Risk Difference	0.0450	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1a Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	2 (2.4%)	8 (9.0%)
Odds ratio (95% CI)	0.257 (0.053, 1.256)	
P-value for Odds Ratio	0.0933	
Relative Risk (95% CI)	0.28 (0.06, 1.28)	
P-value for Relative Risk	0.0997	
Heterogeneity p-value of RR	0.4771	
Risk difference (95% CI)	-5.79 (-20.06, 8.47)	
P-value for Risk Difference	0.4261	

Data cut-off as of April 07, 2025.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	11 (16.9%)
Distant recurrence, n (%)	4 (7.1%)	11 (16.9%)
Number of censored participants, n (%)	52 (92.9%)	54 (83.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0649	
HR (95% CI) [c][d]	0.347 (0.108, 1.119)	
Heterogeneity p-value [c][e]	0.9171	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.3 (86.1, 99.1)	95.3 (86.1, 98.5)
6 months	94.4 (83.7, 98.2)	92.1 (82.0, 96.6)
12 months	94.4 (83.7, 98.2)	82.2 (69.3, 90.1)
18 months	94.4 (83.7, 98.2)	82.2 (69.3, 90.1)
24 months	91.2 (77.3, 96.7)	82.2 (69.3, 90.1)
30 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
36 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
42 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
48 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
54 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	17 (12.1%)
Distant recurrence, n (%)	8 (5.2%)	17 (12.1%)
Number of censored participants, n (%)	145 (94.8%)	124 (87.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (29.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0198	
HR (95% CI) [c][d]	0.378 (0.161, 0.883)	
Heterogeneity p-value [c][e]	0.9171	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (94.8, 99.7)	97.8 (93.4, 99.3)
6 months	97.3 (92.9, 99.0)	93.9 (88.1, 96.9)
12 months	97.3 (92.9, 99.0)	90.3 (83.4, 94.4)
18 months	95.3 (89.6, 97.9)	89.0 (81.6, 93.5)
24 months	94.1 (87.7, 97.2)	87.4 (79.2, 92.5)
30 months	94.1 (87.7, 97.2)	83.4 (73.1, 90.0)
36 months	94.1 (87.7, 97.2)	83.4 (73.1, 90.0)
42 months	91.6 (82.3, 96.1)	83.4 (73.1, 90.0)
48 months	91.6 (82.3, 96.1)	83.4 (73.1, 90.0)
54 months	91.6 (82.3, 96.1)	77.8 (61.3, 87.9)
60 months	91.6 (82.3, 96.1)	77.8 (61.3, 87.9)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	11 (16.9%)
Distant recurrence, n (%)	4 (7.1%)	11 (16.9%)
Number of censored participants, n (%)	52 (92.9%)	54 (83.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.7, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0649	
HR (95% CI) [c][d]	0.347 (0.108, 1.119)	
Heterogeneity p-value [c][e]	0.8014	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.3 (86.1, 99.1)	95.3 (86.1, 98.5)
6 months	94.4 (83.7, 98.2)	92.1 (82.0, 96.6)
12 months	94.4 (83.7, 98.2)	82.2 (69.3, 90.1)
18 months	94.4 (83.7, 98.2)	82.2 (69.3, 90.1)
24 months	91.2 (77.3, 96.7)	82.2 (69.3, 90.1)
30 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
36 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
42 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
48 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
54 months	91.2 (77.3, 96.7)	77.4 (60.7, 87.7)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	9 (13.0%)
Distant recurrence, n (%)	5 (6.3%)	9 (13.0%)
Number of censored participants, n (%)	75 (93.8%)	60 (87.0%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	NR (27.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.1663	
HR (95% CI) [c][d]	0.461 (0.151, 1.414)	
Heterogeneity p-value [c][e]	0.8014	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.4, 99.8)	98.5 (90.0, 99.8)
6 months	97.4 (90.1, 99.4)	95.5 (86.7, 98.5)
12 months	97.4 (90.1, 99.4)	90.4 (79.8, 95.6)
18 months	95.4 (86.2, 98.6)	90.4 (79.8, 95.6)
24 months	93.1 (82.1, 97.5)	87.6 (75.3, 94.1)
30 months	93.1 (82.1, 97.5)	84.4 (70.1, 92.2)
36 months	93.1 (82.1, 97.5)	84.4 (70.1, 92.2)
42 months	88.2 (70.5, 95.6)	84.4 (70.1, 92.2)
48 months	88.2 (70.5, 95.6)	84.4 (70.1, 92.2)
54 months	88.2 (70.5, 95.6)	76.0 (51.6, 89.2)
60 months	NE (NE, NE)	76.0 (51.6, 89.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	8 (11.1%)
Distant recurrence, n (%)	3 (4.1%)	8 (11.1%)
Number of censored participants, n (%)	70 (95.9%)	64 (88.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (17.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0322	
HR (95% CI) [c][d]	0.211 (0.044, 1.007)	
Heterogeneity p-value [c][e]	0.8014	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (90.4, 99.8)	97.1 (88.8, 99.3)
6 months	97.1 (89.0, 99.3)	92.2 (82.3, 96.7)
12 months	97.1 (89.0, 99.3)	90.3 (79.7, 95.6)
18 months	95.0 (85.0, 98.4)	87.3 (74.5, 94.0)
24 months	95.0 (85.0, 98.4)	87.3 (74.5, 94.0)
30 months	95.0 (85.0, 98.4)	82.2 (64.4, 91.6)
36 months	95.0 (85.0, 98.4)	82.2 (64.4, 91.6)
42 months	95.0 (85.0, 98.4)	82.2 (64.4, 91.6)
48 months	95.0 (85.0, 98.4)	82.2 (64.4, 91.6)
54 months	95.0 (85.0, 98.4)	82.2 (64.4, 91.6)
60 months	95.0 (85.0, 98.4)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	9 (5.2%)	24 (13.8%)
Distant recurrence, n (%)	9 (5.2%)	24 (13.8%)
Number of censored participants, n (%)	165 (94.8%)	150 (86.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (29.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0019	
HR (95% CI) [c][d]	0.314 (0.145, 0.679)	
Heterogeneity p-value [c][e]	0.2864	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (94.6, 99.4)	96.4 (92.2, 98.4)
6 months	97.0 (93.1, 98.8)	93.3 (88.3, 96.3)
12 months	97.0 (93.1, 98.8)	87.5 (81.0, 91.9)
18 months	95.4 (90.5, 97.8)	86.5 (79.7, 91.1)
24 months	94.4 (89.0, 97.2)	85.2 (77.8, 90.2)
30 months	94.4 (89.0, 97.2)	81.9 (73.2, 88.0)
36 months	94.4 (89.0, 97.2)	81.9 (73.2, 88.0)
42 months	92.2 (83.9, 96.3)	81.9 (73.2, 88.0)
48 months	92.2 (83.9, 96.3)	81.9 (73.2, 88.0)
54 months	92.2 (83.9, 96.3)	76.8 (62.2, 86.4)
60 months	92.2 (83.9, 96.3)	76.8 (62.2, 86.4)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	3 (8.6%)	4 (12.5%)
Distant recurrence, n (%)	3 (8.6%)	4 (12.5%)
Number of censored participants, n (%)	32 (91.4%)	28 (87.5%)
Q1 (95% CI), (months)[a]	NR (22.8, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (27.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.6231	
HR (95% CI) [c][d]	0.680 (0.144, 3.197)	
Heterogeneity p-value [c][e]	0.2864	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.1 (80.9, 99.6)	100 (100, 100)
6 months	93.8 (77.4, 98.4)	93.1 (75.1, 98.2)
12 months	93.8 (77.4, 98.4)	88.9 (69.1, 96.3)
18 months	93.8 (77.4, 98.4)	88.9 (69.1, 96.3)
24 months	86.6 (60.4, 96.0)	88.9 (69.1, 96.3)
30 months	86.6 (60.4, 96.0)	77.8 (44.4, 92.5)
36 months	86.6 (60.4, 96.0)	77.8 (44.4, 92.5)
42 months	86.6 (60.4, 96.0)	77.8 (44.4, 92.5)
48 months	86.6 (60.4, 96.0)	77.8 (44.4, 92.5)
54 months	NE (NE, NE)	77.8 (44.4, 92.5)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Distant recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (2.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0338	
HR (95% CI) [c][d]	0.140 (0.017, 1.167)	
Heterogeneity p-value [c][e]	0.2036	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.2 (81.9, 99.6)	90.0 (72.1, 96.7)
6 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
12 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
18 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
24 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
30 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
36 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
42 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
48 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
54 months	97.2 (81.9, 99.6)	79.6 (60.1, 90.3)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	5 (5.6%)	14 (15.6%)
Distant recurrence, n (%)	5 (5.6%)	14 (15.6%)
Number of censored participants, n (%)	85 (94.4%)	76 (84.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (11.6, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0140	
HR (95% CI) [c][d]	0.298 (0.107, 0.830)	
Heterogeneity p-value [c][e]	0.2036	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (92.0, 99.8)	96.5 (89.6, 98.9)
6 months	96.5 (89.6, 98.9)	95.3 (88.0, 98.2)
12 months	96.5 (89.6, 98.9)	85.1 (74.6, 91.5)
18 months	96.5 (89.6, 98.9)	83.3 (72.2, 90.2)
24 months	92.7 (82.9, 97.0)	83.3 (72.2, 90.2)
30 months	92.7 (82.9, 97.0)	80.0 (66.8, 88.4)
36 months	92.7 (82.9, 97.0)	80.0 (66.8, 88.4)
42 months	92.7 (82.9, 97.0)	80.0 (66.8, 88.4)
48 months	92.7 (82.9, 97.0)	80.0 (66.8, 88.4)
54 months	92.7 (82.9, 97.0)	72.7 (52.0, 85.6)
60 months	92.7 (82.9, 97.0)	72.7 (52.0, 85.6)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	6 (7.3%)	8 (9.4%)
Distant recurrence, n (%)	6 (7.3%)	8 (9.4%)
Number of censored participants, n (%)	76 (92.7%)	77 (90.6%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	NR (27.0, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.5274	
HR (95% CI) [c][d]	0.711 (0.246, 2.054)	
Heterogeneity p-value [c][e]	0.2036	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.5 (90.5, 99.4)	100 (100, 100)
6 months	96.2 (88.8, 98.8)	96.2 (88.7, 98.8)
12 months	96.2 (88.8, 98.8)	93.3 (84.5, 97.2)
18 months	91.9 (80.8, 96.7)	93.3 (84.5, 97.2)
24 months	91.9 (80.8, 96.7)	90.4 (78.9, 95.8)
30 months	91.9 (80.8, 96.7)	84.0 (68.7, 92.2)
36 months	91.9 (80.8, 96.7)	84.0 (68.7, 92.2)
42 months	85.7 (65.4, 94.6)	84.0 (68.7, 92.2)
48 months	85.7 (65.4, 94.6)	84.0 (68.7, 92.2)
54 months	85.7 (65.4, 94.6)	84.0 (68.7, 92.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	11 (5.8%)	25 (13.2%)
Distant recurrence, n (%)	11 (5.8%)	25 (13.2%)
Number of censored participants, n (%)	178 (94.2%)	164 (86.8%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (29.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0063	
HR (95% CI) [c][d]	0.383 (0.188, 0.782)	
Heterogeneity p-value [c][e]	0.7352	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.8 (94.4, 99.2)	96.7 (92.9, 98.5)
6 months	96.2 (92.2, 98.2)	93.8 (89.1, 96.5)
12 months	96.2 (92.2, 98.2)	88.3 (82.3, 92.4)
18 months	95.4 (91.0, 97.7)	87.4 (81.0, 91.7)
24 months	93.5 (88.1, 96.5)	86.2 (79.3, 90.9)
30 months	93.5 (88.1, 96.5)	81.7 (73.0, 87.8)
36 months	93.5 (88.1, 96.5)	81.7 (73.0, 87.8)
42 months	91.5 (83.7, 95.6)	81.7 (73.0, 87.8)
48 months	91.5 (83.7, 95.6)	81.7 (73.0, 87.8)
54 months	91.5 (83.7, 95.6)	77.6 (65.0, 86.2)
60 months	91.5 (83.7, 95.6)	77.6 (65.0, 86.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	3 (17.6%)
Distant recurrence, n (%)	1 (5.0%)	3 (17.6%)
Number of censored participants, n (%)	19 (95.0%)	14 (82.4%)
Q1 (95% CI), (months)[a]	NR (17.5, NE)	NR (4.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.3608	
HR (95% CI) [c][d]	0.347 (0.033, 3.675)	
Heterogeneity p-value [c][e]	0.7352	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	88.2 (60.6, 96.9)
12 months	100 (100, 100)	81.4 (52.6, 93.6)
18 months	91.7 (53.9, 98.8)	81.4 (52.6, 93.6)
24 months	91.7 (53.9, 98.8)	81.4 (52.6, 93.6)
30 months	91.7 (53.9, 98.8)	81.4 (52.6, 93.6)
36 months	91.7 (53.9, 98.8)	81.4 (52.6, 93.6)
42 months	91.7 (53.9, 98.8)	81.4 (52.6, 93.6)
48 months	91.7 (53.9, 98.8)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	9 (5.4%)	26 (14.7%)
Distant recurrence, n (%)	9 (5.4%)	26 (14.7%)
Number of censored participants, n (%)	157 (94.6%)	151 (85.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (27.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0013	
HR (95% CI) [c][d]	0.308 (0.144, 0.658)	
Heterogeneity p-value [c][e]	0.2351	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (94.4, 99.4)	97.1 (93.2, 98.8)
6 months	97.5 (93.6, 99.1)	92.8 (87.6, 95.8)
12 months	97.5 (93.6, 99.1)	87.0 (80.6, 91.5)
18 months	95.8 (90.8, 98.1)	86.0 (79.2, 90.7)
24 months	93.7 (87.6, 96.9)	84.7 (77.4, 89.8)
30 months	93.7 (87.6, 96.9)	79.9 (70.7, 86.5)
36 months	93.7 (87.6, 96.9)	79.9 (70.7, 86.5)
42 months	91.1 (81.7, 95.8)	79.9 (70.7, 86.5)
48 months	91.1 (81.7, 95.8)	79.9 (70.7, 86.5)
54 months	91.1 (81.7, 95.8)	75.2 (61.3, 84.7)
60 months	91.1 (81.7, 95.8)	75.2 (61.3, 84.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	2 (6.9%)
Distant recurrence, n (%)	3 (7.0%)	2 (6.9%)
Number of censored participants, n (%)	40 (93.0%)	27 (93.1%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (9.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.8748	
HR (95% CI) [c][d]	1.155 (0.192, 6.930)	
Heterogeneity p-value [c][e]	0.2351	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.6 (84.3, 99.7)	96.6 (77.9, 99.5)
6 months	92.3 (78.1, 97.5)	96.6 (77.9, 99.5)
12 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
18 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
24 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
30 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
36 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
42 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
48 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
54 months	92.3 (78.1, 97.5)	91.7 (70.2, 97.9)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	5 (3.8%)	15 (11.5%)
Distant recurrence, n (%)	5 (3.8%)	15 (11.5%)
Number of censored participants, n (%)	128 (96.2%)	116 (88.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	NR (29.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0147	
HR (95% CI) [c][d]	0.303 (0.110, 0.837)	
Heterogeneity p-value [c][e]	0.6996	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.7, 99.9)	96.9 (92.1, 98.8)
6 months	97.6 (92.9, 99.2)	93.8 (88.0, 96.9)
12 months	97.6 (92.9, 99.2)	90.1 (83.2, 94.3)
18 months	96.5 (90.7, 98.7)	90.1 (83.2, 94.3)
24 months	96.5 (90.7, 98.7)	88.3 (80.3, 93.2)
30 months	96.5 (90.7, 98.7)	84.1 (73.6, 90.7)
36 months	96.5 (90.7, 98.7)	84.1 (73.6, 90.7)
42 months	92.6 (78.6, 97.6)	84.1 (73.6, 90.7)
48 months	92.6 (78.6, 97.6)	84.1 (73.6, 90.7)
54 months	92.6 (78.6, 97.6)	84.1 (73.6, 90.7)
60 months	92.6 (78.6, 97.6)	84.1 (73.6, 90.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	7 (9.2%)	13 (17.3%)
Distant recurrence, n (%)	7 (9.2%)	13 (17.3%)
Number of censored participants, n (%)	69 (90.8%)	62 (82.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (10.5, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (48.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0299	
HR (95% CI) [c][d]	0.370 (0.146, 0.940)	
Heterogeneity p-value [c][e]	0.6996	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.0 (88.0, 98.7)	97.1 (88.8, 99.3)
6 months	94.6 (86.2, 97.9)	92.3 (82.5, 96.7)
12 months	94.6 (86.2, 97.9)	82.9 (70.3, 90.5)
18 months	92.8 (83.4, 97.0)	80.3 (66.8, 88.7)
24 months	88.7 (77.5, 94.6)	80.3 (66.8, 88.7)
30 months	88.7 (77.5, 94.6)	76.3 (60.5, 86.4)
36 months	88.7 (77.5, 94.6)	76.3 (60.5, 86.4)
42 months	88.7 (77.5, 94.6)	76.3 (60.5, 86.4)
48 months	88.7 (77.5, 94.6)	76.3 (60.5, 86.4)
54 months	88.7 (77.5, 94.6)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	10 (8.0%)	20 (17.1%)
Distant recurrence, n (%)	10 (8.0%)	20 (17.1%)
Number of censored participants, n (%)	115 (92.0%)	97 (82.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	48.5 (17.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0373	
HR (95% CI) [c][d]	0.454 (0.212, 0.972)	
Heterogeneity p-value [c][e]	0.4082	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	96.7 (91.6, 98.8)	95.7 (89.9, 98.2)
6 months	94.2 (88.3, 97.2)	90.4 (83.3, 94.5)
12 months	94.2 (88.3, 97.2)	85.1 (76.7, 90.6)
18 months	93.0 (86.5, 96.5)	83.6 (74.8, 89.6)
24 months	90.1 (82.0, 94.7)	81.9 (72.3, 88.4)
30 months	90.1 (82.0, 94.7)	79.6 (69.0, 86.9)
36 months	90.1 (82.0, 94.7)	79.6 (69.0, 86.9)
42 months	90.1 (82.0, 94.7)	79.6 (69.0, 86.9)
48 months	90.1 (82.0, 94.7)	79.6 (69.0, 86.9)
54 months	90.1 (82.0, 94.7)	73.0 (54.8, 84.8)
60 months	NE (NE, NE)	73.0 (54.8, 84.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	2 (2.4%)	8 (9.0%)
Distant recurrence, n (%)	2 (2.4%)	8 (9.0%)
Number of censored participants, n (%)	82 (97.6%)	81 (91.0%)
Q1 (95% CI), (months)[a]	NR (37.6, NE)	NR (27.0, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0351	
HR (95% CI) [c][d]	0.218 (0.046, 1.032)	
Heterogeneity p-value [c][e]	0.4082	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.9.1 Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	98.8 (92.0, 99.8)
6 months	100 (100, 100)	97.5 (90.4, 99.4)
12 months	100 (100, 100)	91.4 (81.8, 96.1)
18 months	98.2 (88.2, 99.8)	91.4 (81.8, 96.1)
24 months	98.2 (88.2, 99.8)	91.4 (81.8, 96.1)
30 months	98.2 (88.2, 99.8)	83.8 (67.6, 92.3)
36 months	98.2 (88.2, 99.8)	83.8 (67.6, 92.3)
42 months	93.6 (73.6, 98.6)	83.8 (67.6, 92.3)
48 months	93.6 (73.6, 98.6)	83.8 (67.6, 92.3)
54 months	93.6 (73.6, 98.6)	83.8 (67.6, 92.3)
60 months	93.6 (73.6, 98.6)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided nominal p-value, no multiplicity adjustment.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events. Non-white includes not reported and unknown values.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	11 (16.9%)
Distant recurrence, n (%)	4 (7.1%)	11 (16.9%)
Number of censored participants, n (%)	52 (92.9%)	54 (83.1%)
Proportionality Test p-value[a][b]	0.1272	
Hazard ratio(interaction)	2.250 (0.794, 6.379)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	17 (12.1%)
Distant recurrence, n (%)	8 (5.2%)	17 (12.1%)
Number of censored participants, n (%)	145 (94.8%)	124 (87.9%)
Proportionality Test p-value[a][b]	0.8664	
Hazard ratio(interaction)	1.074 (0.469, 2.460)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	11 (16.9%)
Distant recurrence, n (%)	4 (7.1%)	11 (16.9%)
Number of censored participants, n (%)	52 (92.9%)	54 (83.1%)
Proportionality Test p-value[a][b]	0.1272	
Hazard ratio(interaction)	2.250 (0.794, 6.379)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	9 (13.0%)
Distant recurrence, n (%)	5 (6.3%)	9 (13.0%)
Number of censored participants, n (%)	75 (93.8%)	60 (87.0%)
Proportionality Test p-value[a][b]	0.9888	
Hazard ratio(interaction)	1.008 (0.325, 3.128)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	8 (11.1%)
Distant recurrence, n (%)	3 (4.1%)	8 (11.1%)
Number of censored participants, n (%)	70 (95.9%)	64 (88.9%)
Proportionality Test p-value[a][b]	0.6776	
Hazard ratio(interaction)	1.386 (0.297, 6.471)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	9 (5.2%)	24 (13.8%)
Distant recurrence, n (%)	9 (5.2%)	24 (13.8%)
Number of censored participants, n (%)	165 (94.8%)	150 (86.2%)
Proportionality Test p-value[a][b]	0.5781	
Hazard ratio(interaction)	1.230 (0.594, 2.547)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	3 (8.6%)	4 (12.5%)
Distant recurrence, n (%)	3 (8.6%)	4 (12.5%)
Number of censored participants, n (%)	32 (91.4%)	28 (87.5%)
Proportionality Test p-value[a][b]	0.4337	
Hazard ratio(interaction)	1.803 (0.412, 7.883)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	6 (19.4%)
Distant recurrence, n (%)	1 (2.7%)	6 (19.4%)
Number of censored participants, n (%)	36 (97.3%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.9957	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	5 (5.6%)	14 (15.6%)
Distant recurrence, n (%)	5 (5.6%)	14 (15.6%)
Number of censored participants, n (%)	85 (94.4%)	76 (84.4%)
Proportionality Test p-value[a][b]	0.6355	
Hazard ratio(interaction)	1.313 (0.426, 4.051)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	6 (7.3%)	8 (9.4%)
Distant recurrence, n (%)	6 (7.3%)	8 (9.4%)
Number of censored participants, n (%)	76 (92.7%)	77 (90.6%)
Proportionality Test p-value[a][b]	0.3384	
Hazard ratio(interaction)	1.532 (0.640, 3.672)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	11 (5.8%)	25 (13.2%)
Distant recurrence, n (%)	11 (5.8%)	25 (13.2%)
Number of censored participants, n (%)	178 (94.2%)	164 (86.8%)
Proportionality Test p-value[a][b]	0.2702	
Hazard ratio(interaction)	1.431 (0.757, 2.708)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	3 (17.6%)
Distant recurrence, n (%)	1 (5.0%)	3 (17.6%)
Number of censored participants, n (%)	19 (95.0%)	14 (82.4%)
Proportionality Test p-value[a][b]	0.9970	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	9 (5.4%)	26 (14.7%)
Distant recurrence, n (%)	9 (5.4%)	26 (14.7%)
Number of censored participants, n (%)	157 (94.6%)	151 (85.3%)
Proportionality Test p-value[a][b]	0.7317	
Hazard ratio(interaction)	1.132 (0.556, 2.306)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	3 (7.0%)	2 (6.9%)
Distant recurrence, n (%)	3 (7.0%)	2 (6.9%)
Number of censored participants, n (%)	40 (93.0%)	27 (93.1%)
Proportionality Test p-value[a][b]	0.4594	
Hazard ratio(interaction)	3.146 (0.151, 65.501)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	5 (3.8%)	15 (11.5%)
Distant recurrence, n (%)	5 (3.8%)	15 (11.5%)
Number of censored participants, n (%)	128 (96.2%)	116 (88.5%)
Proportionality Test p-value[a][b]	0.9979	
Hazard ratio(interaction)	0.999 (0.370, 2.692)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	7 (9.2%)	13 (17.3%)
Distant recurrence, n (%)	7 (9.2%)	13 (17.3%)
Number of censored participants, n (%)	69 (90.8%)	62 (82.7%)
Proportionality Test p-value[a][b]	0.1018	
Hazard ratio(interaction)	1.996 (0.872, 4.570)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	10 (8.0%)	20 (17.1%)
Distant recurrence, n (%)	10 (8.0%)	20 (17.1%)
Number of censored participants, n (%)	115 (92.0%)	97 (82.9%)
Proportionality Test p-value[a][b]	0.2335	
Hazard ratio(interaction)	1.552 (0.753, 3.197)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.2.10.1 Test of Proportional Hazards Assumption for Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

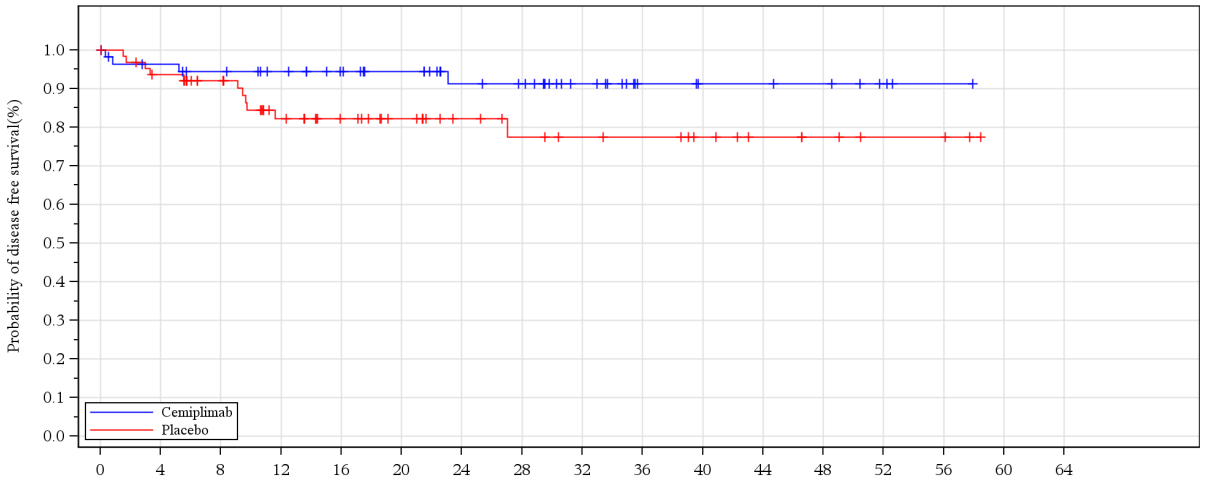
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	2 (2.4%)	8 (9.0%)
Distant recurrence, n (%)	2 (2.4%)	8 (9.0%)
Number of censored participants, n (%)	82 (97.6%)	81 (91.0%)
Proportionality Test p-value[a][b]	0.1677	
Hazard ratio(interaction)	0.066 (0.001, 3.137)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	51 (3)	48 (5)	44 (9)	39 (14)	35 (18)	28 (24)	26 (26)	17 (35)	9 (43)	7 (45)	7 (45)	6 (46)	3 (49)	1 (51)	0 (52)	0 (52)
Placebo	65 (0)	58 (3)	50 (10)	38 (17)	31 (24)	25 (30)	19 (36)	16 (38)	14 (40)	13 (41)	10 (44)	7 (47)	5 (49)	3 (51)	3 (51)	0 (54)	0 (54)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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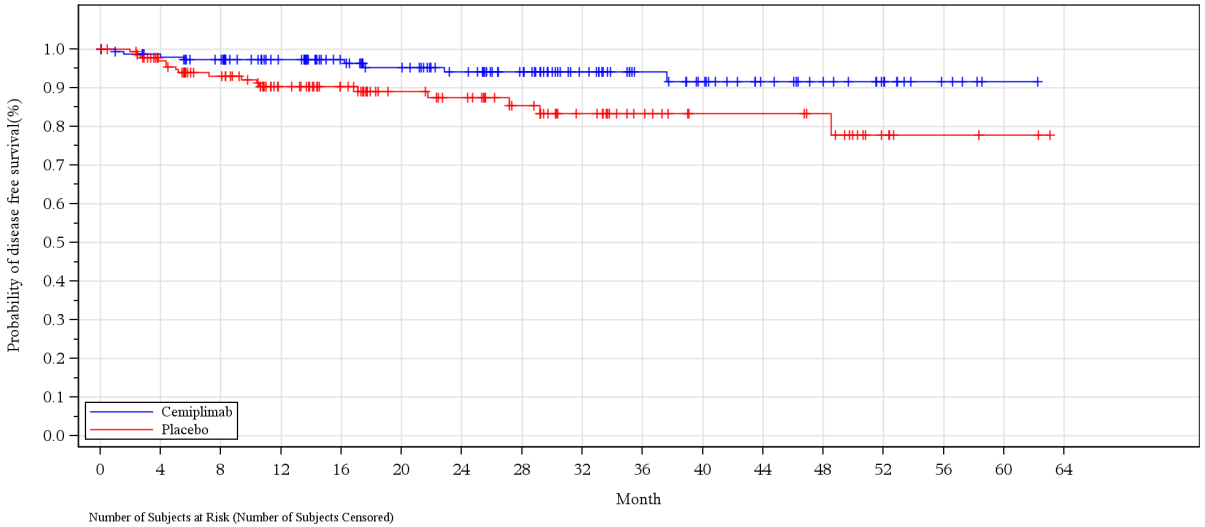
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 1: >=65



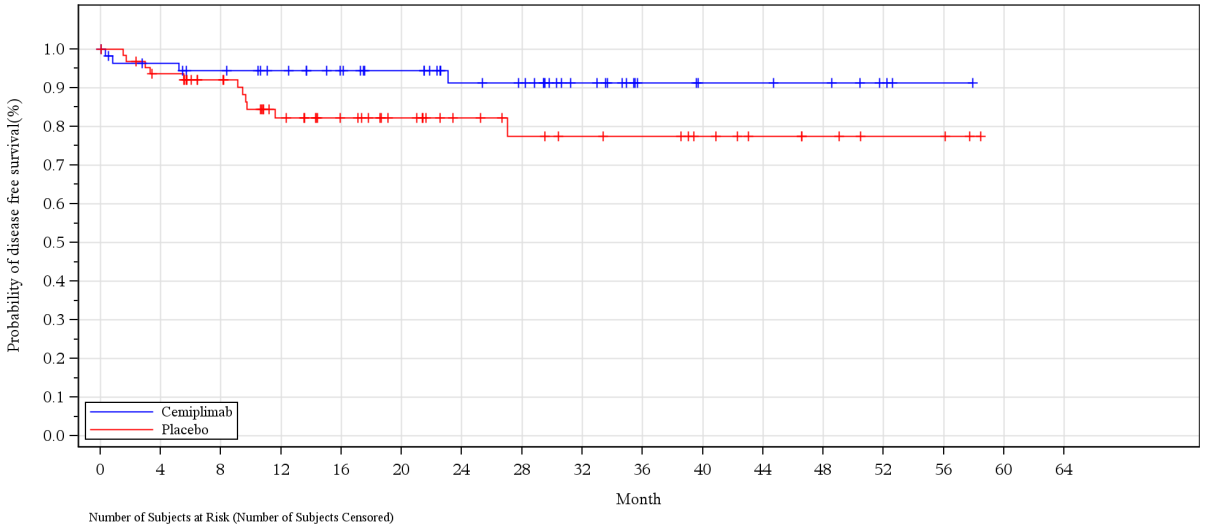
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	143 (7)	137 (12)	117 (32)	99 (50)	90 (57)	79 (67)	68 (78)	51 (95)	38 (108)	32 (113)	23 (122)	18 (128)	12 (133)	5 (140)	1 (144)	0 (145)
Placebo	141 (0)	124 (13)	108 (24)	86 (43)	72 (57)	57 (71)	52 (75)	42 (84)	32 (93)	23 (102)	17 (108)	17 (108)	15 (110)	6 (118)	3 (121)	2 (122)	0 (124)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: <65



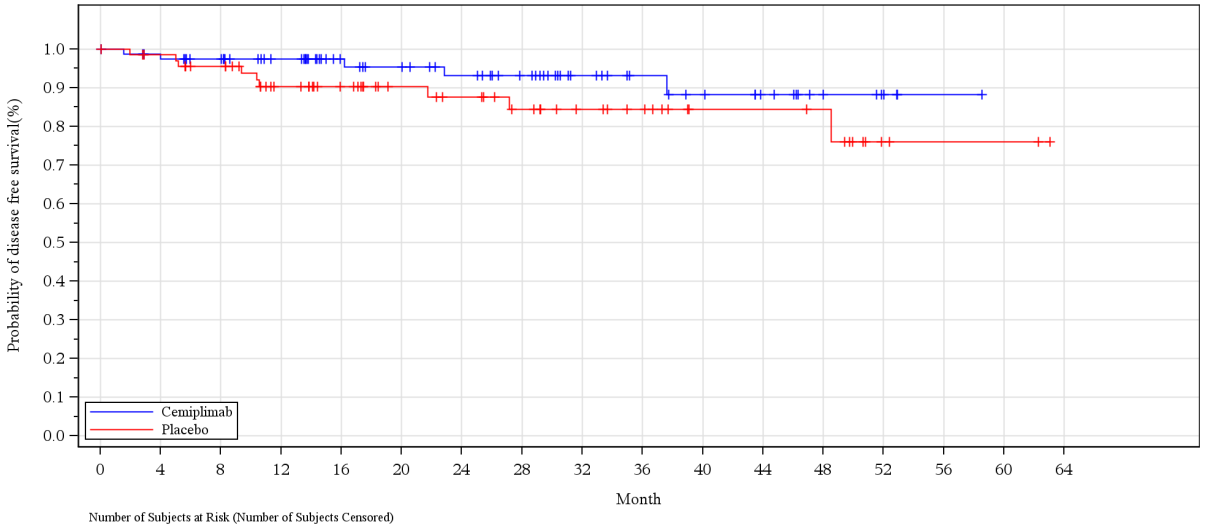
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	51 (3)	48 (5)	44 (9)	39 (14)	35 (18)	28 (24)	26 (26)	17 (35)	9 (43)	7 (45)	7 (45)	6 (46)	3 (49)	1 (51)	0 (52)	0 (52)
Placebo	65 (0)	58 (3)	50 (10)	38 (17)	31 (24)	25 (30)	19 (36)	16 (38)	14 (40)	13 (41)	10 (44)	7 (47)	5 (49)	3 (51)	3 (51)	0 (54)	0 (54)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



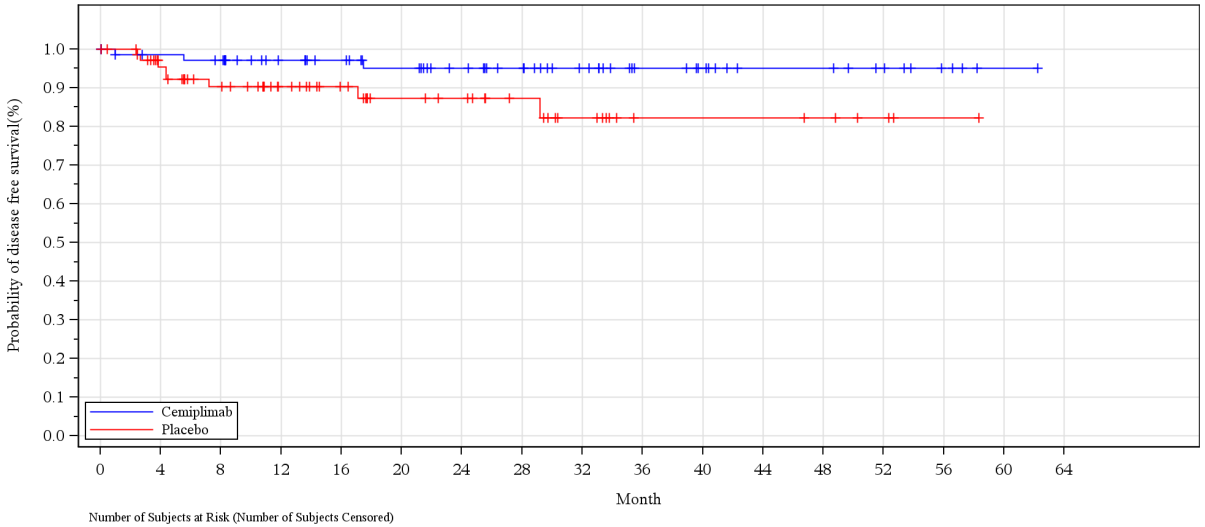
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	75 (3)	71 (7)	62 (16)	49 (29)	45 (32)	40 (36)	34 (42)	24 (52)	19 (57)	16 (59)	12 (63)	7 (69)	4 (71)	1 (74)	0 (75)	0 (75)
Placebo	69 (0)	65 (3)	60 (6)	48 (15)	41 (22)	33 (30)	30 (32)	25 (36)	20 (41)	17 (44)	11 (50)	11 (50)	10 (51)	3 (57)	2 (58)	2 (58)	0 (60)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Age group 2: >=75



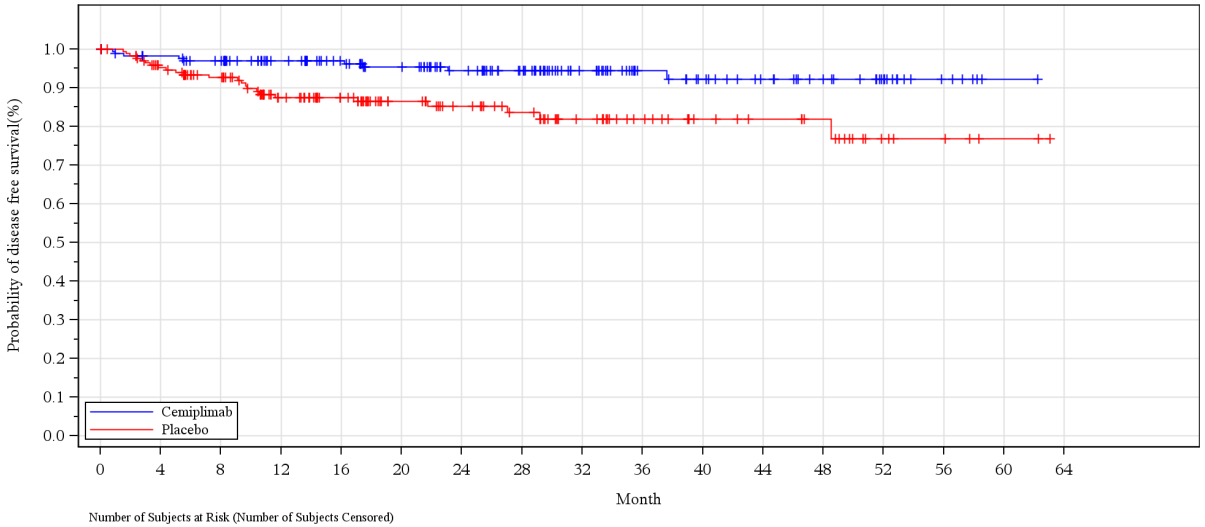
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	68 (4)	66 (5)	55 (16)	50 (21)	45 (25)	39 (31)	34 (36)	27 (43)	19 (51)	16 (54)	11 (59)	11 (59)	8 (62)	4 (66)	1 (69)	0 (70)
Placebo	72 (0)	59 (10)	48 (18)	38 (28)	31 (35)	24 (41)	22 (43)	17 (48)	12 (52)	6 (58)	6 (58)	6 (58)	5 (59)	3 (61)	1 (63)	0 (64)	0 (64)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Male



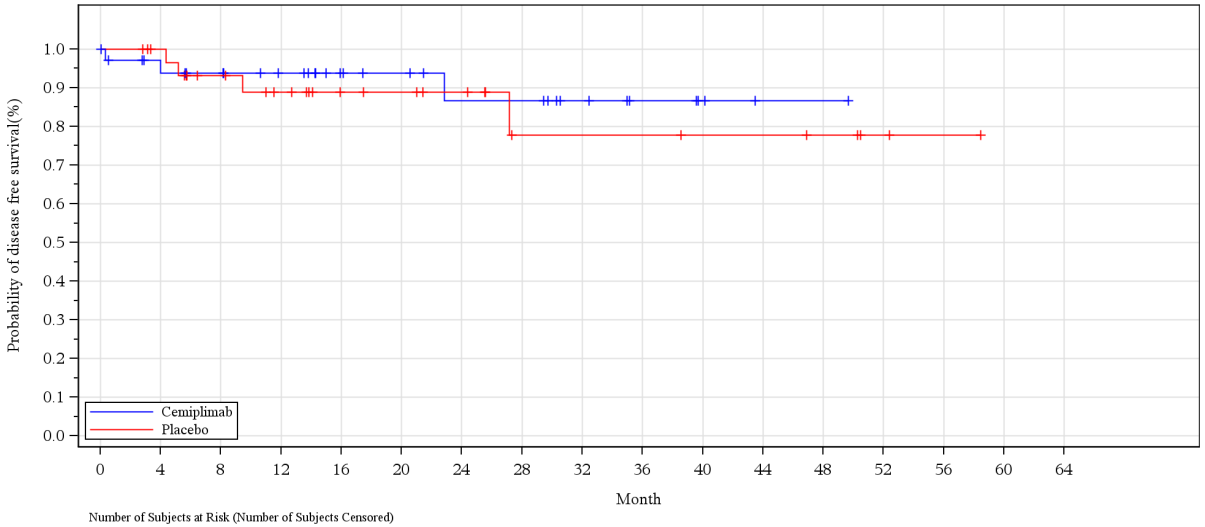
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	165 (6)	158 (11)	138 (31)	121 (48)	110 (57)	95 (71)	82 (84)	60 (106)	42 (124)	36 (129)	29 (136)	23 (143)	15 (150)	6 (159)	1 (164)	0 (165)
Placebo	174 (0)	153 (13)	135 (27)	105 (50)	89 (66)	69 (85)	60 (93)	52 (100)	40 (111)	30 (121)	22 (129)	19 (132)	16 (135)	7 (143)	5 (145)	2 (148)	0 (150)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Gender group: Female



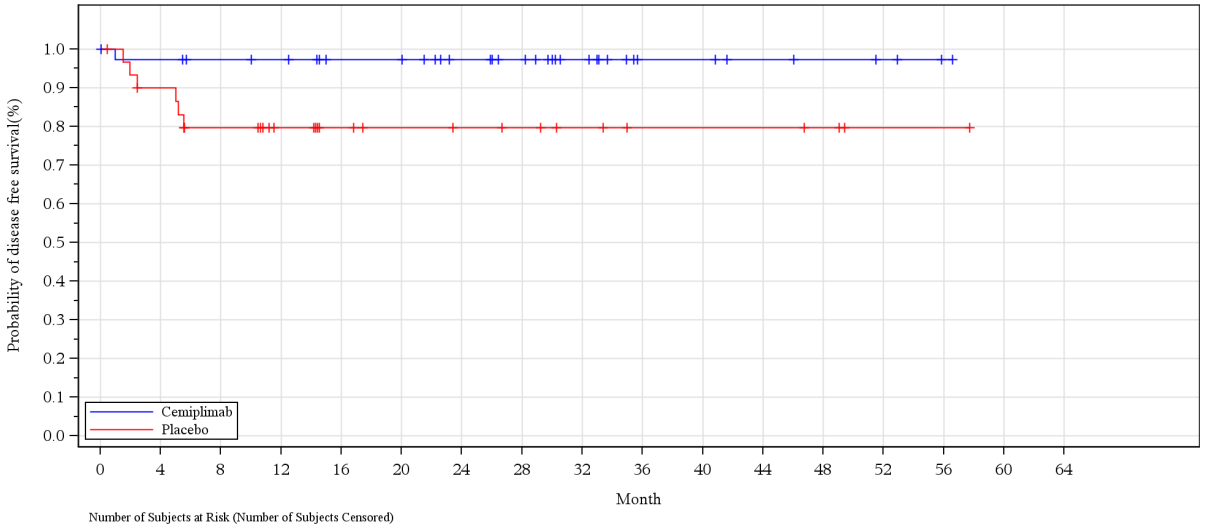
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	29 (4)	27 (6)	23 (10)	17 (16)	15 (18)	12 (20)	12 (20)	8 (24)	5 (27)	3 (29)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	32 (0)	29 (3)	23 (7)	19 (10)	14 (15)	13 (16)	11 (18)	6 (22)	6 (22)	6 (22)	5 (23)	5 (23)	4 (24)	2 (26)	1 (27)	0 (28)	0 (28)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



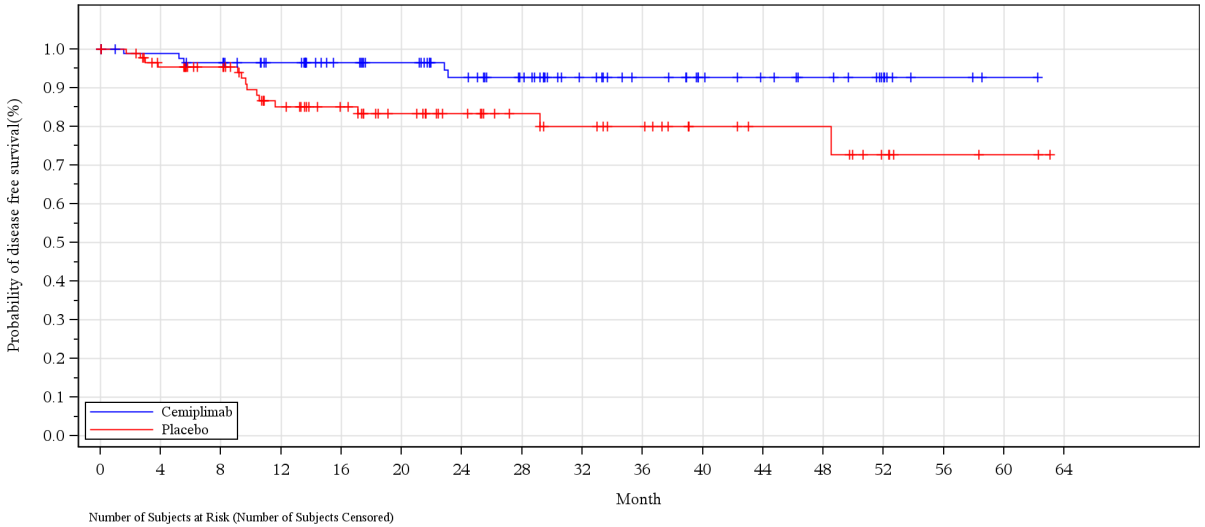
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	35 (1)	33 (3)	32 (4)	28 (8)	28 (8)	23 (13)	20 (16)	14 (22)	7 (29)	7 (29)	5 (31)	4 (32)	3 (33)	1 (35)	0 (36)	0 (36)
Placebo	31 (0)	26 (2)	21 (4)	16 (9)	12 (13)	10 (15)	9 (16)	8 (17)	6 (19)	4 (21)	4 (21)	4 (21)	3 (22)	1 (24)	1 (24)	0 (25)	0 (25)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



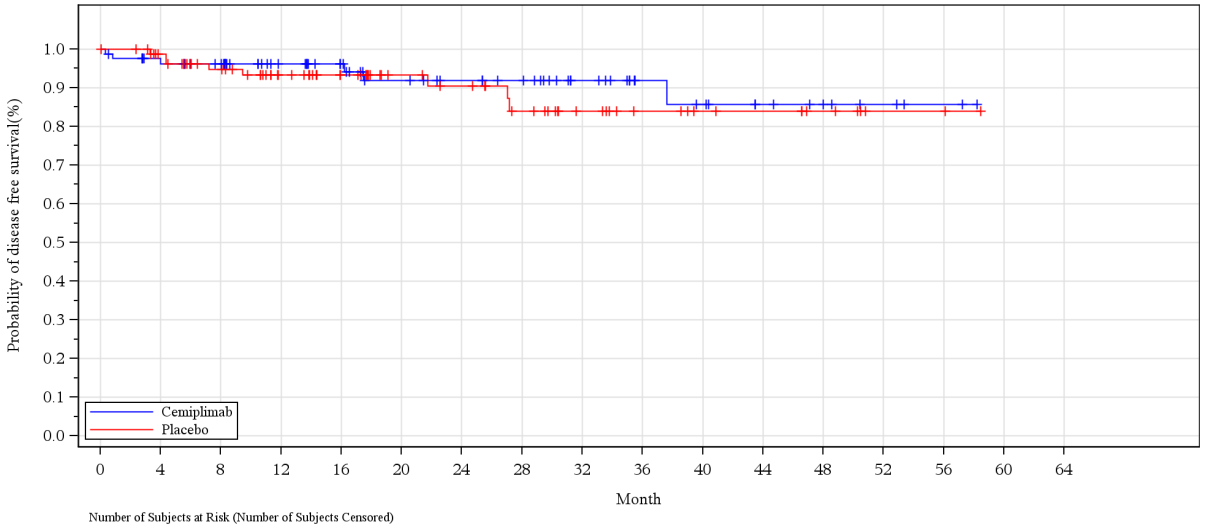
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	85 (4)	82 (5)	74 (13)	63 (24)	58 (29)	49 (36)	42 (43)	31 (54)	25 (60)	19 (66)	16 (69)	13 (72)	8 (77)	3 (82)	1 (84)	0 (85)
Placebo	90 (0)	79 (7)	71 (15)	55 (24)	47 (32)	38 (40)	31 (47)	25 (53)	22 (55)	19 (58)	13 (64)	11 (66)	11 (66)	6 (70)	3 (73)	2 (74)	0 (76)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



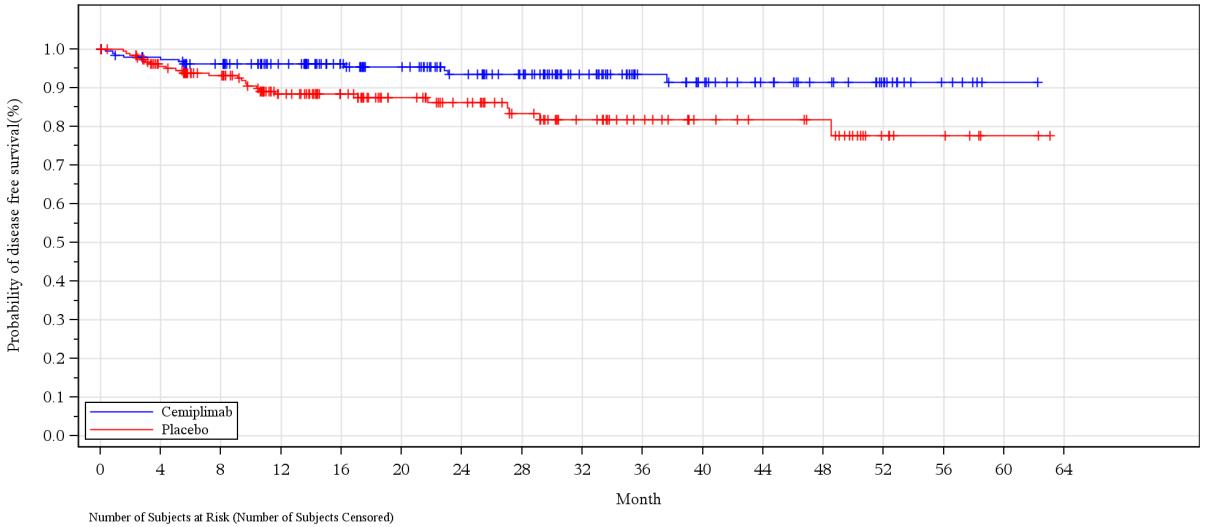
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	74 (5)	70 (9)	55 (24)	47 (32)	39 (38)	35 (42)	32 (45)	23 (54)	15 (62)	13 (63)	9 (67)	7 (70)	4 (72)	2 (74)	0 (76)	0 (76)
Placebo	85 (0)	77 (7)	66 (15)	53 (27)	44 (36)	34 (46)	31 (48)	25 (52)	18 (59)	13 (64)	10 (67)	9 (68)	6 (71)	2 (75)	2 (75)	0 (77)	0 (77)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: White



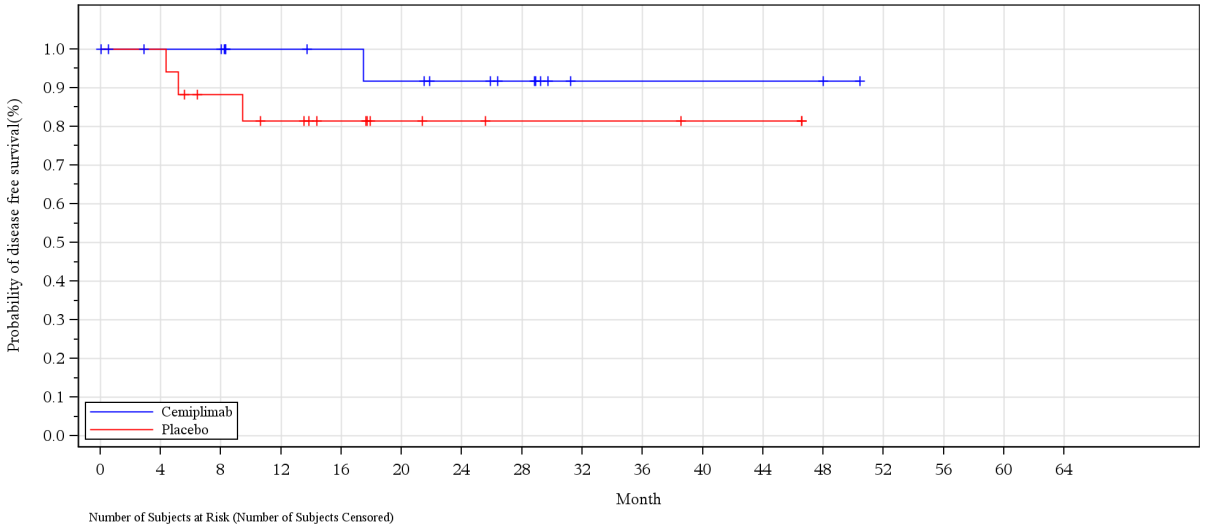
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	177 (7)	168 (14)	148 (34)	126 (56)	114 (67)	98 (81)	87 (92)	66 (113)	45 (134)	37 (141)	28 (150)	22 (156)	15 (163)	6 (172)	1 (177)	0 (178)
Placebo	189 (0)	165 (16)	145 (32)	113 (57)	95 (75)	77 (92)	67 (101)	55 (111)	43 (122)	33 (132)	25 (140)	22 (143)	20 (145)	9 (155)	6 (158)	2 (162)	0 (164)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Race: Non-white



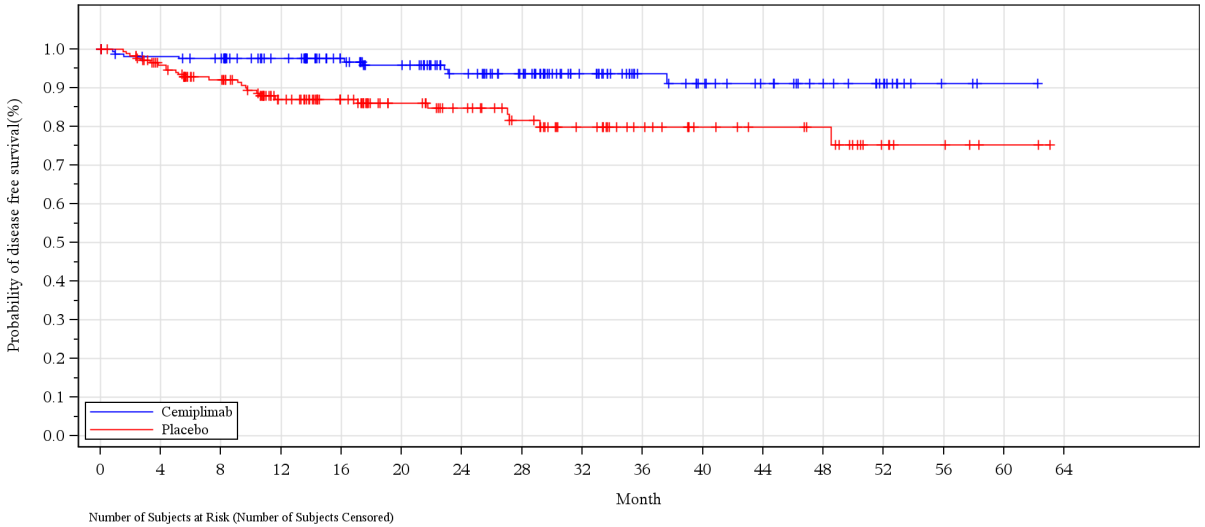
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	17 (3)	17 (3)	13 (7)	12 (8)	11 (8)	9 (10)	7 (12)	2 (17)	2 (17)	2 (17)	2 (17)	2 (18)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	17 (0)	17 (0)	13 (2)	11 (3)	8 (6)	5 (9)	4 (10)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



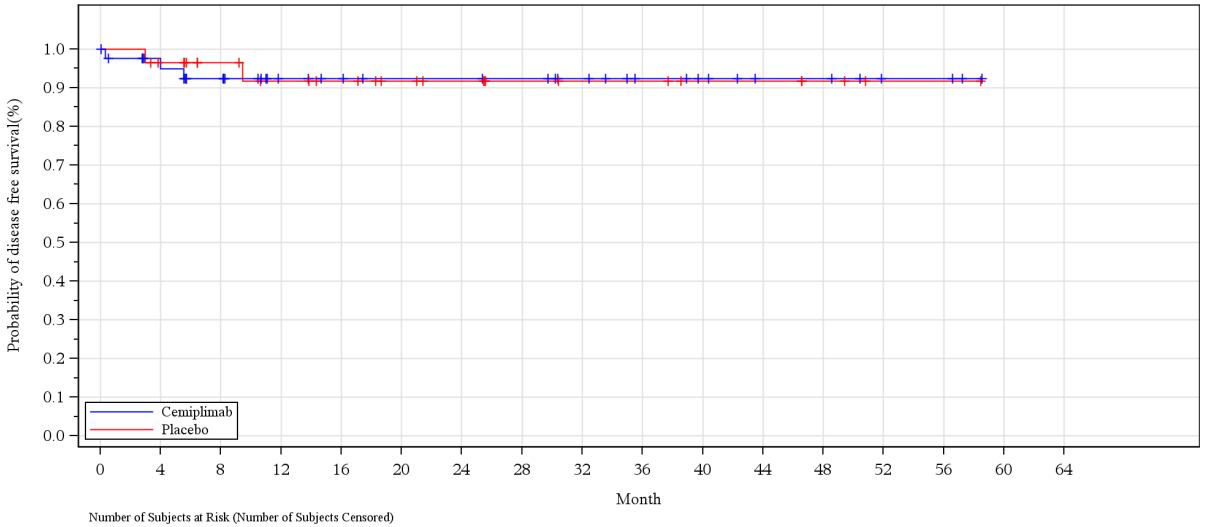
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	158 (5)	154 (8)	138 (24)	117 (45)	106 (54)	88 (70)	76 (82)	53 (105)	36 (122)	30 (127)	24 (133)	18 (140)	12 (145)	3 (154)	1 (156)	0 (157)
Placebo	177 (0)	156 (14)	137 (27)	106 (51)	87 (70)	69 (87)	60 (95)	50 (103)	39 (113)	29 (123)	22 (130)	19 (133)	17 (135)	8 (143)	5 (146)	2 (149)	0 (151)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



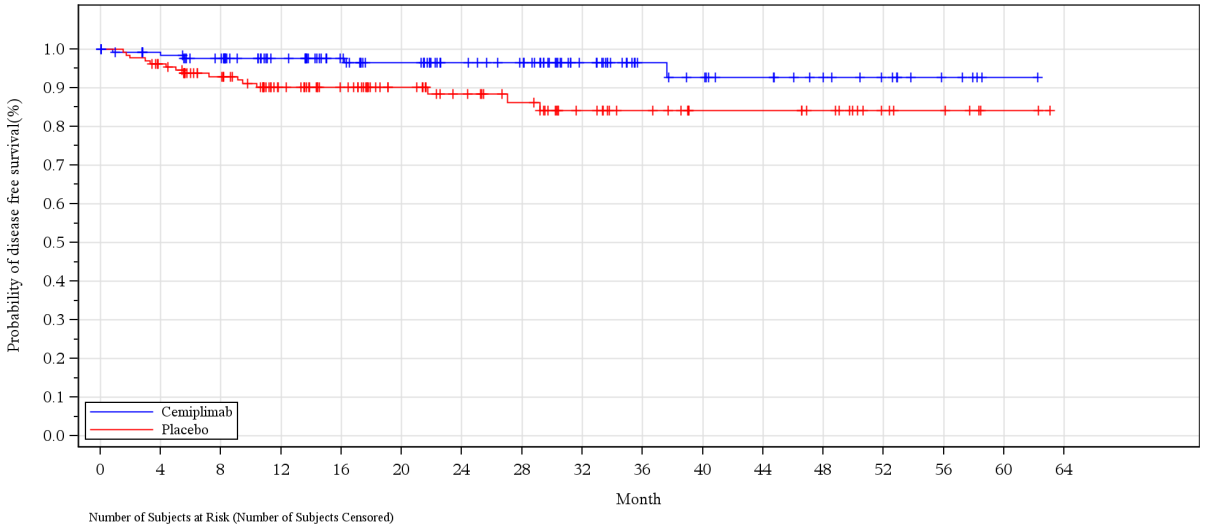
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	36 (5)	31 (9)	23 (17)	21 (19)	19 (21)	19 (21)	18 (22)	15 (25)	11 (29)	9 (31)	6 (34)	6 (34)	3 (37)	3 (37)	0 (40)	0 (40)
Placebo	29 (0)	26 (2)	21 (7)	18 (9)	16 (11)	13 (14)	11 (16)	8 (19)	7 (20)	7 (20)	5 (22)	5 (22)	3 (24)	1 (26)	1 (26)	0 (27)	0 (27)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 0



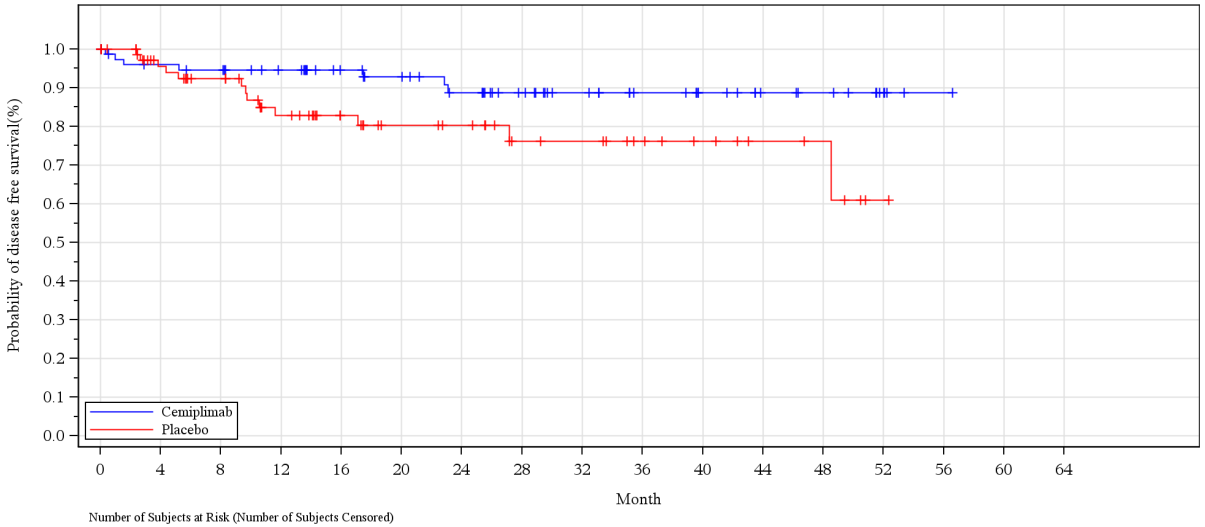
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	124 (7)	117 (13)	99 (31)	85 (45)	76 (53)	64 (65)	59 (70)	40 (89)	25 (104)	22 (106)	18 (110)	14 (115)	10 (118)	5 (123)	1 (127)	0 (128)
Placebo	131 (0)	122 (4)	105 (17)	83 (36)	71 (48)	56 (63)	47 (71)	41 (76)	30 (86)	24 (92)	18 (98)	18 (98)	15 (101)	8 (108)	6 (110)	2 (114)	0 (116)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	70 (3)	68 (4)	62 (10)	53 (19)	49 (22)	43 (26)	35 (34)	28 (41)	22 (47)	17 (52)	12 (57)	10 (59)	5 (64)	1 (68)	0 (69)	0 (69)
Placebo	75 (0)	60 (12)	53 (17)	41 (24)	32 (33)	26 (38)	24 (40)	17 (46)	16 (47)	12 (51)	9 (54)	6 (57)	5 (58)	1 (61)	0 (62)	0 (62)	0 (62)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
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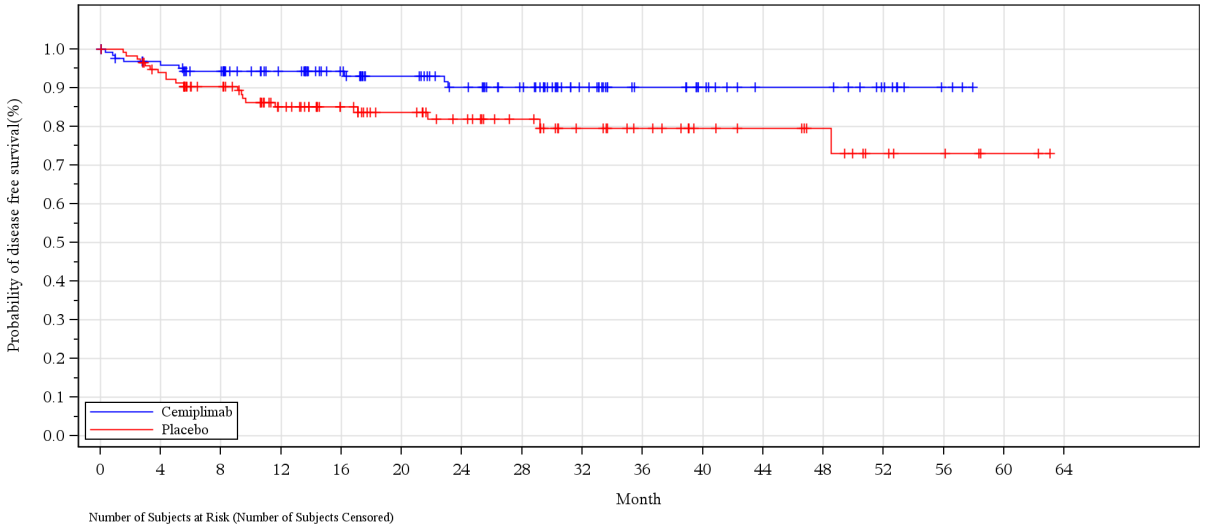
Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Nodal



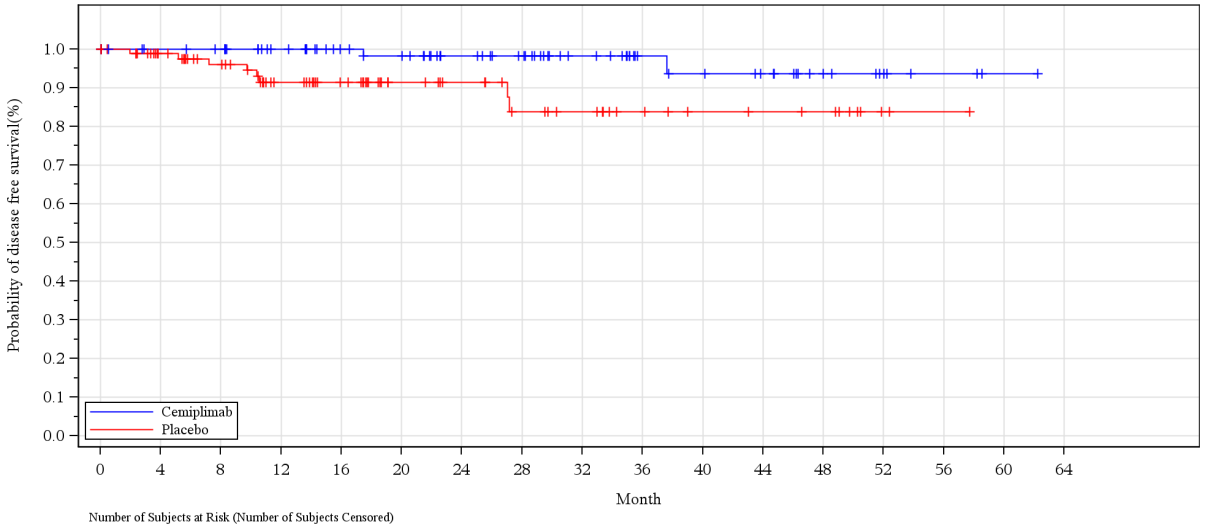
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	115 (5)	108 (10)	93 (25)	80 (38)	70 (47)	61 (54)	53 (62)	37 (78)	26 (89)	20 (95)	14 (101)	14 (101)	9 (106)	3 (112)	0 (115)	0 (115)
Placebo	117 (0)	106 (4)	92 (14)	73 (28)	60 (41)	51 (49)	44 (55)	37 (62)	28 (70)	23 (75)	17 (81)	15 (83)	12 (86)	7 (90)	5 (92)	2 (95)	0 (97)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

Figure 14.2.2.3.1 Kaplan-Meier Curve of Freedom from Distant Recurrence by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	79 (5)	77 (7)	68 (16)	58 (26)	55 (28)	46 (37)	41 (42)	31 (52)	21 (62)	19 (63)	16 (66)	10 (73)	6 (76)	3 (79)	1 (81)	0 (82)
Placebo	89 (0)	76 (12)	66 (20)	51 (32)	43 (40)	31 (52)	27 (56)	21 (60)	18 (63)	13 (68)	10 (71)	9 (72)	8 (73)	2 (79)	1 (80)	0 (81)	0 (81)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
Non-white includes not reported and unknown values.
'/home/wenju.shi/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-ffdr-sub.sas' (wenju.shi 04DEC2025 7:22 SAS Linux 9.4)

2.5 Zeit bis zur ersten Folgetherapie oder Tod

2.5.1 1. Datenschnitt

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Number of censored participants, n (%)	53 (94.6%)	46 (70.8%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0007	
HR (95% CI) [c][d]	0.152 (0.044, 0.527)	
Heterogeneity p-value [c][e]	0.6869	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	92.2 (82.2, 96.7)
6 months	100 (100, 100)	88.9 (78.1, 94.5)
12 months	95.6 (83.5, 98.9)	70.5 (56.7, 80.6)
18 months	95.6 (83.5, 98.9)	66.1 (51.8, 77.0)
24 months	95.6 (83.5, 98.9)	66.1 (51.8, 77.0)
30 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
36 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
42 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
48 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
54 months	NE (NE, NE)	66.1 (51.8, 77.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	33 (23.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	28 (19.9%)
Post Radiotherapy, n (%)	1 (0.7%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	6 (3.9%)	2 (1.4%)
Number of censored participants, n (%)	145 (94.8%)	108 (76.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	19.8 (9.3, 50.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.208 (0.095, 0.455)	
Heterogeneity p-value [c][e]	0.6869	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.3 (95.2, 99.9)	99.3 (94.8, 99.9)
6 months	97.8 (93.4, 99.3)	89.7 (82.9, 93.9)
12 months	96.1 (90.8, 98.4)	79.6 (71.1, 85.9)
18 months	96.1 (90.8, 98.4)	76.2 (67.0, 83.1)
24 months	94.8 (88.5, 97.7)	73.3 (63.5, 80.9)
30 months	93.4 (86.1, 96.9)	69.8 (59.2, 78.2)
36 months	91.3 (82.4, 95.8)	69.8 (59.2, 78.2)
42 months	91.3 (82.4, 95.8)	66.6 (54.5, 76.2)
48 months	91.3 (82.4, 95.8)	66.6 (54.5, 76.2)
54 months	91.3 (82.4, 95.8)	59.2 (40.7, 73.7)
60 months	91.3 (82.4, 95.8)	59.2 (40.7, 73.7)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Number of censored participants, n (%)	53 (94.6%)	46 (70.8%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0007	
HR (95% CI) [c][d]	0.152 (0.044, 0.527)	
Heterogeneity p-value [c][e]	0.6480	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	92.2 (82.2, 96.7)
6 months	100 (100, 100)	88.9 (78.1, 94.5)
12 months	95.6 (83.5, 98.9)	70.5 (56.7, 80.6)
18 months	95.6 (83.5, 98.9)	66.1 (51.8, 77.0)
24 months	95.6 (83.5, 98.9)	66.1 (51.8, 77.0)
30 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
36 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
42 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
48 months	91.3 (73.6, 97.3)	66.1 (51.8, 77.0)
54 months	NE (NE, NE)	66.1 (51.8, 77.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	17 (24.6%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	4 (5.0%)	1 (1.4%)
Number of censored participants, n (%)	75 (93.8%)	52 (75.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	24.7 (10.3, 50.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Stratified log-rank test p-value [b][c]	0.0064	
HR (95% CI) [c][d]	0.266 (0.096, 0.735)	
Heterogeneity p-value [c][e]	0.6480	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.1, 99.8)	98.5 (89.7, 99.8)
6 months	95.9 (87.7, 98.6)	90.6 (80.2, 95.7)
12 months	94.2 (85.3, 97.8)	85.3 (73.5, 92.1)
18 months	94.2 (85.3, 97.8)	81.0 (68.1, 89.1)
24 months	94.2 (85.3, 97.8)	76.0 (61.7, 85.5)
30 months	91.6 (80.3, 96.6)	69.9 (54.1, 81.2)
36 months	91.6 (80.3, 96.6)	69.9 (54.1, 81.2)
42 months	91.6 (80.3, 96.6)	64.5 (46.1, 78.0)
48 months	91.6 (80.3, 96.6)	64.5 (46.1, 78.0)
54 months	91.6 (80.3, 96.6)	51.6 (24.2, 73.4)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	16 (22.2%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	14 (19.4%)
Post Radiotherapy, n (%)	0	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	1 (1.4%)
Number of censored participants, n (%)	70 (95.9%)	56 (77.8%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	9.3 (7.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0004	
HR (95% CI) [c][d]	0.108 (0.024, 0.474)	
Heterogeneity p-value [c][e]	0.6480	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	88.8 (77.8, 94.5)
12 months	98.1 (87.4, 99.7)	73.6 (60.0, 83.3)
18 months	98.1 (87.4, 99.7)	70.7 (56.2, 81.2)
24 months	95.3 (82.1, 98.8)	70.7 (56.2, 81.2)
30 months	95.3 (82.1, 98.8)	70.7 (56.2, 81.2)
36 months	91.2 (73.7, 97.2)	70.7 (56.2, 81.2)
42 months	91.2 (73.7, 97.2)	70.7 (56.2, 81.2)
48 months	91.2 (73.7, 97.2)	70.7 (56.2, 81.2)
54 months	91.2 (73.7, 97.2)	70.7 (56.2, 81.2)
60 months	91.2 (73.7, 97.2)	70.7 (56.2, 81.2)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	9 (5.2%)	40 (23.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	33 (19.0%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	7 (4.0%)	3 (1.7%)
Number of censored participants, n (%)	165 (94.8%)	134 (77.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	19.8 (9.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.191 (0.092, 0.395)	
Heterogeneity p-value [c][e]	0.7828	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (95.8, 99.9)	97.0 (92.9, 98.7)
6 months	98.8 (95.1, 99.7)	89.2 (83.2, 93.1)
12 months	96.6 (92.0, 98.6)	78.8 (71.1, 84.6)
18 months	96.6 (92.0, 98.6)	75.1 (66.8, 81.5)
24 months	95.6 (90.2, 98.0)	72.7 (64.1, 79.6)
30 months	93.0 (86.0, 96.6)	71.4 (62.4, 78.6)
36 months	91.0 (82.5, 95.5)	71.4 (62.4, 78.6)
42 months	91.0 (82.5, 95.5)	68.8 (58.6, 77.0)
48 months	91.0 (82.5, 95.5)	68.8 (58.6, 77.0)
54 months	91.0 (82.5, 95.5)	61.9 (44.9, 75.1)
60 months	91.0 (82.5, 95.5)	61.9 (44.9, 75.1)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	12 (37.5%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	0
Number of censored participants, n (%)	33 (94.3%)	20 (62.5%)
Q1 (95% CI), (months)[a]	NR (11.4, NE)	7.1 (4.7, 27.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (9.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0387	
HR (95% CI) [c][d]	0.226 (0.049, 1.047)	
Heterogeneity p-value [c][e]	0.7828	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.9 (79.8, 99.6)
6 months	96.2 (75.7, 99.4)	90.5 (73.4, 96.8)
12 months	91.3 (69.3, 97.8)	66.8 (47.0, 80.7)
18 months	91.3 (69.3, 97.8)	62.7 (42.5, 77.5)
24 months	91.3 (69.3, 97.8)	62.7 (42.5, 77.5)
30 months	91.3 (69.3, 97.8)	53.7 (29.8, 72.7)
36 months	91.3 (69.3, 97.8)	53.7 (29.8, 72.7)
42 months	91.3 (69.3, 97.8)	53.7 (29.8, 72.7)
48 months	91.3 (69.3, 97.8)	53.7 (29.8, 72.7)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	7 (22.6%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	1 (3.2%)
Number of censored participants, n (%)	36 (97.3%)	24 (77.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.3 (5.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0057	
HR (95% CI) [c][d]	0.092 (0.011, 0.755)	
Heterogeneity p-value [c][e]	0.7432	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	93.5 (76.6, 98.3)
6 months	97.1 (81.4, 99.6)	89.7 (71.1, 96.6)
12 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
18 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
24 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
30 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
36 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
42 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
48 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
54 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
60 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	7 (7.8%)	28 (31.1%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	22 (24.4%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Number of censored participants, n (%)	83 (92.2%)	62 (68.9%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	10.3 (7.0, 24.7)
Median (95% CI), (months)[a]	NR (NE, NE)	50.1 (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.214 (0.093, 0.491)	
Heterogeneity p-value [c][e]	0.7432	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.8, 99.8)	96.5 (89.5, 98.9)
6 months	98.8 (91.8, 99.8)	86.9 (77.6, 92.5)
12 months	96.1 (88.4, 98.7)	74.5 (63.2, 82.8)
18 months	96.1 (88.4, 98.7)	67.5 (55.2, 77.1)
24 months	94.0 (84.4, 97.8)	65.5 (52.9, 75.5)
30 months	89.1 (76.6, 95.2)	63.3 (50.3, 73.7)
36 months	86.1 (71.8, 93.4)	63.3 (50.3, 73.7)
42 months	86.1 (71.8, 93.4)	59.6 (45.2, 71.3)
48 months	86.1 (71.8, 93.4)	59.6 (45.2, 71.3)
54 months	86.1 (71.8, 93.4)	49.6 (27.9, 68.1)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	3 (3.7%)	17 (20.0%)
Received Cemiplimab in Part 2, n (%)	0	17 (20.0%)
Post Radiotherapy, n (%)	1 (1.2%)	0
Post Other Systemic Therapy, n (%)	2 (2.4%)	0
Number of censored participants, n (%)	79 (96.3%)	68 (80.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	27.5 (7.6, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0015	
HR (95% CI) [c][d]	0.172 (0.050, 0.586)	
Heterogeneity p-value [c][e]	0.7432	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	98.8 (91.6, 99.8)
6 months	98.4 (89.4, 99.8)	92.0 (83.0, 96.3)
12 months	94.8 (84.6, 98.3)	80.0 (68.4, 87.6)
18 months	94.8 (84.6, 98.3)	78.3 (66.4, 86.3)
24 months	94.8 (84.6, 98.3)	75.4 (62.3, 84.4)
30 months	94.8 (84.6, 98.3)	71.4 (56.3, 82.1)
36 months	94.8 (84.6, 98.3)	71.4 (56.3, 82.1)
42 months	94.8 (84.6, 98.3)	71.4 (56.3, 82.1)
48 months	94.8 (84.6, 98.3)	71.4 (56.3, 82.1)
54 months	94.8 (84.6, 98.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	11 (5.8%)	48 (25.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	41 (21.7%)
Post Radiotherapy, n (%)	2 (1.1%)	4 (2.1%)
Post Other Systemic Therapy, n (%)	8 (4.2%)	3 (1.6%)
Number of censored participants, n (%)	178 (94.2%)	141 (74.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.3 (8.3, 37.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.191 (0.099, 0.370)	
Heterogeneity p-value [c][e]	0.9878	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (96.1, 99.9)	96.7 (92.7, 98.5)
6 months	98.3 (94.7, 99.4)	88.4 (82.5, 92.3)
12 months	95.5 (90.8, 97.9)	76.3 (68.8, 82.2)
18 months	95.5 (90.8, 97.9)	72.9 (65.0, 79.3)
24 months	94.5 (89.2, 97.3)	70.8 (62.6, 77.6)
30 months	92.3 (85.8, 95.9)	68.2 (59.4, 75.5)
36 months	90.6 (82.9, 94.9)	68.2 (59.4, 75.5)
42 months	90.6 (82.9, 94.9)	66.0 (56.3, 74.0)
48 months	90.6 (82.9, 94.9)	66.0 (56.3, 74.0)
54 months	90.6 (82.9, 94.9)	60.5 (46.1, 72.2)
60 months	90.6 (82.9, 94.9)	60.5 (46.1, 72.2)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	0	4 (23.5%)
Received Cemiplimab in Part 2, n (%)	0	4 (23.5%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	0	0
Number of censored participants, n (%)	20 (100%)	13 (76.5%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.3 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (12.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.1354	
HR (95% CI) [c][d]	NE (NE, NE)	
Heterogeneity p-value [c][e]	0.9878	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	100 (100, 100)
12 months	100 (100, 100)	80.4 (50.6, 93.2)
18 months	100 (100, 100)	72.3 (41.5, 88.7)
24 months	100 (100, 100)	72.3 (41.5, 88.7)
30 months	100 (100, 100)	72.3 (41.5, 88.7)
36 months	100 (100, 100)	72.3 (41.5, 88.7)
42 months	100 (100, 100)	72.3 (41.5, 88.7)
48 months	100 (100, 100)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	7 (4.2%)	43 (24.3%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	36 (20.3%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	5 (3.0%)	3 (1.7%)
Number of censored participants, n (%)	159 (95.8%)	134 (75.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	18.0 (9.3, 37.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.147 (0.066, 0.327)	
Heterogeneity p-value [c][e]	0.3477	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (95.6, 99.9)	97.0 (93.0, 98.8)
6 months	99.4 (95.6, 99.9)	90.1 (84.3, 93.8)
12 months	97.9 (93.6, 99.3)	77.8 (70.2, 83.8)
18 months	97.9 (93.6, 99.3)	74.2 (66.0, 80.7)
24 months	96.7 (91.2, 98.8)	71.8 (63.2, 78.8)
30 months	93.9 (86.4, 97.3)	69.0 (59.7, 76.5)
36 months	91.7 (82.1, 96.2)	69.0 (59.7, 76.5)
42 months	91.7 (82.1, 96.2)	66.5 (56.1, 74.9)
48 months	91.7 (82.1, 96.2)	66.5 (56.1, 74.9)
54 months	91.7 (82.1, 96.2)	60.5 (44.8, 72.9)
60 months	91.7 (82.1, 96.2)	60.5 (44.8, 72.9)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	4 (9.3%)	9 (31.0%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	3 (7.0%)	0
Number of censored participants, n (%)	39 (90.7%)	20 (69.0%)
Q1 (95% CI), (months)[a]	NR (9.0, NE)	7.2 (4.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.6, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0461	
HR (95% CI) [c][d]	0.318 (0.097, 1.041)	
Heterogeneity p-value [c][e]	0.3477	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.4 (77.2, 99.5)
6 months	94.0 (78.1, 98.5)	85.3 (65.4, 94.2)
12 months	86.8 (68.3, 94.9)	69.8 (48.5, 83.6)
18 months	86.8 (68.3, 94.9)	65.1 (43.4, 80.2)
24 months	86.8 (68.3, 94.9)	65.1 (43.4, 80.2)
30 months	86.8 (68.3, 94.9)	65.1 (43.4, 80.2)
36 months	86.8 (68.3, 94.9)	65.1 (43.4, 80.2)
42 months	86.8 (68.3, 94.9)	65.1 (43.4, 80.2)
48 months	86.8 (68.3, 94.9)	65.1 (43.4, 80.2)
54 months	86.8 (68.3, 94.9)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	7 (5.3%)	26 (19.8%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	23 (17.6%)
Post Radiotherapy, n (%)	2 (1.5%)	0
Post Other Systemic Therapy, n (%)	4 (3.0%)	3 (2.3%)
Number of censored participants, n (%)	126 (94.7%)	105 (80.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	23.1 (8.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0002	
HR (95% CI) [c][d]	0.229 (0.099, 0.530)	
Heterogeneity p-value [c][e]	0.2589	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.8 (91.7, 98.8)
6 months	99.1 (93.7, 99.9)	92.5 (86.1, 96.0)
12 months	95.9 (89.5, 98.5)	80.2 (71.5, 86.6)
18 months	95.9 (89.5, 98.5)	77.9 (68.7, 84.7)
24 months	94.4 (86.8, 97.7)	74.7 (64.7, 82.3)
30 months	92.7 (84.2, 96.8)	74.7 (64.7, 82.3)
36 months	89.7 (78.1, 95.4)	74.7 (64.7, 82.3)
42 months	89.7 (78.1, 95.4)	74.7 (64.7, 82.3)
48 months	89.7 (78.1, 95.4)	74.7 (64.7, 82.3)
54 months	89.7 (78.1, 95.4)	74.7 (64.7, 82.3)
60 months	89.7 (78.1, 95.4)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	4 (5.3%)	26 (34.7%)
Received Cemiplimab in Part 2, n (%)	0	22 (29.3%)
Post Radiotherapy, n (%)	0	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	0
Number of censored participants, n (%)	72 (94.7%)	49 (65.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	10.0 (5.4, 18.0)
Median (95% CI), (months)[a]	NR (NE, NE)	50.1 (24.7, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.117 (0.041, 0.339)	
Heterogeneity p-value [c][e]	0.2589	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (90.5, 99.8)	97.2 (89.2, 99.3)
6 months	97.2 (89.2, 99.3)	83.9 (72.8, 90.7)
12 months	95.7 (87.2, 98.6)	70.3 (57.3, 80.0)
18 months	95.7 (87.2, 98.6)	64.0 (50.3, 74.9)
24 months	95.7 (87.2, 98.6)	64.0 (50.3, 74.9)
30 months	92.6 (80.1, 97.4)	58.2 (43.5, 70.4)
36 months	92.6 (80.1, 97.4)	58.2 (43.5, 70.4)
42 months	92.6 (80.1, 97.4)	54.1 (38.2, 67.5)
48 months	92.6 (80.1, 97.4)	54.1 (38.2, 67.5)
54 months	92.6 (80.1, 97.4)	36.0 (9.6, 64.1)
60 months	NE (NE, NE)	36.0 (9.6, 64.1)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	10 (8.0%)	30 (25.6%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	25 (21.4%)
Post Radiotherapy, n (%)	1 (0.8%)	3 (2.6%)
Post Other Systemic Therapy, n (%)	8 (6.4%)	2 (1.7%)
Number of censored participants, n (%)	115 (92.0%)	87 (74.4%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	12.3 (7.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0003	
HR (95% CI) [c][d]	0.288 (0.140, 0.593)	
Heterogeneity p-value [c][e]	0.0555	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.1 (94.0, 99.9)	97.3 (91.9, 99.1)
6 months	97.3 (91.8, 99.1)	87.9 (80.1, 92.8)
12 months	93.0 (85.7, 96.6)	75.4 (65.7, 82.7)
18 months	93.0 (85.7, 96.6)	71.3 (60.9, 79.3)
24 months	91.3 (83.0, 95.6)	69.5 (58.7, 78.0)
30 months	89.2 (79.6, 94.5)	69.5 (58.7, 78.0)
36 months	86.3 (74.5, 92.9)	69.5 (58.7, 78.0)
42 months	86.3 (74.5, 92.9)	69.5 (58.7, 78.0)
48 months	86.3 (74.5, 92.9)	69.5 (58.7, 78.0)
54 months	86.3 (74.5, 92.9)	60.8 (40.6, 76.0)
60 months	86.3 (74.5, 92.9)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	1 (1.2%)	22 (24.7%)
Received Cemiplimab in Part 2, n (%)	0	20 (22.5%)
Post Radiotherapy, n (%)	1 (1.2%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	0	1 (1.1%)
Number of censored participants, n (%)	83 (98.8%)	67 (75.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	13.3 (7.5, 37.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.037 (0.005, 0.276)	
Heterogeneity p-value [c][e]	0.0555	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.5 (89.5, 98.8)
6 months	100 (100, 100)	91.4 (82.8, 95.8)
12 months	100 (100, 100)	78.2 (66.8, 86.1)
18 months	100 (100, 100)	74.9 (63.0, 83.5)
24 months	100 (100, 100)	72.7 (60.3, 81.9)
30 months	97.7 (84.9, 99.7)	66.9 (52.7, 77.7)
36 months	97.7 (84.9, 99.7)	66.9 (52.7, 77.7)
42 months	97.7 (84.9, 99.7)	62.1 (45.7, 74.9)
48 months	97.7 (84.9, 99.7)	62.1 (45.7, 74.9)
54 months	97.7 (84.9, 99.7)	62.1 (45.7, 74.9)
60 months	NE (NE, NE)	62.1 (45.7, 74.9)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Number of censored participants, n (%)	53 (94.6%)	46 (70.8%)
Proportionality Test p-value[a][b]	0.1980	
Hazard ratio(interaction)	0.088 (0.002, 3.570)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	8 (5.2%)	33 (23.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	28 (19.9%)
Post Radiotherapy, n (%)	1 (0.7%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	6 (3.9%)	2 (1.4%)
Number of censored participants, n (%)	145 (94.8%)	108 (76.6%)
Proportionality Test p-value[a][b]	0.6091	
Hazard ratio(interaction)	0.769 (0.280, 2.108)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	3 (5.4%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Number of censored participants, n (%)	53 (94.6%)	46 (70.8%)
Proportionality Test p-value[a][b]	0.1980	
Hazard ratio(interaction)	0.088 (0.002, 3.570)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	5 (6.3%)	17 (24.6%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	4 (5.0%)	1 (1.4%)
Number of censored participants, n (%)	75 (93.8%)	52 (75.4%)
Proportionality Test p-value[a][b]	0.3197	
Hazard ratio(interaction)	1.962 (0.520, 7.403)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	3 (4.1%)	16 (22.2%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	14 (19.4%)
Post Radiotherapy, n (%)	0	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	1 (1.4%)
Number of censored participants, n (%)	70 (95.9%)	56 (77.8%)
Proportionality Test p-value[a][b]	NE	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	9 (5.2%)	40 (23.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	33 (19.0%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	7 (4.0%)	3 (1.7%)
Number of censored participants, n (%)	165 (94.8%)	134 (77.0%)
Proportionality Test p-value[a][b]	0.1966	
Hazard ratio(interaction)	0.533 (0.205, 1.385)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	12 (37.5%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	0
Number of censored participants, n (%)	33 (94.3%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.6687	
Hazard ratio(interaction)	0.587 (0.051, 6.717)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	7 (22.6%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	1 (3.2%)
Number of censored participants, n (%)	36 (97.3%)	24 (77.4%)
Proportionality Test p-value[a][b]	0.4836	
Hazard ratio(interaction)	4.302 (0.073, 255.03)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	7 (7.8%)	28 (31.1%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	22 (24.4%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Number of censored participants, n (%)	83 (92.2%)	62 (68.9%)
Proportionality Test p-value[a][b]	0.1877	
Hazard ratio(interaction)	0.480 (0.161, 1.430)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	3 (3.7%)	17 (20.0%)
Received Cemiplimab in Part 2, n (%)	0	17 (20.0%)
Post Radiotherapy, n (%)	1 (1.2%)	0
Post Other Systemic Therapy, n (%)	2 (2.4%)	0
Number of censored participants, n (%)	79 (96.3%)	68 (80.0%)
Proportionality Test p-value[a][b]	0.9894	
Hazard ratio(interaction)	0.986 (0.120, 8.094)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	11 (5.8%)	48 (25.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	41 (21.7%)
Post Radiotherapy, n (%)	2 (1.1%)	4 (2.1%)
Post Other Systemic Therapy, n (%)	8 (4.2%)	3 (1.6%)
Number of censored participants, n (%)	178 (94.2%)	141 (74.6%)
Proportionality Test p-value[a][b]	0.2019	
Hazard ratio(interaction)	0.569 (0.239, 1.353)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	0	4 (23.5%)
Received Cemiplimab in Part 2, n (%)	0	4 (23.5%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	0	0
Number of censored participants, n (%)	20 (100%)	13 (76.5%)
Proportionality Test p-value[a][b]	NE	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	7 (4.2%)	43 (24.3%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	36 (20.3%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	5 (3.0%)	3 (1.7%)
Number of censored participants, n (%)	159 (95.8%)	134 (75.7%)
Proportionality Test p-value[a][b]	0.1434	
Hazard ratio(interaction)	0.447 (0.152, 1.314)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	4 (9.3%)	9 (31.0%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	3 (7.0%)	0
Number of censored participants, n (%)	39 (90.7%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.6844	
Hazard ratio(interaction)	0.576 (0.040, 8.256)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	7 (5.3%)	26 (19.8%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	23 (17.6%)
Post Radiotherapy, n (%)	2 (1.5%)	0
Post Other Systemic Therapy, n (%)	4 (3.0%)	3 (2.3%)
Number of censored participants, n (%)	126 (94.7%)	105 (80.2%)
Proportionality Test p-value[a][b]	0.0191	
Hazard ratio(interaction)	0.137 (0.026, 0.723)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	4 (5.3%)	26 (34.7%)
Received Cemiplimab in Part 2, n (%)	0	22 (29.3%)
Post Radiotherapy, n (%)	0	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	0
Number of censored participants, n (%)	72 (94.7%)	49 (65.3%)
Proportionality Test p-value[a][b]	0.4246	
Hazard ratio(interaction)	1.820 (0.418, 7.921)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	10 (8.0%)	30 (25.6%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	25 (21.4%)
Post Radiotherapy, n (%)	1 (0.8%)	3 (2.6%)
Post Other Systemic Therapy, n (%)	8 (6.4%)	2 (1.7%)
Number of censored participants, n (%)	115 (92.0%)	87 (74.4%)
Proportionality Test p-value[a][b]	0.1839	
Hazard ratio(interaction)	0.503 (0.183, 1.386)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

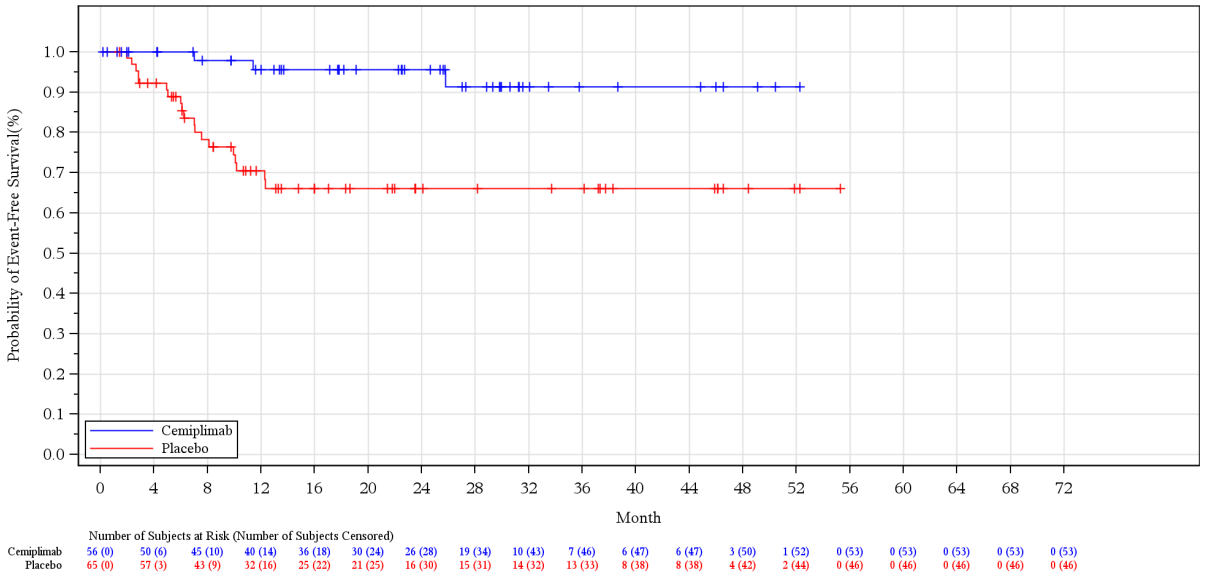
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	1 (1.2%)	22 (24.7%)
Received Cemiplimab in Part 2, n (%)	0	20 (22.5%)
Post Radiotherapy, n (%)	1 (1.2%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	0	1 (1.1%)
Number of censored participants, n (%)	83 (98.8%)	67 (75.3%)
Proportionality Test p-value[a][b]	0.3233	
Hazard ratio(interaction)	0.088 (0.001, 10.965)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65



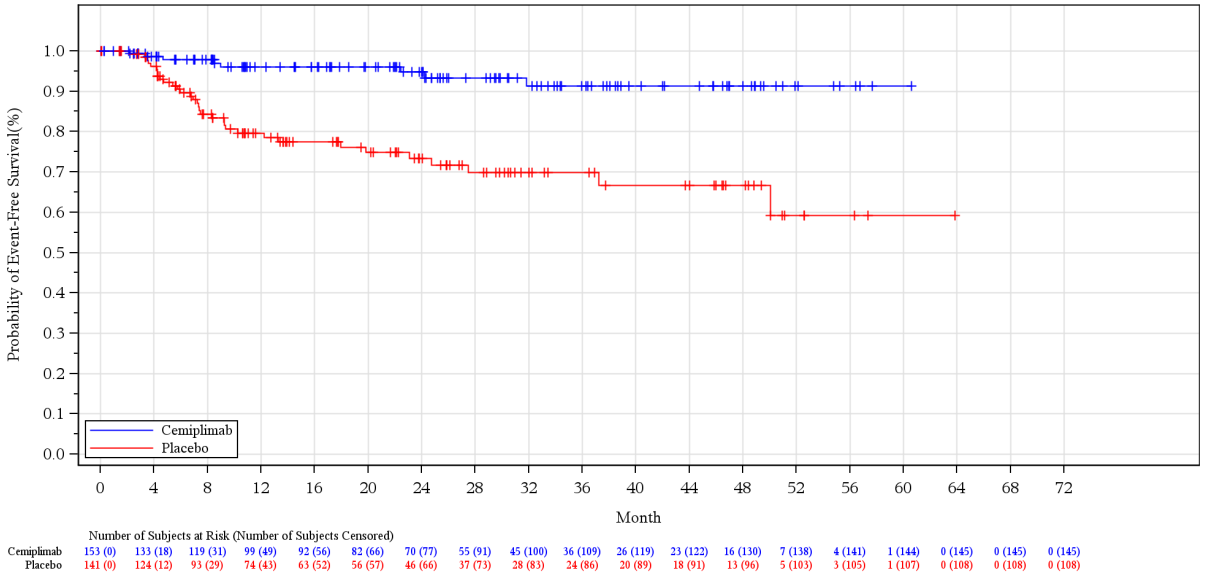
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	50 (6)	45 (10)	40 (14)	36 (18)	30 (24)	26 (28)	19 (34)	10 (43)	7 (46)	6 (47)	6 (47)	3 (50)	1 (52)	0 (53)	0 (53)	0 (53)	0 (53)	0 (53)
Placebo	65 (0)	57 (3)	43 (9)	32 (16)	25 (22)	21 (25)	16 (30)	15 (31)	14 (32)	13 (33)	8 (38)	8 (38)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	133 (18)	119 (31)	99 (49)	92 (56)	82 (66)	70 (77)	55 (91)	45 (100)	36 (109)	26 (119)	23 (122)	16 (130)	7 (138)	4 (141)	1 (144)	0 (145)	0 (145)	0 (145)
Placebo	141 (0)	124 (12)	93 (29)	74 (43)	63 (52)	56 (57)	46 (66)	37 (73)	28 (83)	24 (86)	20 (89)	18 (91)	13 (96)	5 (103)	3 (105)	1 (107)	0 (108)	0 (108)	0 (108)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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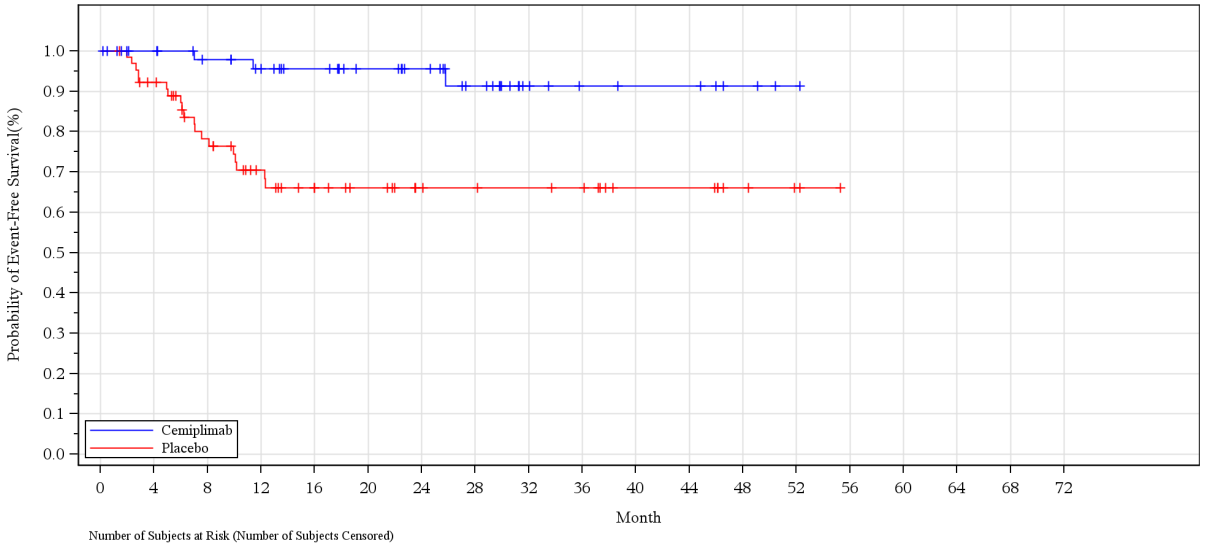
Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

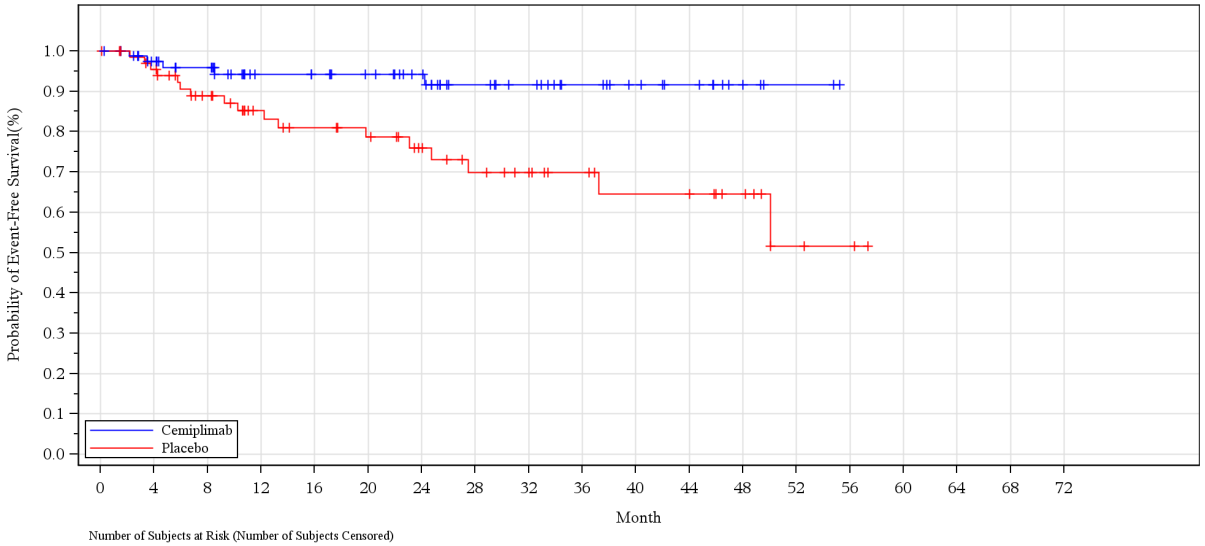
Cemiplimab	56 (0)	50 (6)	45 (10)	40 (14)	36 (18)	30 (24)	26 (28)	19 (34)	10 (43)	7 (46)	6 (47)	6 (47)	3 (50)	1 (52)	0 (53)	0 (53)	0 (53)	0 (53)	0 (53)
Placebo	65 (0)	57 (3)	43 (9)	32 (16)	25 (22)	21 (25)	16 (30)	15 (31)	14 (32)	13 (33)	8 (38)	8 (38)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



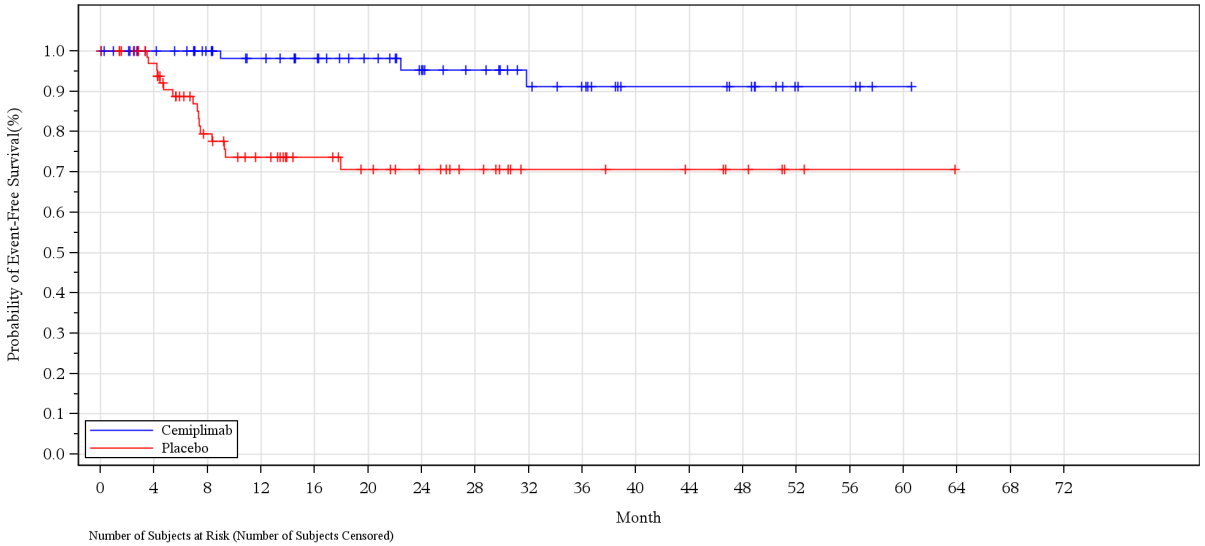
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	69 (9)	63 (14)	49 (27)	47 (29)	43 (33)	37 (39)	27 (48)	23 (52)	17 (58)	13 (62)	10 (65)	5 (71)	2 (73)	0 (75)	0 (75)	0 (75)	0 (75)	0 (75)
Placebo	69 (0)	62 (4)	51 (11)	40 (20)	36 (22)	33 (24)	27 (29)	22 (32)	19 (36)	15 (39)	12 (41)	11 (42)	8 (45)	3 (49)	2 (50)	0 (52)	0 (52)	0 (52)	0 (52)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

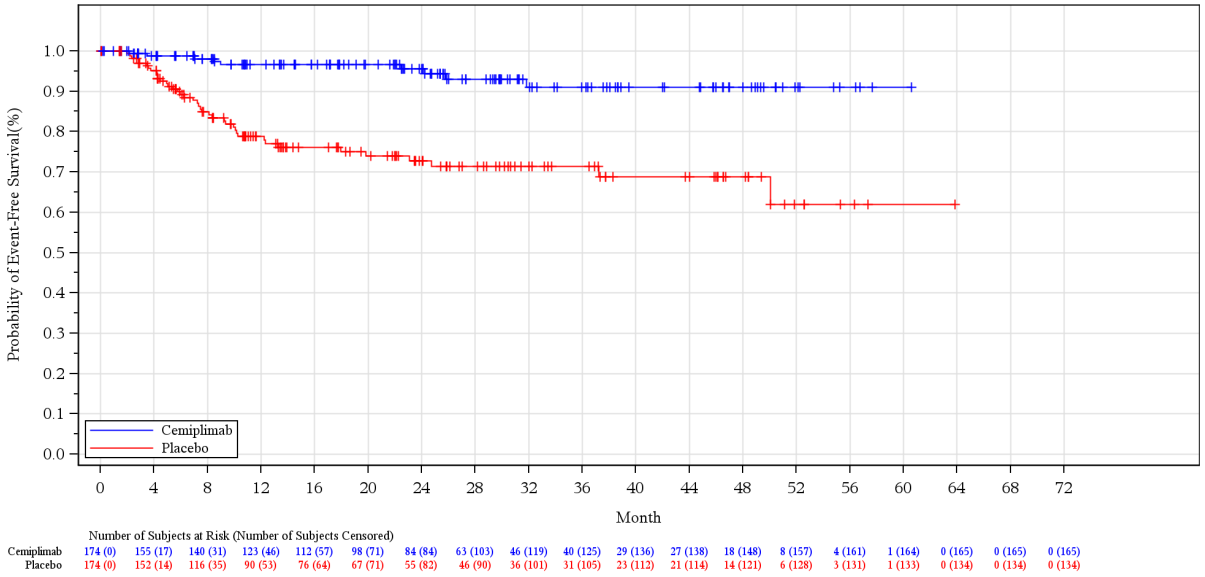
Cemiplimab	73 (0)	64 (9)	56 (17)	50 (22)	45 (27)	39 (33)	33 (38)	28 (43)	22 (48)	19 (51)	13 (57)	13 (57)	11 (59)	5 (65)	4 (66)	1 (69)	0 (70)	0 (70)	0 (70)
Placebo	72 (0)	62 (8)	42 (18)	34 (23)	27 (30)	23 (33)	19 (37)	15 (41)	9 (47)	9 (47)	8 (48)	7 (49)	5 (51)	2 (54)	1 (55)	1 (55)	0 (56)	0 (56)	0 (56)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

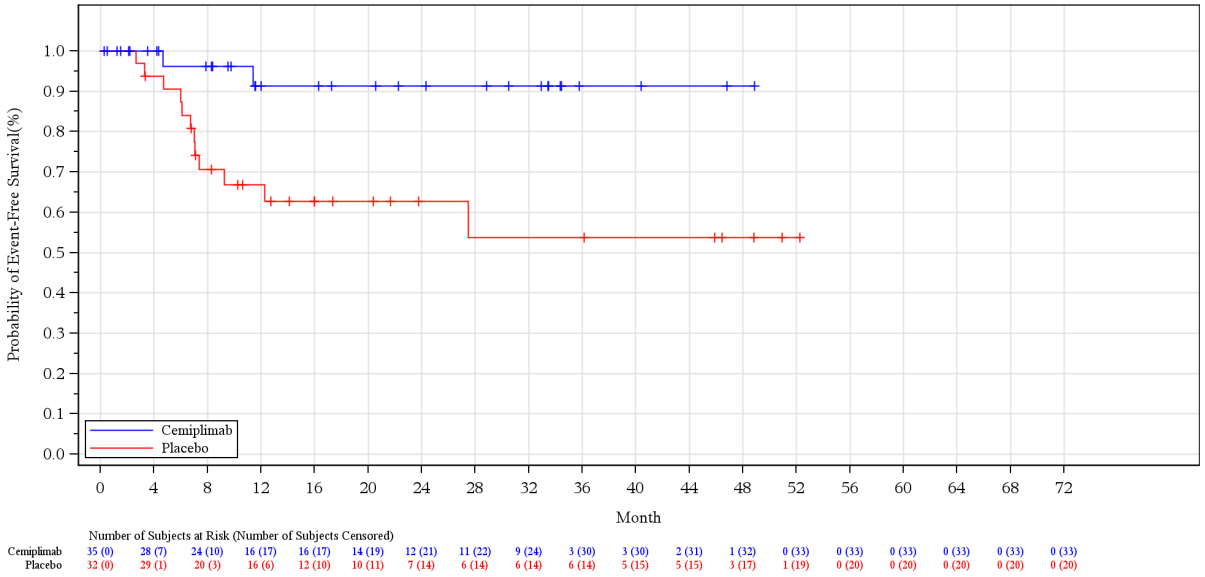
Cemiplimab	174 (0)	155 (17)	140 (31)	123 (46)	112 (57)	98 (71)	84 (84)	63 (103)	46 (119)	40 (125)	29 (136)	27 (138)	18 (148)	8 (157)	4 (161)	1 (164)	0 (165)	0 (165)	0 (165)
Placebo	174 (0)	152 (14)	116 (35)	90 (53)	76 (64)	67 (71)	55 (82)	46 (90)	36 (101)	31 (105)	23 (112)	21 (114)	14 (121)	6 (128)	3 (131)	1 (133)	0 (134)	0 (134)	0 (134)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

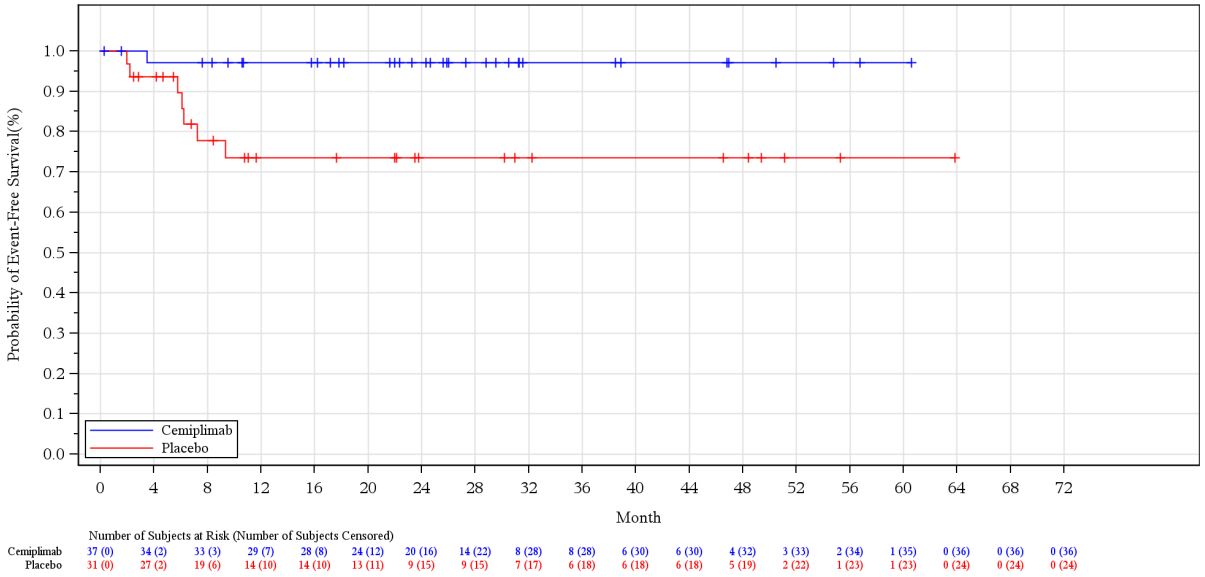
Cemiplimab	35 (0)	28 (7)	24 (10)	16 (17)	16 (17)	14 (19)	12 (21)	11 (22)	9 (24)	3 (30)	3 (30)	2 (31)	1 (32)	0 (33)	0 (33)	0 (33)	0 (33)	0 (33)	0 (33)
Placebo	32 (0)	29 (1)	20 (3)	16 (6)	12 (10)	10 (11)	7 (14)	6 (14)	6 (14)	6 (14)	5 (15)	5 (15)	3 (17)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

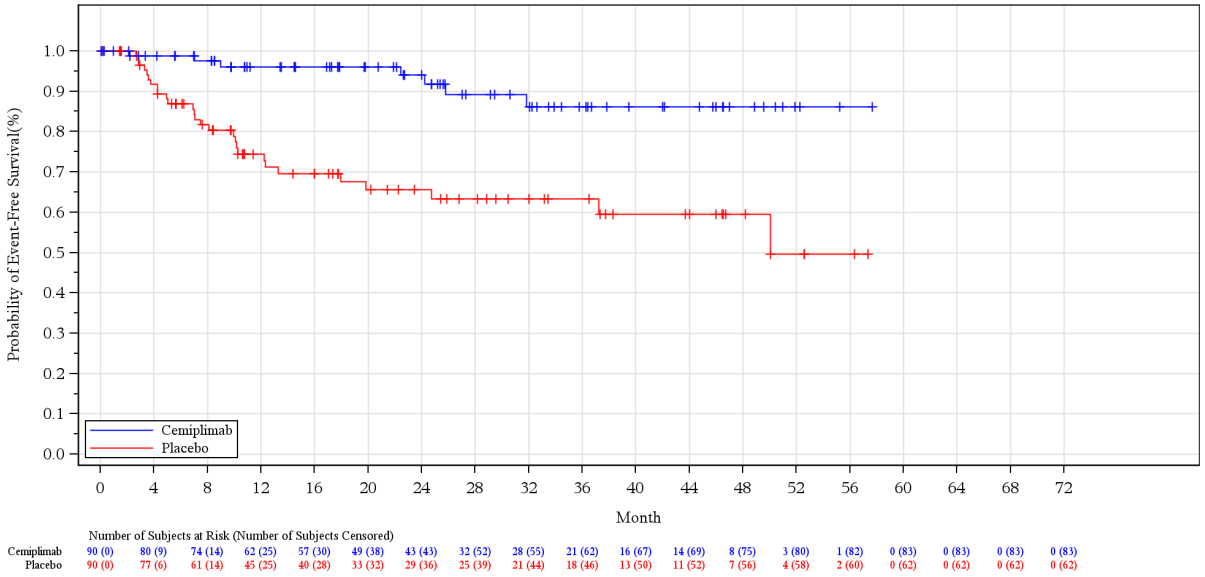
Cemiplimab	37 (0)	34 (2)	33 (3)	29 (7)	28 (8)	24 (12)	20 (16)	14 (22)	8 (28)	8 (28)	6 (30)	6 (30)	4 (32)	3 (33)	2 (34)	1 (35)	0 (36)	0 (36)	0 (36)
Placebo	31 (0)	27 (2)	19 (6)	14 (10)	14 (10)	13 (11)	9 (15)	9 (15)	7 (17)	6 (18)	6 (18)	6 (18)	5 (19)	2 (22)	1 (23)	1 (23)	0 (24)	0 (24)	0 (24)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

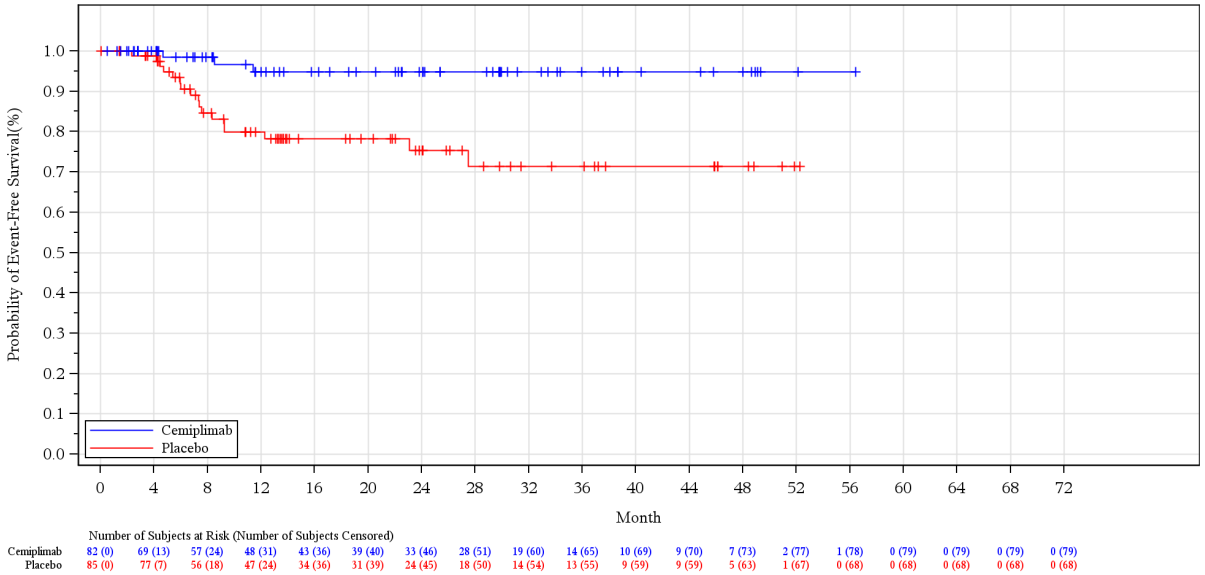
Cemiplimab	90 (0)	80 (9)	74 (14)	62 (25)	57 (30)	49 (38)	43 (43)	32 (52)	28 (55)	21 (62)	16 (67)	14 (69)	8 (75)	3 (80)	1 (82)	0 (83)	0 (83)	0 (83)	0 (83)
Placebo	90 (0)	77 (6)	61 (14)	45 (25)	40 (28)	33 (32)	29 (36)	25 (39)	21 (44)	18 (46)	13 (50)	11 (52)	7 (56)	4 (58)	2 (60)	0 (62)	0 (62)	0 (62)	0 (62)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

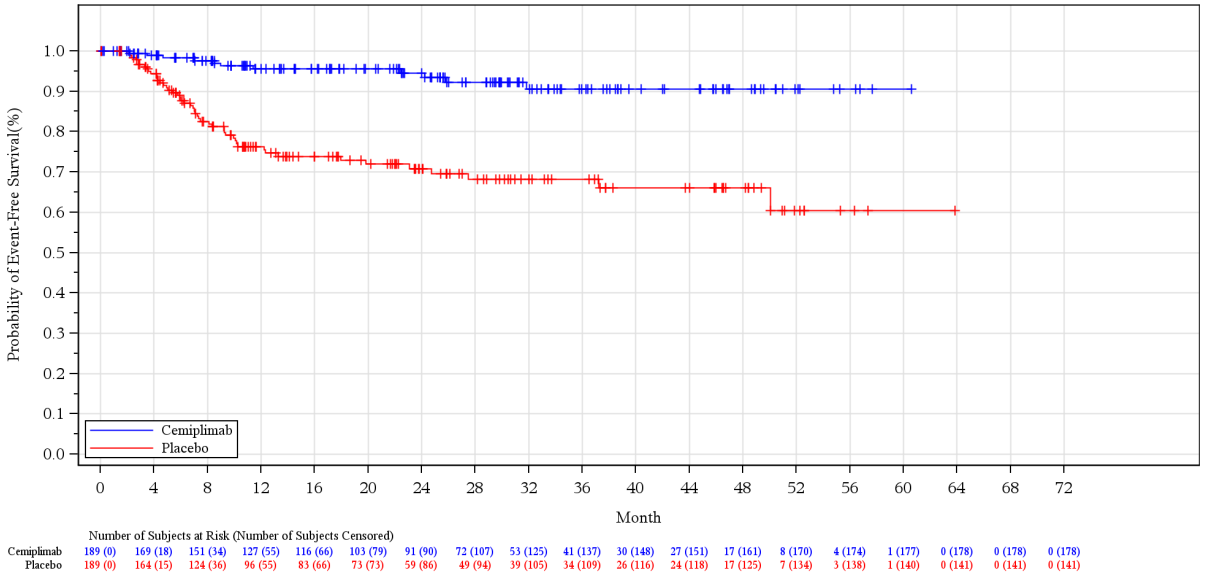
Cemiplimab	82 (0)	69 (13)	57 (24)	48 (31)	43 (36)	39 (40)	33 (46)	28 (51)	19 (60)	14 (65)	10 (69)	9 (70)	7 (73)	2 (77)	1 (78)	0 (79)	0 (79)	0 (79)	0 (79)
Placebo	85 (0)	77 (7)	56 (18)	47 (24)	34 (36)	31 (39)	24 (45)	18 (50)	14 (54)	13 (55)	9 (59)	9 (59)	5 (63)	1 (67)	0 (68)	0 (68)	0 (68)	0 (68)	0 (68)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

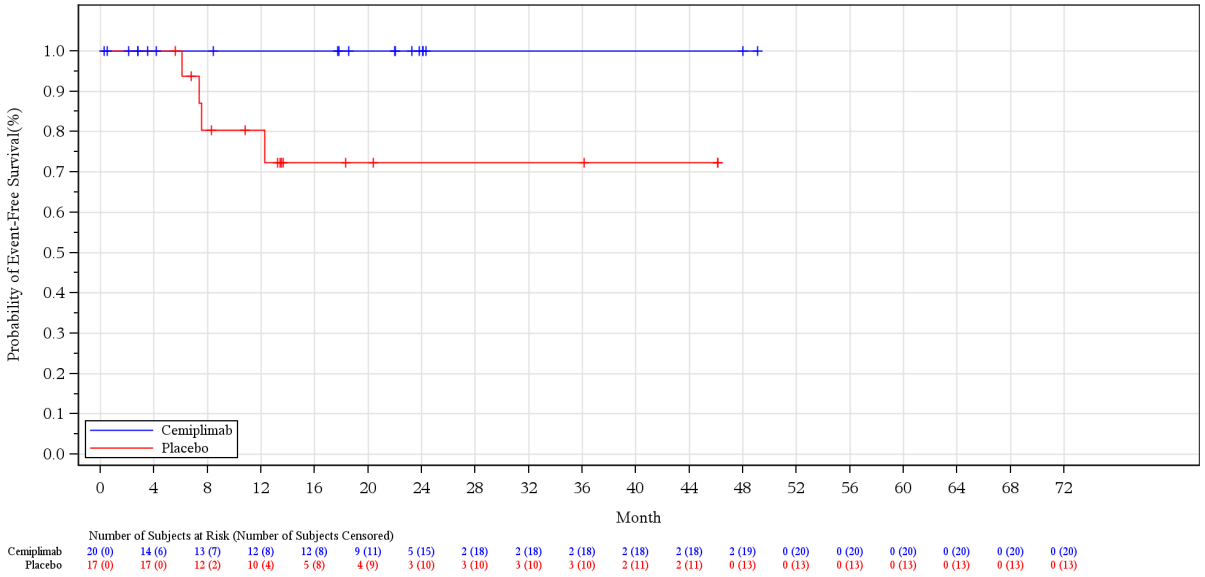
Cemiplimab	189 (0)	169 (18)	151 (34)	127 (55)	116 (66)	103 (79)	91 (90)	72 (107)	53 (125)	41 (137)	30 (148)	27 (151)	17 (161)	8 (170)	4 (174)	1 (177)	0 (178)	0 (178)	0 (178)
Placebo	189 (0)	164 (15)	124 (36)	96 (55)	83 (66)	73 (73)	59 (86)	49 (94)	39 (105)	34 (109)	26 (116)	24 (118)	17 (125)	7 (134)	3 (138)	1 (140)	0 (141)	0 (141)	0 (141)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

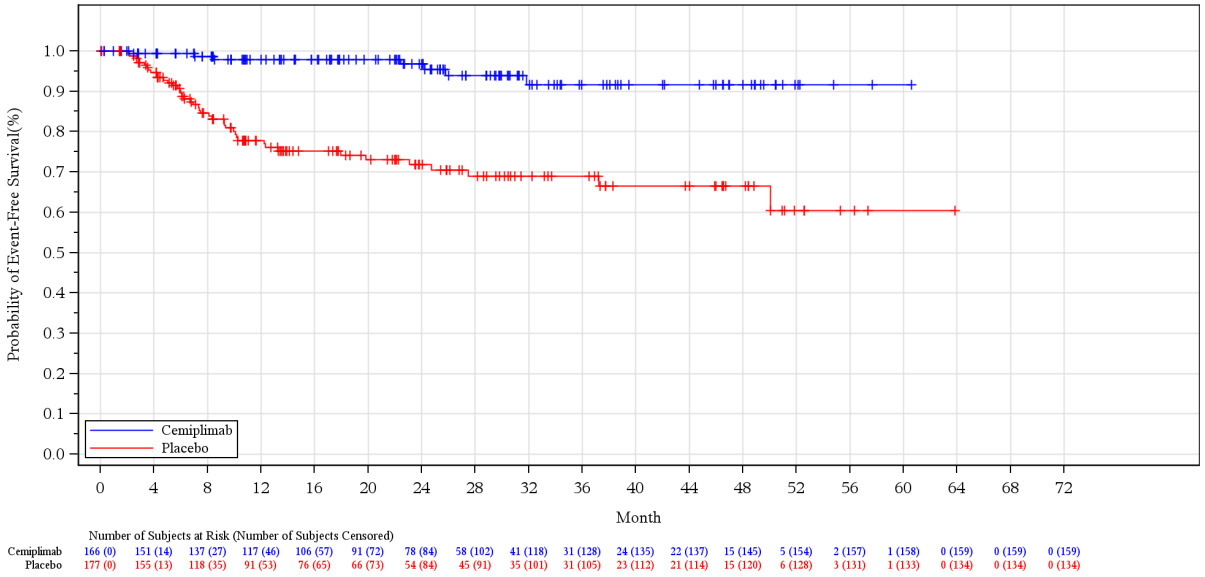
Cemiplimab	20 (0)	14 (6)	13 (7)	12 (8)	12 (8)	9 (11)	5 (15)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	2 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	17 (0)	17 (0)	12 (2)	10 (4)	5 (8)	4 (9)	3 (10)	3 (10)	3 (10)	3 (10)	2 (11)	2 (11)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

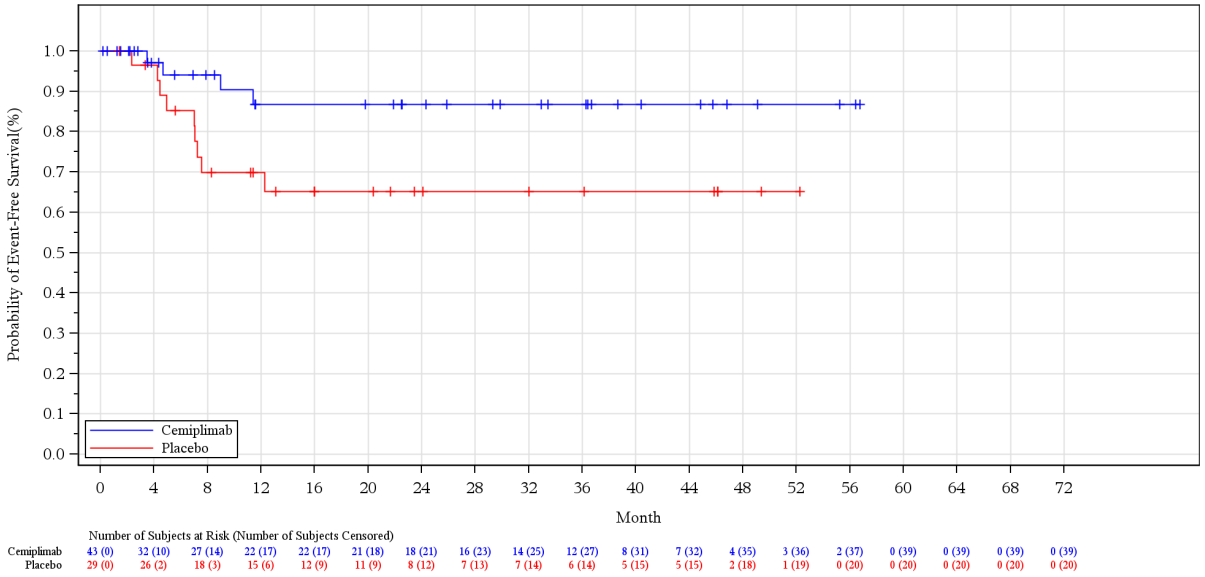
Cemiplimab	166 (0)	151 (14)	137 (27)	117 (46)	106 (57)	91 (72)	78 (84)	58 (102)	41 (118)	31 (128)	24 (135)	22 (137)	15 (145)	5 (154)	2 (157)	1 (158)	0 (159)	0 (159)	0 (159)
Placebo	177 (0)	155 (13)	118 (35)	91 (53)	76 (65)	66 (73)	54 (84)	45 (91)	35 (101)	31 (105)	23 (112)	21 (114)	15 (120)	6 (128)	3 (131)	1 (133)	0 (134)	0 (134)	0 (134)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

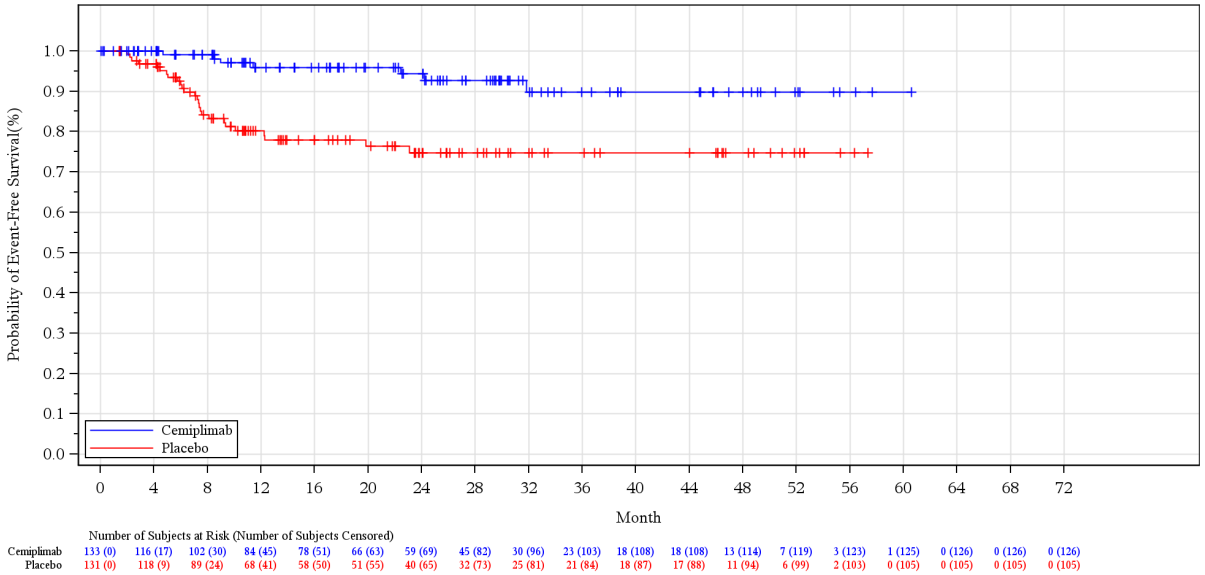
Cemiplimab	43 (0)	32 (10)	27 (14)	22 (17)	22 (17)	21 (18)	18 (21)	16 (23)	14 (25)	12 (27)	8 (31)	7 (32)	4 (35)	3 (36)	2 (37)	0 (39)	0 (39)	0 (39)	0 (39)
Placebo	29 (0)	26 (2)	18 (3)	15 (6)	12 (9)	11 (9)	8 (12)	7 (13)	7 (14)	6 (14)	5 (15)	5 (15)	2 (18)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

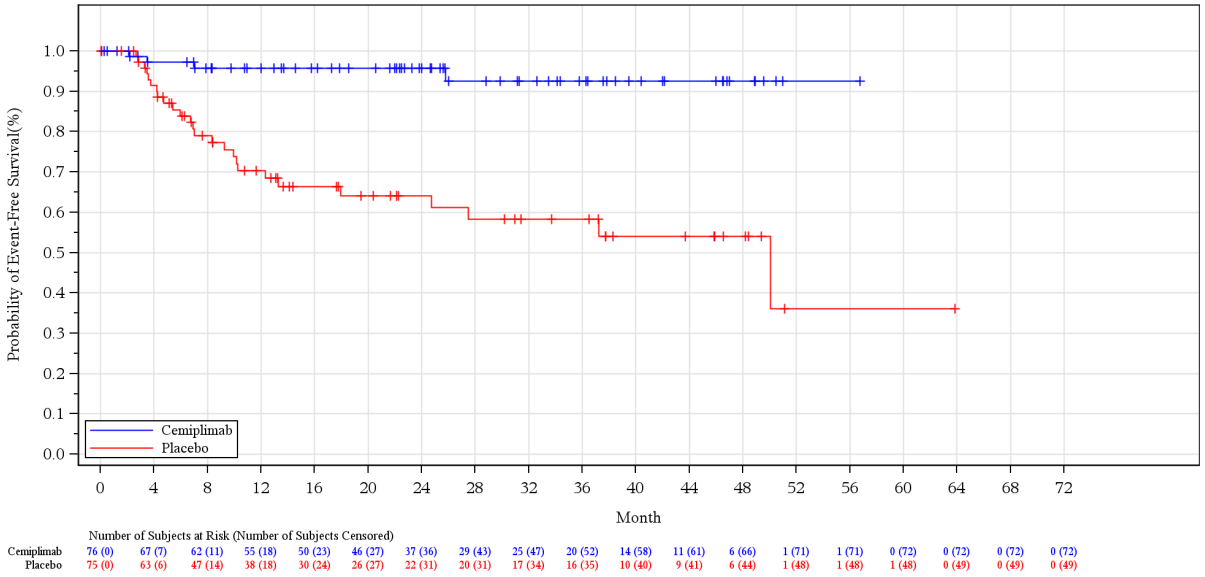
Cemiplimab	133 (0)	116 (17)	102 (30)	84 (45)	78 (51)	66 (63)	59 (69)	45 (82)	30 (96)	23 (103)	18 (108)	18 (108)	13 (114)	7 (119)	3 (123)	1 (125)	0 (126)	0 (126)	0 (126)
Placebo	131 (0)	118 (9)	89 (24)	68 (41)	58 (50)	51 (55)	40 (65)	32 (73)	25 (81)	21 (84)	18 (87)	17 (88)	11 (94)	6 (99)	2 (103)	0 (105)	0 (105)	0 (105)	0 (105)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

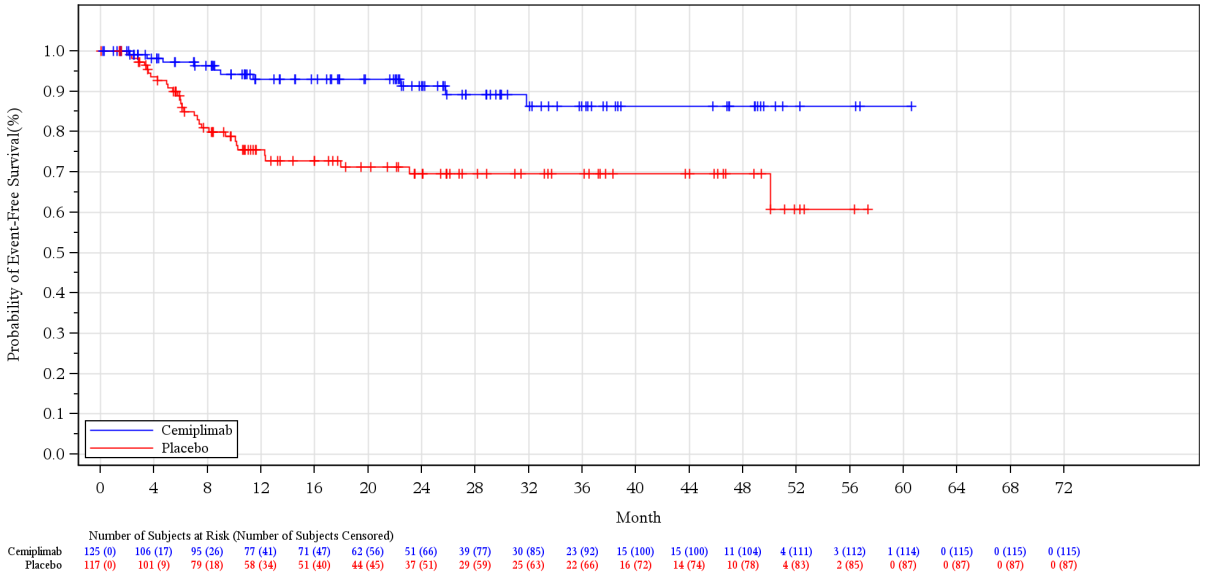
Cemiplimab	76 (0)	67 (7)	62 (11)	55 (18)	50 (23)	46 (27)	37 (36)	29 (43)	25 (47)	20 (52)	14 (58)	11 (61)	6 (66)	1 (71)	1 (71)	0 (72)	0 (72)	0 (72)	0 (72)
Placebo	75 (0)	63 (6)	47 (14)	38 (18)	30 (24)	26 (27)	22 (31)	20 (31)	17 (34)	16 (35)	10 (40)	9 (41)	6 (44)	1 (48)	1 (48)	1 (48)	0 (49)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

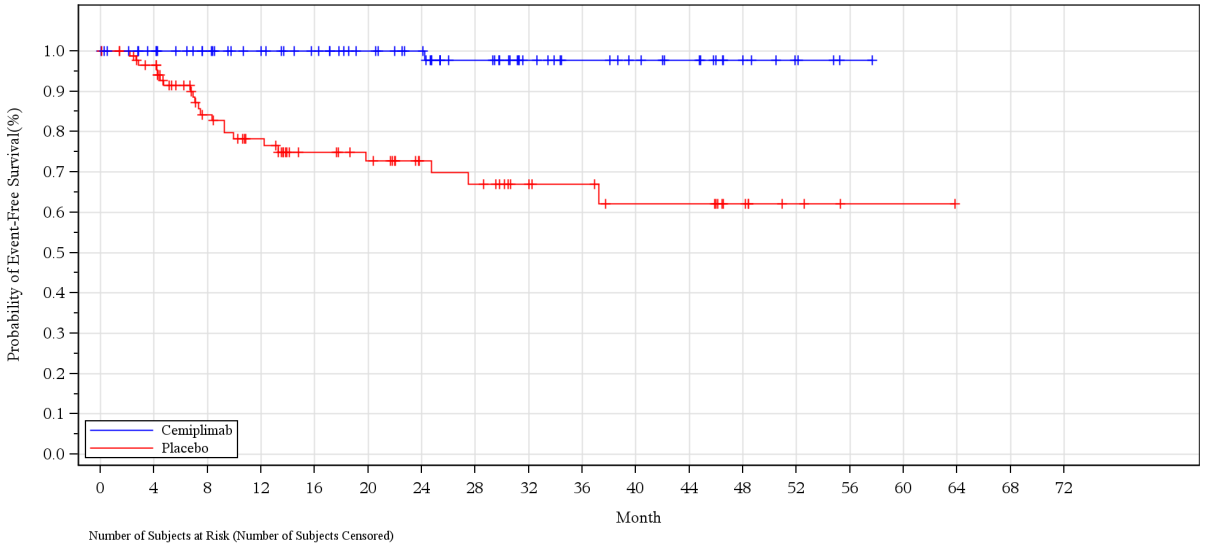
Cemiplimab	125 (0)	106 (17)	95 (26)	77 (41)	71 (47)	62 (56)	51 (66)	39 (77)	30 (85)	23 (92)	15 (100)	15 (100)	11 (104)	4 (111)	3 (112)	1 (114)	0 (115)	0 (115)	0 (115)
Placebo	117 (0)	101 (9)	79 (18)	58 (34)	51 (40)	44 (45)	37 (51)	29 (59)	25 (63)	22 (66)	16 (72)	14 (74)	10 (78)	4 (83)	2 (85)	0 (87)	0 (87)	0 (87)	0 (87)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	77 (7)	69 (15)	62 (22)	57 (27)	50 (34)	45 (39)	35 (48)	25 (58)	20 (63)	17 (66)	14 (69)	8 (76)	4 (79)	1 (82)	0 (83)	0 (83)	0 (83)	0 (83)
Placebo	89 (0)	80 (6)	57 (20)	48 (25)	37 (34)	33 (37)	25 (45)	23 (45)	17 (52)	15 (53)	12 (55)	12 (55)	7 (60)	3 (64)	1 (66)	1 (66)	0 (67)	0 (67)	0 (67)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	5 (8.9%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	51 (91.1%)	46 (70.8%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0056	
HR (95% CI) [c][d]	0.261 (0.094, 0.721)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Heterogeneity p-value [c][e]	0.7642	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (87.8, 99.7)	92.2 (82.2, 96.7)
6 months	98.2 (87.8, 99.7)	88.9 (78.1, 94.5)
12 months	93.9 (82.1, 98.0)	70.5 (56.7, 80.6)
18 months	91.3 (78.3, 96.7)	66.1 (51.8, 77.0)
24 months	91.3 (78.3, 96.7)	66.1 (51.8, 77.0)
30 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
36 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
42 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
48 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
54 months	NE (NE, NE)	66.1 (51.8, 77.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	14 (9.2%)	38 (27.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	28 (19.9%)
Post Radiotherapy, n (%)	1 (0.7%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	6 (3.9%)	2 (1.4%)
Death, n (%)	6 (3.9%)	5 (3.5%)
Number of censored participants, n (%)	139 (90.8%)	103 (73.0%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	14.1 (7.5, 37.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0001	
HR (95% CI) [c][d]	0.311 (0.167, 0.578)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Heterogeneity p-value [c][e]	0.7642	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (94.7, 99.7)	99.3 (94.8, 99.9)
6 months	97.2 (92.6, 98.9)	89.0 (82.1, 93.3)
12 months	94.6 (89.0, 97.4)	78.3 (69.7, 84.7)
18 months	94.6 (89.0, 97.4)	72.7 (63.3, 80.1)
24 months	91.1 (83.7, 95.2)	70.0 (60.1, 77.9)
30 months	86.7 (77.6, 92.3)	66.6 (56.0, 75.2)
36 months	84.8 (74.9, 91.0)	66.6 (56.0, 75.2)
42 months	84.8 (74.9, 91.0)	63.6 (51.7, 73.3)
48 months	84.8 (74.9, 91.0)	63.6 (51.7, 73.3)
54 months	84.8 (74.9, 91.0)	50.9 (32.0, 67.0)
60 months	84.8 (74.9, 91.0)	50.9 (32.0, 67.0)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	5 (8.9%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	51 (91.1%)	46 (70.8%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0056	
HR (95% CI) [c][d]	0.261 (0.094, 0.721)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Heterogeneity p-value [c][e]	0.6928	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (87.8, 99.7)	92.2 (82.2, 96.7)
6 months	98.2 (87.8, 99.7)	88.9 (78.1, 94.5)
12 months	93.9 (82.1, 98.0)	70.5 (56.7, 80.6)
18 months	91.3 (78.3, 96.7)	66.1 (51.8, 77.0)
24 months	91.3 (78.3, 96.7)	66.1 (51.8, 77.0)
30 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
36 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
42 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
48 months	87.2 (70.5, 94.7)	66.1 (51.8, 77.0)
54 months	NE (NE, NE)	66.1 (51.8, 77.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	8 (10.0%)	19 (27.5%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	4 (5.0%)	1 (1.4%)
Death, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	72 (90.0%)	50 (72.5%)
Q1 (95% CI), (months)[a]	NR (25.4, NE)	23.1 (10.3, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	50.1 (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Stratified log-rank test p-value [b][c]	0.0205	
HR (95% CI) [c][d]	0.379 (0.162, 0.887)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Heterogeneity p-value [c][e]	0.6928	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.1, 99.8)	98.5 (89.7, 99.8)
6 months	95.9 (87.7, 98.6)	90.6 (80.2, 95.7)
12 months	94.2 (85.3, 97.8)	85.3 (73.5, 92.1)
18 months	94.2 (85.3, 97.8)	78.8 (65.4, 87.5)
24 months	92.0 (81.6, 96.7)	73.9 (59.5, 83.9)
30 months	83.5 (68.5, 91.8)	68.0 (52.3, 79.5)
36 months	83.5 (68.5, 91.8)	68.0 (52.3, 79.5)
42 months	83.5 (68.5, 91.8)	62.8 (44.7, 76.4)
48 months	83.5 (68.5, 91.8)	62.8 (44.7, 76.4)
54 months	83.5 (68.5, 91.8)	41.8 (16.9, 65.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	6 (8.2%)	19 (26.4%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	14 (19.4%)
Post Radiotherapy, n (%)	0	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	1 (1.4%)
Death, n (%)	3 (4.1%)	3 (4.2%)
Number of censored participants, n (%)	67 (91.8%)	53 (73.6%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	8.3 (6.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0016	
HR (95% CI) [c][d]	0.225 (0.083, 0.615)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Heterogeneity p-value [c][e]	0.6928	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (90.4, 99.8)	100 (100, 100)
6 months	98.6 (90.4, 99.8)	87.4 (76.3, 93.5)
12 months	95.1 (85.4, 98.4)	71.1 (57.5, 81.0)
18 months	95.1 (85.4, 98.4)	66.2 (51.8, 77.2)
24 months	89.9 (76.9, 95.8)	66.2 (51.8, 77.2)
30 months	89.9 (76.9, 95.8)	66.2 (51.8, 77.2)
36 months	86.0 (70.0, 93.8)	66.2 (51.8, 77.2)
42 months	86.0 (70.0, 93.8)	66.2 (51.8, 77.2)
48 months	86.0 (70.0, 93.8)	66.2 (51.8, 77.2)
54 months	86.0 (70.0, 93.8)	66.2 (51.8, 77.2)
60 months	86.0 (70.0, 93.8)	66.2 (51.8, 77.2)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	15 (8.6%)	42 (24.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	33 (19.0%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	7 (4.0%)	3 (1.7%)
Death, n (%)	6 (3.4%)	2 (1.1%)
Number of censored participants, n (%)	159 (91.4%)	132 (75.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	18.0 (9.3, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.303 (0.167, 0.549)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Heterogeneity p-value [c][e]	0.7001	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (95.3, 99.7)	97.0 (92.9, 98.7)
6 months	98.2 (94.5, 99.4)	89.2 (83.2, 93.1)
12 months	95.4 (90.5, 97.8)	78.1 (70.5, 84.1)
18 months	94.6 (89.4, 97.3)	74.5 (66.2, 81.0)
24 months	92.6 (86.4, 96.0)	72.2 (63.5, 79.1)
30 months	87.6 (79.4, 92.6)	70.8 (61.8, 78.0)
36 months	85.7 (76.6, 91.5)	70.8 (61.8, 78.0)
42 months	85.7 (76.6, 91.5)	68.3 (58.1, 76.5)
48 months	85.7 (76.6, 91.5)	68.3 (58.1, 76.5)
54 months	85.7 (76.6, 91.5)	55.8 (37.1, 71.0)
60 months	85.7 (76.6, 91.5)	55.8 (37.1, 71.0)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	4 (11.4%)	15 (46.9%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	0
Death, n (%)	2 (5.7%)	3 (9.4%)
Number of censored participants, n (%)	31 (88.6%)	17 (53.1%)
Q1 (95% CI), (months)[a]	NR (11.4, NE)	7.0 (3.4, 12.7)
Median (95% CI), (months)[a]	NR (NE, NE)	27.5 (7.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (27.5, NE)
Stratified log-rank test p-value [b][c]	0.0379	
HR (95% CI) [c][d]	0.318 (0.102, 0.991)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Heterogeneity p-value [c][e]	0.7001	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.1 (80.9, 99.6)	96.9 (79.8, 99.6)
6 months	93.3 (75.6, 98.3)	87.5 (70.0, 95.1)
12 months	88.7 (68.2, 96.3)	64.6 (45.1, 78.7)
18 months	88.7 (68.2, 96.3)	52.5 (32.9, 68.9)
24 months	82.3 (57.8, 93.3)	52.5 (32.9, 68.9)
30 months	82.3 (57.8, 93.3)	45.0 (24.0, 64.0)
36 months	82.3 (57.8, 93.3)	45.0 (24.0, 64.0)
42 months	82.3 (57.8, 93.3)	45.0 (24.0, 64.0)
48 months	82.3 (57.8, 93.3)	45.0 (24.0, 64.0)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	3 (8.1%)	8 (25.8%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	1 (3.2%)
Death, n (%)	2 (5.4%)	1 (3.2%)
Number of censored participants, n (%)	34 (91.9%)	23 (74.2%)
Q1 (95% CI), (months)[a]	NR (21.6, NE)	9.3 (5.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0275	
HR (95% CI) [c][d]	0.248 (0.065, 0.945)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Heterogeneity p-value [c][e]	0.6509	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	93.5 (76.6, 98.3)
6 months	97.1 (81.4, 99.6)	89.7 (71.1, 96.6)
12 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
18 months	97.1 (81.4, 99.6)	73.4 (51.9, 86.5)
24 months	93.1 (74.6, 98.3)	73.4 (51.9, 86.5)
30 months	87.3 (64.0, 95.9)	73.4 (51.9, 86.5)
36 months	87.3 (64.0, 95.9)	73.4 (51.9, 86.5)
42 months	87.3 (64.0, 95.9)	73.4 (51.9, 86.5)
48 months	87.3 (64.0, 95.9)	73.4 (51.9, 86.5)
54 months	87.3 (64.0, 95.9)	55.1 (19.0, 80.8)
60 months	87.3 (64.0, 95.9)	55.1 (19.0, 80.8)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	29 (32.2%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	22 (24.4%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Death, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	82 (91.1%)	61 (67.8%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	10.2 (6.9, 19.8)
Median (95% CI), (months)[a]	NR (NE, NE)	50.1 (24.7, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.238 (0.109, 0.521)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Heterogeneity p-value [c][e]	0.6509	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.7 (91.0, 99.4)	96.5 (89.5, 98.9)
6 months	97.7 (91.0, 99.4)	86.9 (77.6, 92.5)
12 months	95.0 (87.2, 98.1)	73.4 (62.0, 81.8)
18 months	95.0 (87.2, 98.1)	66.5 (54.2, 76.2)
24 months	92.9 (83.4, 97.1)	64.6 (52.0, 74.6)
30 months	88.1 (75.8, 94.4)	62.3 (49.5, 72.8)
36 months	85.1 (71.1, 92.6)	62.3 (49.5, 72.8)
42 months	85.1 (71.1, 92.6)	58.7 (44.5, 70.4)
48 months	85.1 (71.1, 92.6)	58.7 (44.5, 70.4)
54 months	85.1 (71.1, 92.6)	48.9 (27.5, 67.2)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	8 (9.8%)	20 (23.5%)
Received Cemiplimab in Part 2, n (%)	0	17 (20.0%)
Post Radiotherapy, n (%)	1 (1.2%)	0
Post Other Systemic Therapy, n (%)	2 (2.4%)	0
Death, n (%)	5 (6.1%)	3 (3.5%)
Number of censored participants, n (%)	74 (90.2%)	65 (76.5%)
Q1 (95% CI), (months)[a]	NR (25.4, NE)	14.1 (7.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0153	
HR (95% CI) [c][d]	0.376 (0.165, 0.855)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Heterogeneity p-value [c][e]	0.6509	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	98.8 (91.6, 99.8)
6 months	97.2 (89.3, 99.3)	90.8 (81.7, 95.5)
12 months	92.0 (81.7, 96.6)	79.0 (67.5, 86.8)
18 months	90.0 (78.8, 95.4)	73.5 (61.0, 82.6)
24 months	87.7 (75.5, 94.0)	70.8 (57.4, 80.6)
30 months	84.7 (71.1, 92.3)	67.1 (52.2, 78.2)
36 months	84.7 (71.1, 92.3)	67.1 (52.2, 78.2)
42 months	84.7 (71.1, 92.3)	67.1 (52.2, 78.2)
48 months	84.7 (71.1, 92.3)	67.1 (52.2, 78.2)
54 months	84.7 (71.1, 92.3)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	18 (9.5%)	53 (28.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	41 (21.7%)
Post Radiotherapy, n (%)	2 (1.1%)	4 (2.1%)
Post Other Systemic Therapy, n (%)	8 (4.2%)	3 (1.6%)
Death, n (%)	7 (3.7%)	5 (2.6%)
Number of censored participants, n (%)	171 (90.5%)	136 (72.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.2 (7.5, 24.7)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.285 (0.166, 0.489)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Heterogeneity p-value [c][e]	0.9770	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.9 (95.7, 99.7)	96.7 (92.7, 98.5)
6 months	97.7 (94.1, 99.1)	87.8 (82.0, 91.9)
12 months	94.4 (89.5, 97.1)	75.3 (67.8, 81.3)
18 months	93.6 (88.4, 96.5)	70.4 (62.4, 77.0)
24 months	90.9 (84.6, 94.7)	68.4 (60.0, 75.3)
30 months	86.5 (78.8, 91.5)	65.8 (57.0, 73.3)
36 months	84.9 (76.5, 90.5)	65.8 (57.0, 73.3)
42 months	84.9 (76.5, 90.5)	63.7 (54.1, 71.8)
48 months	84.9 (76.5, 90.5)	63.7 (54.1, 71.8)
54 months	84.9 (76.5, 90.5)	53.9 (38.4, 67.1)
60 months	84.9 (76.5, 90.5)	53.9 (38.4, 67.1)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	4 (23.5%)
Received Cemiplimab in Part 2, n (%)	0	4 (23.5%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	0	0
Death, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	19 (95.0%)	13 (76.5%)
Q1 (95% CI), (months)[a]	NR (0.5, NE)	12.3 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (12.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.5619	
HR (95% CI) [c][d]	0.512 (0.052, 5.071)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Heterogeneity p-value [c][e]	0.9770	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.7 (68.1, 99.2)	100 (100, 100)
6 months	94.7 (68.1, 99.2)	100 (100, 100)
12 months	94.7 (68.1, 99.2)	80.4 (50.6, 93.2)
18 months	94.7 (68.1, 99.2)	72.3 (41.5, 88.7)
24 months	94.7 (68.1, 99.2)	72.3 (41.5, 88.7)
30 months	94.7 (68.1, 99.2)	72.3 (41.5, 88.7)
36 months	94.7 (68.1, 99.2)	72.3 (41.5, 88.7)
42 months	94.7 (68.1, 99.2)	72.3 (41.5, 88.7)
48 months	94.7 (68.1, 99.2)	NE (NE, NE)
54 months	NE (NE, NE)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	14 (8.4%)	46 (26.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	36 (20.3%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	5 (3.0%)	3 (1.7%)
Death, n (%)	7 (4.2%)	3 (1.7%)
Number of censored participants, n (%)	152 (91.6%)	131 (74.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.7 (9.3, 27.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.271 (0.149, 0.494)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Heterogeneity p-value [c][e]	0.8777	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (95.1, 99.7)	97.0 (93.0, 98.8)
6 months	98.8 (95.1, 99.7)	90.1 (84.3, 93.8)
12 months	96.6 (92.0, 98.6)	77.2 (69.6, 83.2)
18 months	95.7 (90.7, 98.1)	71.9 (63.5, 78.7)
24 months	92.5 (85.8, 96.1)	69.6 (60.9, 76.8)
30 months	87.1 (78.3, 92.5)	66.8 (57.5, 74.5)
36 months	85.0 (75.1, 91.2)	66.8 (57.5, 74.5)
42 months	85.0 (75.1, 91.2)	64.4 (54.2, 73.0)
48 months	85.0 (75.1, 91.2)	64.4 (54.2, 73.0)
54 months	85.0 (75.1, 91.2)	58.6 (43.4, 70.9)
60 months	85.0 (75.1, 91.2)	58.6 (43.4, 70.9)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	5 (11.6%)	11 (37.9%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	3 (7.0%)	0
Death, n (%)	1 (2.3%)	2 (6.9%)
Number of censored participants, n (%)	38 (88.4%)	18 (62.1%)
Q1 (95% CI), (months)[a]	NR (9.0, NE)	7.1 (3.4, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (7.6, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0343	
HR (95% CI) [c][d]	0.334 (0.115, 0.969)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Heterogeneity p-value [c][e]	0.8777	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.6 (84.3, 99.7)	96.4 (77.2, 99.5)
6 months	91.8 (76.4, 97.3)	82.1 (62.3, 92.1)
12 months	84.7 (66.7, 93.4)	67.2 (46.4, 81.4)
18 months	84.7 (66.7, 93.4)	62.7 (41.6, 78.0)
24 months	84.7 (66.7, 93.4)	62.7 (41.6, 78.0)
30 months	84.7 (66.7, 93.4)	62.7 (41.6, 78.0)
36 months	84.7 (66.7, 93.4)	62.7 (41.6, 78.0)
42 months	84.7 (66.7, 93.4)	62.7 (41.6, 78.0)
48 months	84.7 (66.7, 93.4)	62.7 (41.6, 78.0)
54 months	84.7 (66.7, 93.4)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	9 (6.8%)	27 (20.6%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	23 (17.6%)
Post Radiotherapy, n (%)	2 (1.5%)	0
Post Other Systemic Therapy, n (%)	4 (3.0%)	3 (2.3%)
Death, n (%)	2 (1.5%)	1 (0.8%)
Number of censored participants, n (%)	124 (93.2%)	104 (79.4%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	23.1 (8.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0007	
HR (95% CI) [c][d]	0.289 (0.135, 0.617)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Heterogeneity p-value [c][e]	0.7494	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.7, 99.9)	96.8 (91.7, 98.8)
6 months	98.3 (93.5, 99.6)	92.5 (86.1, 96.0)
12 months	94.3 (87.7, 97.4)	79.4 (70.6, 85.9)
18 months	94.3 (87.7, 97.4)	77.1 (67.9, 84.0)
24 months	92.8 (85.2, 96.6)	74.0 (64.0, 81.6)
30 months	91.1 (82.6, 95.6)	74.0 (64.0, 81.6)
36 months	88.2 (76.9, 94.2)	74.0 (64.0, 81.6)
42 months	88.2 (76.9, 94.2)	74.0 (64.0, 81.6)
48 months	88.2 (76.9, 94.2)	74.0 (64.0, 81.6)
54 months	88.2 (76.9, 94.2)	74.0 (64.0, 81.6)
60 months	88.2 (76.9, 94.2)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	10 (13.2%)	30 (40.0%)
Received Cemiplimab in Part 2, n (%)	0	22 (29.3%)
Post Radiotherapy, n (%)	0	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	0
Death, n (%)	6 (7.9%)	4 (5.3%)
Number of censored participants, n (%)	66 (86.8%)	45 (60.0%)
Q1 (95% CI), (months)[a]	NR (25.4, NE)	9.3 (5.4, 13.3)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (14.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.262 (0.127, 0.540)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Heterogeneity p-value [c][e]	0.7494	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.3 (89.6, 99.3)	97.2 (89.2, 99.3)
6 months	95.9 (87.8, 98.7)	82.6 (71.4, 89.8)
12 months	94.4 (85.8, 97.9)	69.2 (56.3, 79.0)
18 months	92.6 (83.1, 96.9)	59.5 (45.8, 70.8)
24 months	88.6 (77.3, 94.5)	59.5 (45.8, 70.8)
30 months	80.4 (65.8, 89.3)	54.1 (39.7, 66.4)
36 months	80.4 (65.8, 89.3)	54.1 (39.7, 66.4)
42 months	80.4 (65.8, 89.3)	50.2 (35.1, 63.6)
48 months	80.4 (65.8, 89.3)	50.2 (35.1, 63.6)
54 months	80.4 (65.8, 89.3)	25.1 (5.5, 51.7)
60 months	NE (NE, NE)	25.1 (5.5, 51.7)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	12 (9.6%)	32 (27.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	25 (21.4%)
Post Radiotherapy, n (%)	1 (0.8%)	3 (2.6%)
Post Other Systemic Therapy, n (%)	8 (6.4%)	2 (1.7%)
Death, n (%)	2 (1.6%)	2 (1.7%)
Number of censored participants, n (%)	113 (90.4%)	85 (72.6%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	12.3 (7.2, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0005	
HR (95% CI) [c][d]	0.321 (0.164, 0.627)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Heterogeneity p-value [c][e]	0.5280	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.3 (93.5, 99.6)	97.3 (91.9, 99.1)
6 months	96.5 (90.9, 98.7)	87.9 (80.1, 92.8)
12 months	92.2 (84.9, 96.0)	75.4 (65.7, 82.7)
18 months	92.2 (84.9, 96.0)	70.0 (59.5, 78.3)
24 months	89.1 (80.3, 94.1)	68.2 (57.4, 76.9)
30 months	87.1 (77.2, 92.9)	68.2 (57.4, 76.9)
36 months	84.3 (72.5, 91.3)	68.2 (57.4, 76.9)
42 months	84.3 (72.5, 91.3)	68.2 (57.4, 76.9)
48 months	84.3 (72.5, 91.3)	68.2 (57.4, 76.9)
54 months	84.3 (72.5, 91.3)	53.1 (31.7, 70.5)
60 months	84.3 (72.5, 91.3)	NE (NE, NE)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	7 (8.3%)	25 (28.1%)
Received Cemiplimab in Part 2, n (%)	0	20 (22.5%)
Post Radiotherapy, n (%)	1 (1.2%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	0	1 (1.1%)
Death, n (%)	6 (7.1%)	3 (3.4%)
Number of censored participants, n (%)	77 (91.7%)	64 (71.9%)
Q1 (95% CI), (months)[a]	NR (26.0, NE)	12.2 (7.1, 27.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (27.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0003	
HR (95% CI) [c][d]	0.234 (0.100, 0.544)	

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Heterogeneity p-value [c][e]	0.5280	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	96.5 (89.5, 98.8)
6 months	98.8 (91.7, 99.8)	90.3 (81.5, 95.0)
12 months	97.4 (89.9, 99.3)	76.1 (64.7, 84.3)
18 months	95.8 (87.3, 98.6)	71.0 (58.9, 80.2)
24 months	93.9 (84.2, 97.7)	69.0 (56.4, 78.6)
30 months	86.9 (73.8, 93.7)	63.4 (49.5, 74.5)
36 months	86.9 (73.8, 93.7)	63.4 (49.5, 74.5)
42 months	86.9 (73.8, 93.7)	58.9 (43.1, 71.7)
48 months	86.9 (73.8, 93.7)	58.9 (43.1, 71.7)
54 months	86.9 (73.8, 93.7)	58.9 (43.1, 71.7)
60 months	NE (NE, NE)	58.9 (43.1, 71.7)

Data cut-off as of October 4, 2024.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	5 (8.9%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	51 (91.1%)	46 (70.8%)
Proportionality Test p-value[a][b]	0.9459	
Hazard ratio(interaction)	0.959 (0.286, 3.215)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	14 (9.2%)	38 (27.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	28 (19.9%)
Post Radiotherapy, n (%)	1 (0.7%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	6 (3.9%)	2 (1.4%)
Death, n (%)	6 (3.9%)	5 (3.5%)
Number of censored participants, n (%)	139 (90.8%)	103 (73.0%)
Proportionality Test p-value[a][b]	0.5255	
Hazard ratio(interaction)	0.786 (0.374, 1.652)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	5 (8.9%)	19 (29.2%)
Received Cemiplimab in Part 2, n (%)	0	17 (26.2%)
Post Radiotherapy, n (%)	1 (1.8%)	1 (1.5%)
Post Other Systemic Therapy, n (%)	2 (3.6%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	51 (91.1%)	46 (70.8%)
Proportionality Test p-value[a][b]	0.9459	
Hazard ratio(interaction)	0.959 (0.286, 3.215)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	8 (10.0%)	19 (27.5%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	4 (5.0%)	1 (1.4%)
Death, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	72 (90.0%)	50 (72.5%)
Proportionality Test p-value[a][b]	0.9859	
Hazard ratio(interaction)	0.991 (0.361, 2.722)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	6 (8.2%)	19 (26.4%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	14 (19.4%)
Post Radiotherapy, n (%)	0	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	1 (1.4%)
Death, n (%)	3 (4.1%)	3 (4.2%)
Number of censored participants, n (%)	67 (91.8%)	53 (73.6%)
Proportionality Test p-value[a][b]	0.3844	
Hazard ratio(interaction)	0.513 (0.114, 2.311)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	15 (8.6%)	42 (24.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	33 (19.0%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	7 (4.0%)	3 (1.7%)
Death, n (%)	6 (3.4%)	2 (1.1%)
Number of censored participants, n (%)	159 (91.4%)	132 (75.9%)
Proportionality Test p-value[a][b]	0.2323	
Hazard ratio(interaction)	0.642 (0.310, 1.329)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	4 (11.4%)	15 (46.9%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	0
Death, n (%)	2 (5.7%)	3 (9.4%)
Number of censored participants, n (%)	31 (88.6%)	17 (53.1%)
Proportionality Test p-value[a][b]	0.7641	
Hazard ratio(interaction)	1.203 (0.360, 4.017)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	3 (8.1%)	8 (25.8%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	1 (3.2%)
Death, n (%)	2 (5.4%)	1 (3.2%)
Number of censored participants, n (%)	34 (91.9%)	23 (74.2%)
Proportionality Test p-value[a][b]	0.3140	
Hazard ratio(interaction)	0.462 (0.103, 2.078)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	29 (32.2%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	22 (24.4%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Death, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	82 (91.1%)	61 (67.8%)
Proportionality Test p-value[a][b]	0.6976	
Hazard ratio(interaction)	0.831 (0.328, 2.110)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	8 (9.8%)	20 (23.5%)
Received Cemiplimab in Part 2, n (%)	0	17 (20.0%)
Post Radiotherapy, n (%)	1 (1.2%)	0
Post Other Systemic Therapy, n (%)	2 (2.4%)	0
Death, n (%)	5 (6.1%)	3 (3.5%)
Number of censored participants, n (%)	74 (90.2%)	65 (76.5%)
Proportionality Test p-value[a][b]	0.9517	
Hazard ratio(interaction)	0.969 (0.353, 2.665)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	18 (9.5%)	53 (28.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	41 (21.7%)
Post Radiotherapy, n (%)	2 (1.1%)	4 (2.1%)
Post Other Systemic Therapy, n (%)	8 (4.2%)	3 (1.6%)
Death, n (%)	7 (3.7%)	5 (2.6%)
Number of censored participants, n (%)	171 (90.5%)	136 (72.0%)
Proportionality Test p-value[a][b]	0.1239	
Hazard ratio(interaction)	0.586 (0.297, 1.158)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	4 (23.5%)
Received Cemiplimab in Part 2, n (%)	0	4 (23.5%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	0	0
Death, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	19 (95.0%)	13 (76.5%)
Proportionality Test p-value[a][b]	NE	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	14 (8.4%)	46 (26.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	36 (20.3%)
Post Radiotherapy, n (%)	1 (0.6%)	4 (2.3%)
Post Other Systemic Therapy, n (%)	5 (3.0%)	3 (1.7%)
Death, n (%)	7 (4.2%)	3 (1.7%)
Number of censored participants, n (%)	152 (91.6%)	131 (74.0%)
Proportionality Test p-value[a][b]	0.1193	
Hazard ratio(interaction)	0.525 (0.234, 1.181)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	5 (11.6%)	11 (37.9%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	3 (7.0%)	0
Death, n (%)	1 (2.3%)	2 (6.9%)
Number of censored participants, n (%)	38 (88.4%)	18 (62.1%)
Proportionality Test p-value[a][b]	0.3284	
Hazard ratio(interaction)	1.987 (0.501, 7.877)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	9 (6.8%)	27 (20.6%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	23 (17.6%)
Post Radiotherapy, n (%)	2 (1.5%)	0
Post Other Systemic Therapy, n (%)	4 (3.0%)	3 (2.3%)
Death, n (%)	2 (1.5%)	1 (0.8%)
Number of censored participants, n (%)	124 (93.2%)	104 (79.4%)
Proportionality Test p-value[a][b]	0.2022	
Hazard ratio(interaction)	0.460 (0.139, 1.518)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	10 (13.2%)	30 (40.0%)
Received Cemiplimab in Part 2, n (%)	0	22 (29.3%)
Post Radiotherapy, n (%)	0	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	0
Death, n (%)	6 (7.9%)	4 (5.3%)
Number of censored participants, n (%)	66 (86.8%)	45 (60.0%)
Proportionality Test p-value[a][b]	0.9208	
Hazard ratio(interaction)	1.039 (0.486, 2.222)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	12 (9.6%)	32 (27.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	25 (21.4%)
Post Radiotherapy, n (%)	1 (0.8%)	3 (2.6%)
Post Other Systemic Therapy, n (%)	8 (6.4%)	2 (1.7%)
Death, n (%)	2 (1.6%)	2 (1.7%)
Number of censored participants, n (%)	113 (90.4%)	85 (72.6%)
Proportionality Test p-value[a][b]	0.6703	
Hazard ratio(interaction)	0.834 (0.363, 1.920)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

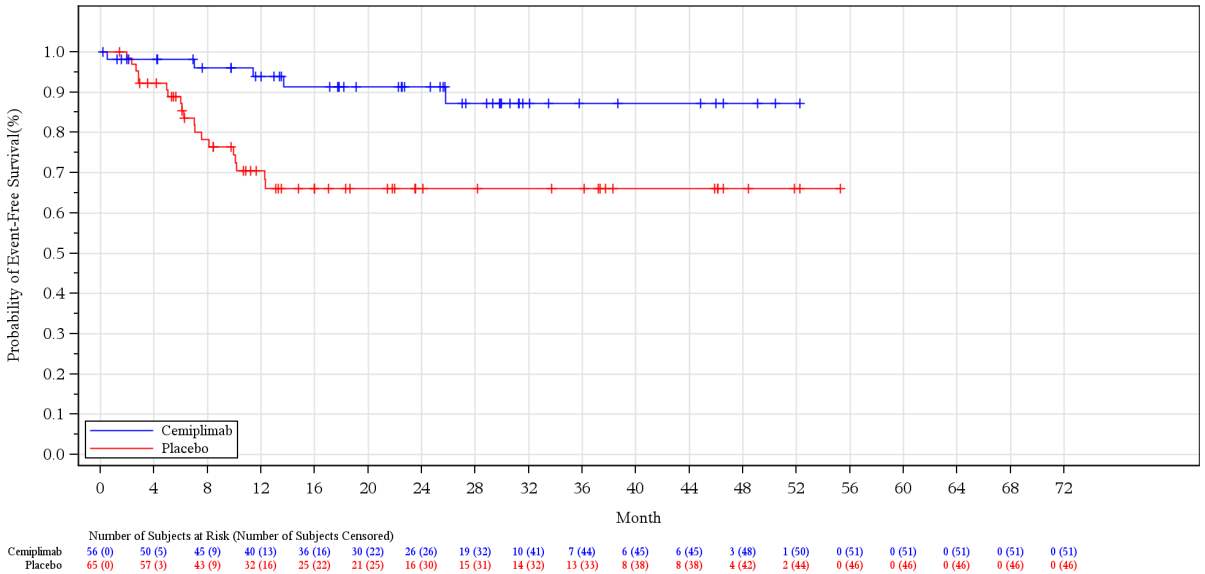
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	7 (8.3%)	25 (28.1%)
Received Cemiplimab in Part 2, n (%)	0	20 (22.5%)
Post Radiotherapy, n (%)	1 (1.2%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	0	1 (1.1%)
Death, n (%)	6 (7.1%)	3 (3.4%)
Number of censored participants, n (%)	77 (91.7%)	64 (71.9%)
Proportionality Test p-value[a][b]	0.5909	
Hazard ratio(interaction)	0.758 (0.276, 2.080)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65



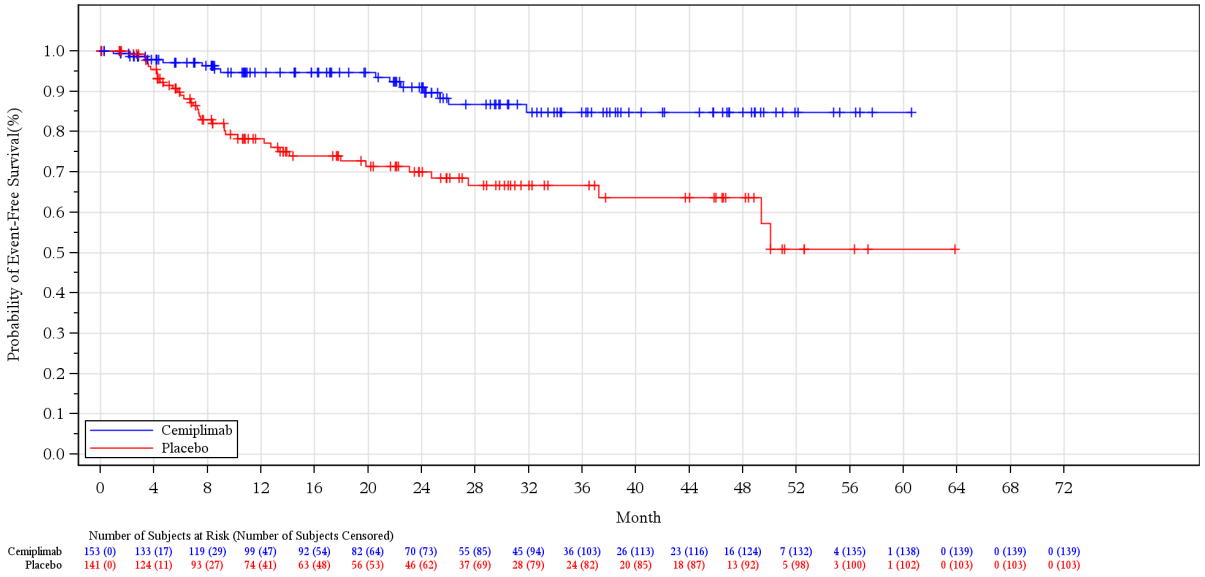
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	50 (5)	45 (9)	40 (13)	36 (16)	30 (22)	26 (26)	19 (32)	10 (41)	7 (44)	6 (45)	6 (45)	3 (48)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	65 (0)	57 (3)	43 (9)	32 (16)	25 (22)	21 (25)	16 (30)	15 (31)	14 (32)	13 (33)	8 (38)	8 (38)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

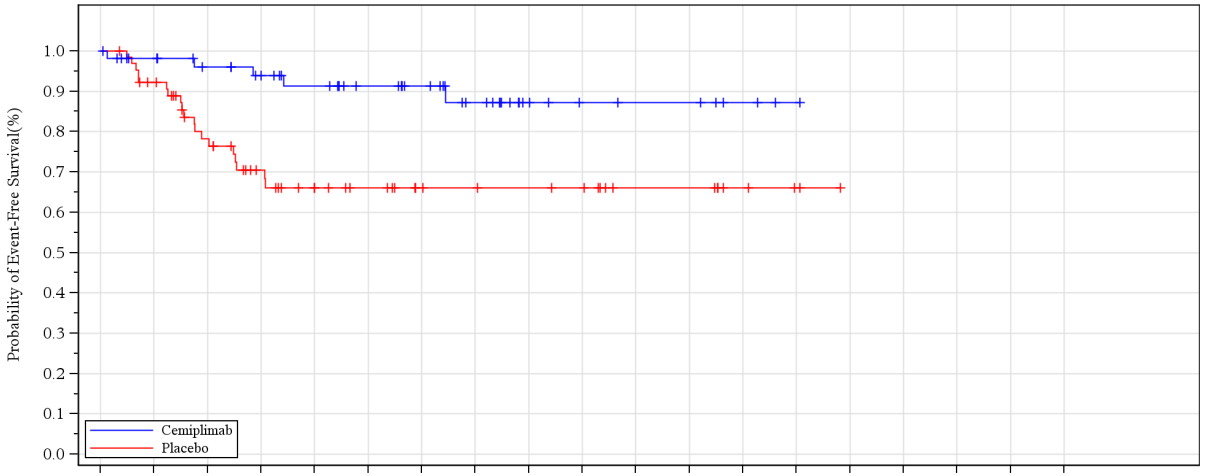
Cemiplimab	153 (0)	133 (17)	119 (29)	99 (47)	92 (54)	82 (64)	70 (73)	55 (85)	45 (94)	36 (103)	26 (113)	23 (116)	16 (124)	7 (132)	4 (135)	1 (138)	0 (139)	0 (139)	0 (139)
Placebo	141 (0)	124 (11)	93 (27)	74 (41)	63 (48)	56 (53)	46 (62)	37 (69)	28 (79)	24 (82)	20 (85)	18 (87)	13 (92)	5 (98)	3 (100)	1 (102)	0 (103)	0 (103)	0 (103)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

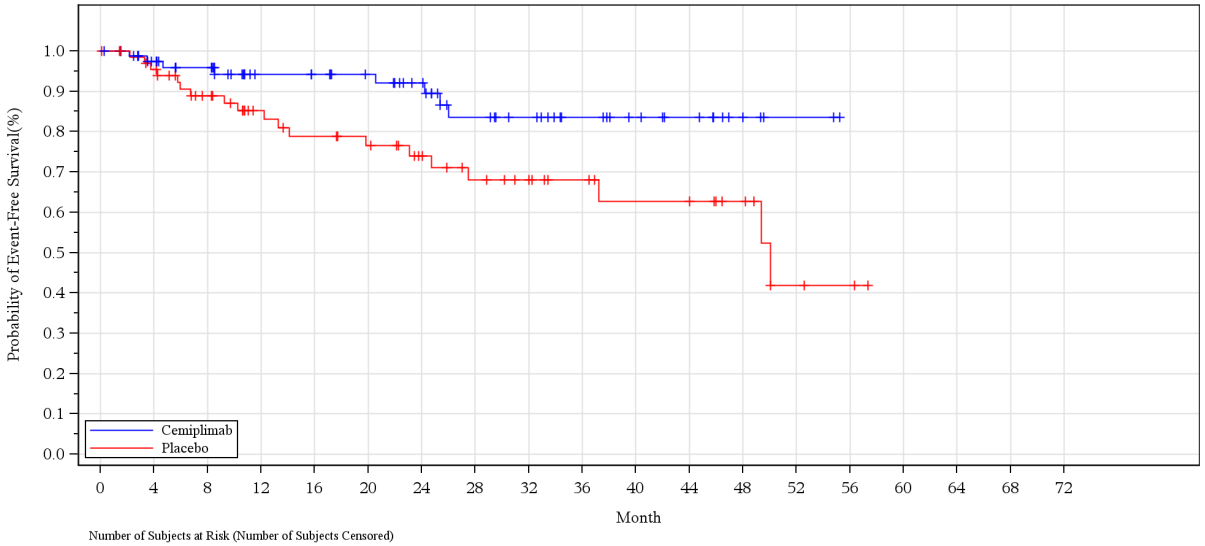
Cemiplimab	56 (0)	50 (5)	45 (9)	40 (13)	36 (16)	30 (22)	26 (26)	19 (32)	10 (41)	7 (44)	6 (45)	6 (45)	3 (48)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	65 (0)	57 (3)	43 (9)	32 (16)	25 (22)	21 (25)	16 (30)	15 (31)	14 (32)	13 (33)	8 (38)	8 (38)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

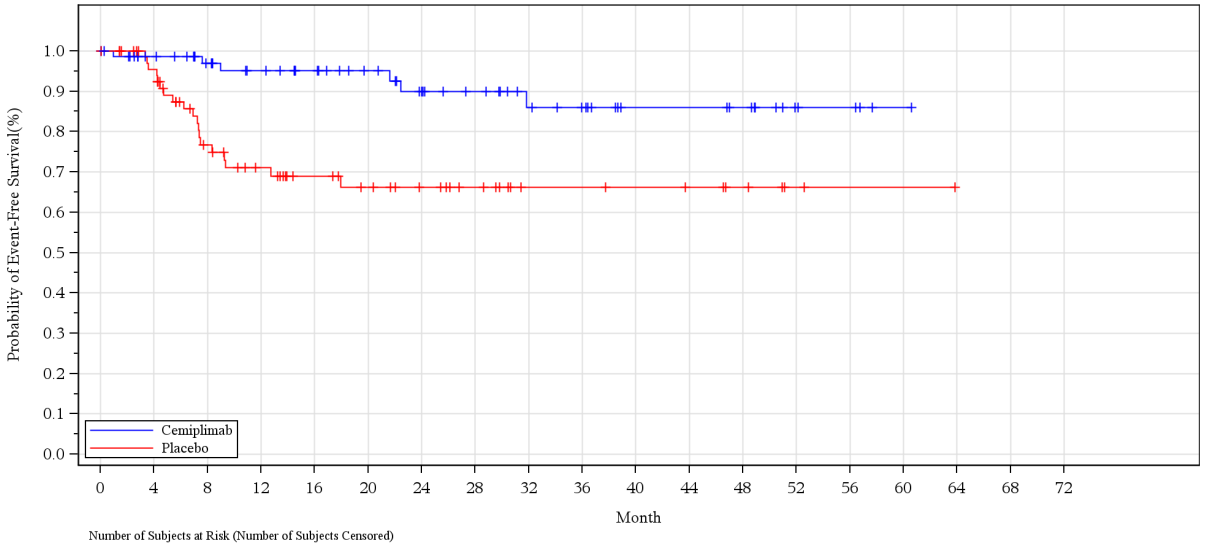
Cemiplimab	80 (0)	69 (9)	63 (14)	49 (27)	47 (29)	43 (33)	37 (38)	27 (45)	23 (49)	17 (55)	13 (59)	10 (62)	5 (68)	2 (70)	0 (72)	0 (72)	0 (72)	0 (72)	0 (72)
Placebo	69 (0)	62 (4)	51 (11)	40 (20)	36 (21)	33 (23)	27 (28)	22 (31)	19 (35)	15 (38)	12 (40)	11 (41)	8 (44)	3 (47)	2 (48)	0 (50)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

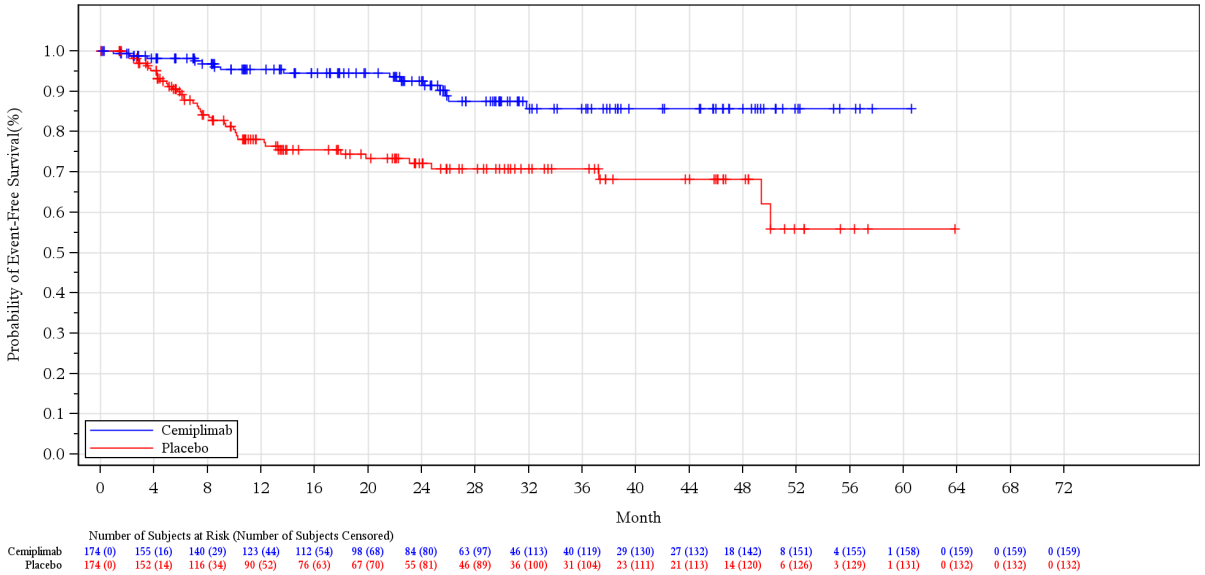
Cemiplimab	73 (0)	64 (8)	56 (15)	50 (20)	45 (25)	39 (31)	33 (35)	28 (40)	22 (45)	19 (48)	13 (54)	13 (54)	11 (56)	5 (62)	4 (63)	1 (66)	0 (67)	0 (67)	0 (67)
Placebo	72 (0)	62 (7)	42 (16)	34 (21)	27 (27)	23 (30)	19 (34)	15 (38)	9 (44)	9 (44)	8 (45)	7 (46)	5 (48)	2 (51)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male



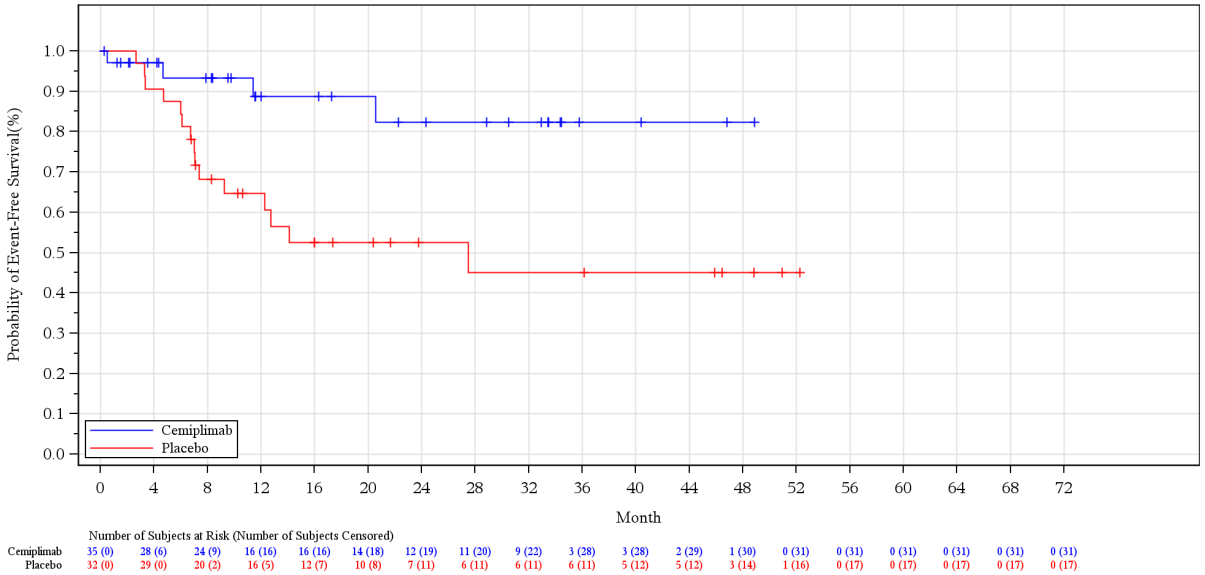
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	155 (16)	140 (29)	123 (44)	112 (54)	98 (68)	84 (80)	63 (97)	46 (113)	40 (119)	29 (130)	27 (132)	18 (142)	8 (151)	4 (155)	1 (158)	0 (159)	0 (159)	0 (159)
Placebo	174 (0)	152 (14)	116 (34)	90 (52)	76 (63)	67 (70)	55 (81)	46 (89)	36 (100)	31 (104)	23 (111)	21 (113)	14 (120)	6 (126)	3 (129)	1 (131)	0 (132)	0 (132)	0 (132)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

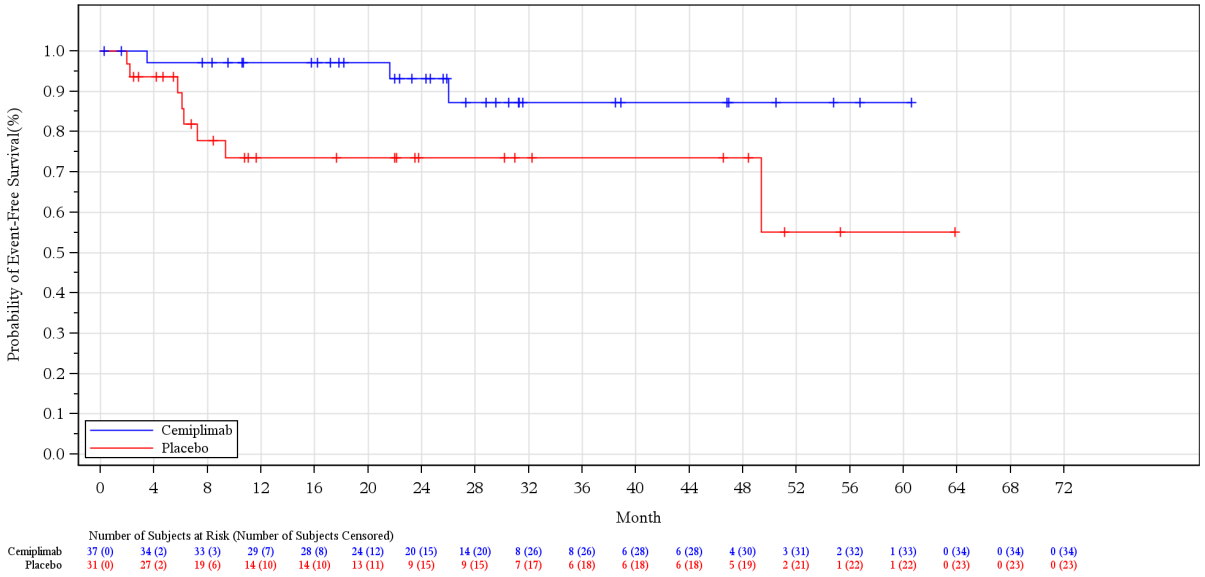
Cemiplimab	35 (0)	28 (6)	24 (9)	16 (16)	16 (16)	14 (18)	12 (19)	11 (20)	9 (22)	3 (28)	3 (28)	2 (29)	1 (30)	0 (31)	0 (31)	0 (31)	0 (31)	0 (31)	0 (31)
Placebo	32 (0)	29 (0)	20 (2)	16 (5)	12 (7)	10 (8)	7 (11)	6 (11)	6 (11)	6 (11)	5 (12)	5 (12)	3 (14)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

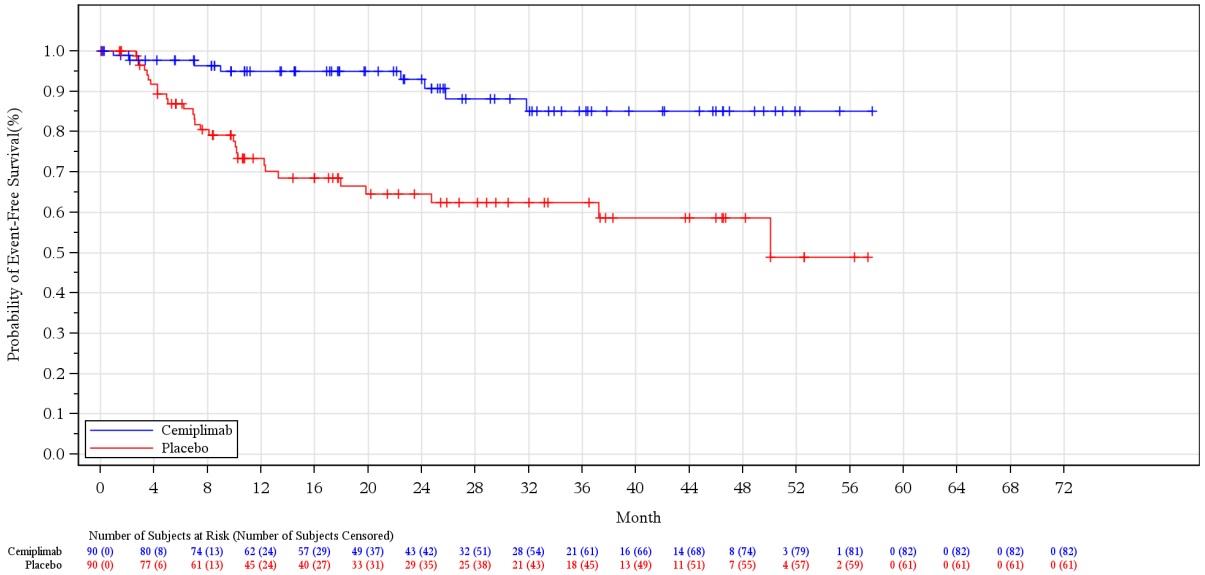
Cemiplimab	37 (0)	34 (2)	33 (3)	29 (7)	28 (8)	24 (12)	20 (15)	14 (20)	8 (26)	8 (26)	6 (28)	6 (28)	4 (30)	3 (31)	2 (32)	1 (33)	0 (34)	0 (34)	0 (34)
Placebo	31 (0)	27 (2)	19 (6)	14 (10)	14 (10)	13 (11)	9 (15)	9 (15)	7 (17)	6 (18)	6 (18)	6 (18)	5 (19)	2 (21)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

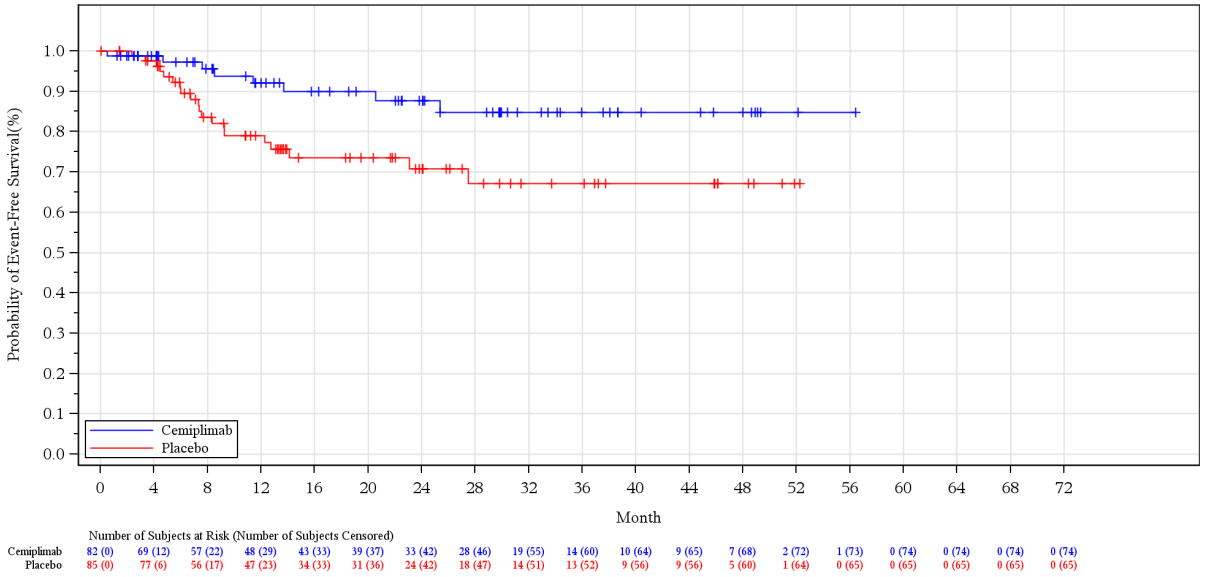
Cemiplimab	90 (0)	80 (8)	74 (13)	62 (24)	57 (29)	49 (37)	43 (42)	32 (51)	28 (54)	21 (61)	16 (66)	14 (68)	8 (74)	3 (79)	1 (81)	0 (82)	0 (82)	0 (82)	0 (82)
Placebo	90 (0)	77 (6)	61 (13)	45 (24)	40 (27)	33 (31)	29 (35)	25 (38)	21 (43)	18 (45)	13 (49)	11 (51)	7 (55)	4 (57)	2 (59)	0 (61)	0 (61)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

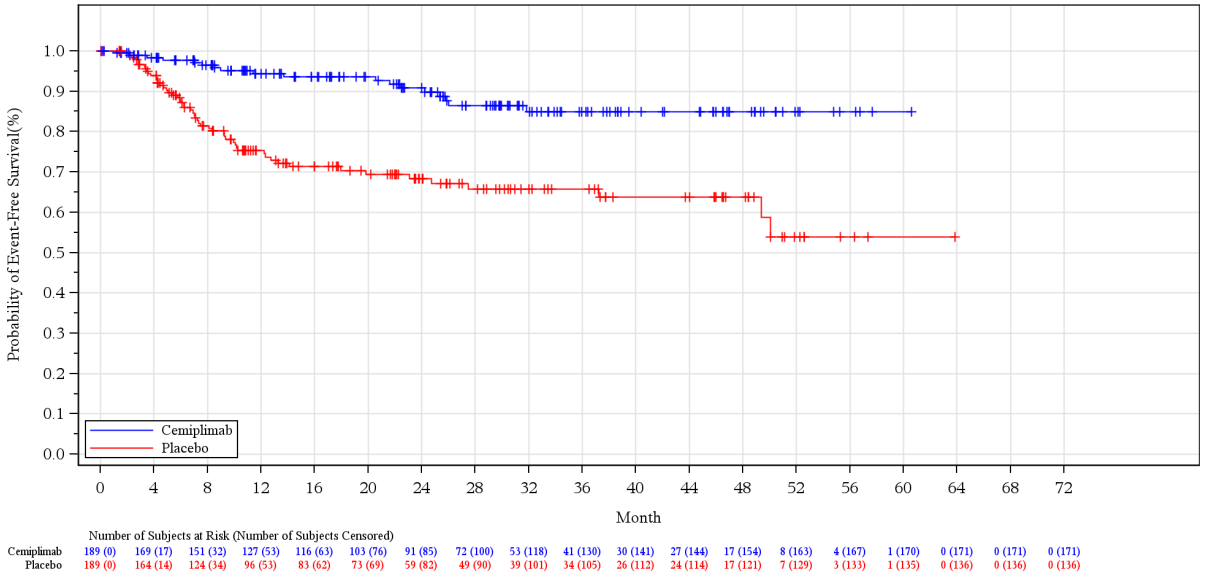
Cemiplimab	82 (0)	69 (12)	57 (22)	48 (29)	43 (33)	39 (37)	33 (42)	28 (46)	19 (55)	14 (60)	10 (64)	9 (65)	7 (68)	2 (72)	1 (73)	0 (74)	0 (74)	0 (74)	0 (74)
Placebo	85 (0)	77 (6)	56 (17)	47 (23)	34 (33)	31 (36)	24 (42)	18 (47)	14 (51)	13 (52)	9 (56)	9 (56)	5 (60)	1 (64)	0 (65)	0 (65)	0 (65)	0 (65)	0 (65)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

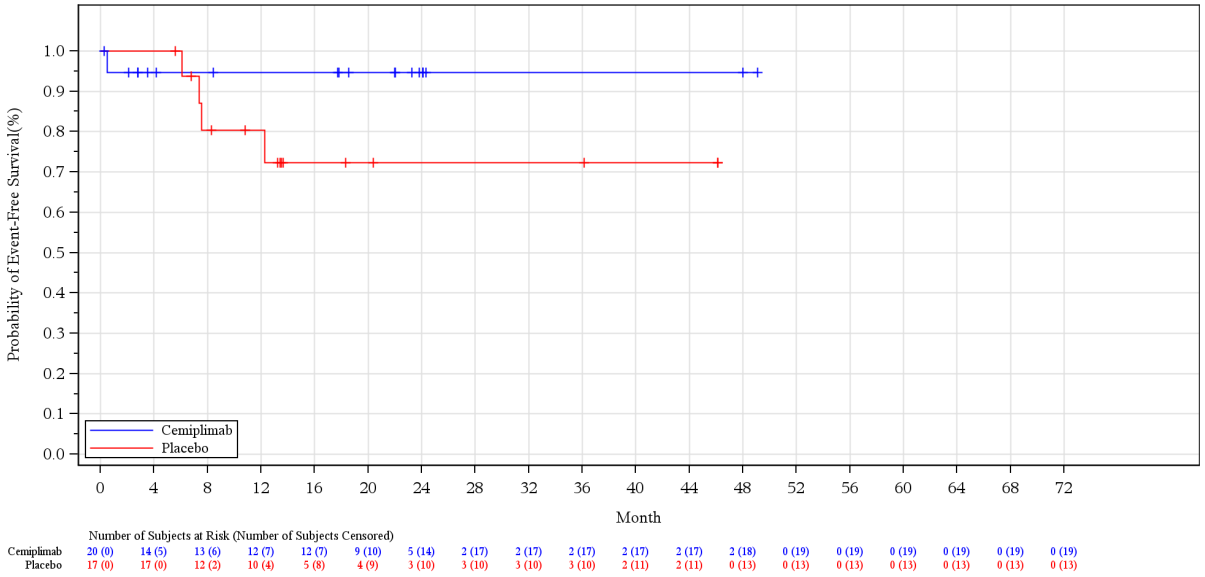
Cemiplimab	189 (0)	169 (17)	151 (32)	127 (53)	116 (63)	103 (76)	91 (85)	72 (100)	53 (118)	41 (130)	30 (141)	27 (144)	17 (154)	8 (163)	4 (167)	1 (170)	0 (171)	0 (171)	0 (171)
Placebo	189 (0)	164 (14)	124 (34)	96 (53)	83 (62)	73 (69)	59 (82)	49 (90)	39 (101)	34 (105)	26 (112)	24 (114)	17 (121)	7 (129)	3 (133)	1 (135)	0 (136)	0 (136)	0 (136)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

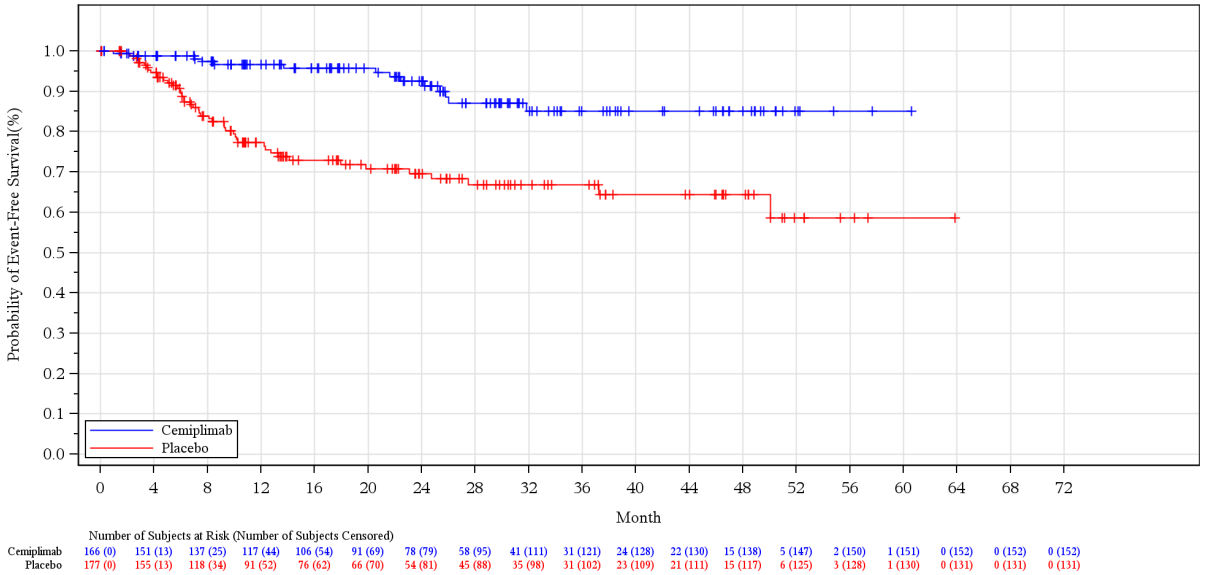
Cemiplimab	20 (0)	14 (5)	13 (6)	12 (7)	12 (7)	9 (10)	5 (14)	2 (17)	2 (17)	2 (17)	2 (17)	2 (17)	2 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	17 (0)	17 (0)	12 (2)	10 (4)	5 (8)	4 (9)	3 (10)	3 (10)	3 (10)	3 (10)	2 (11)	2 (11)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

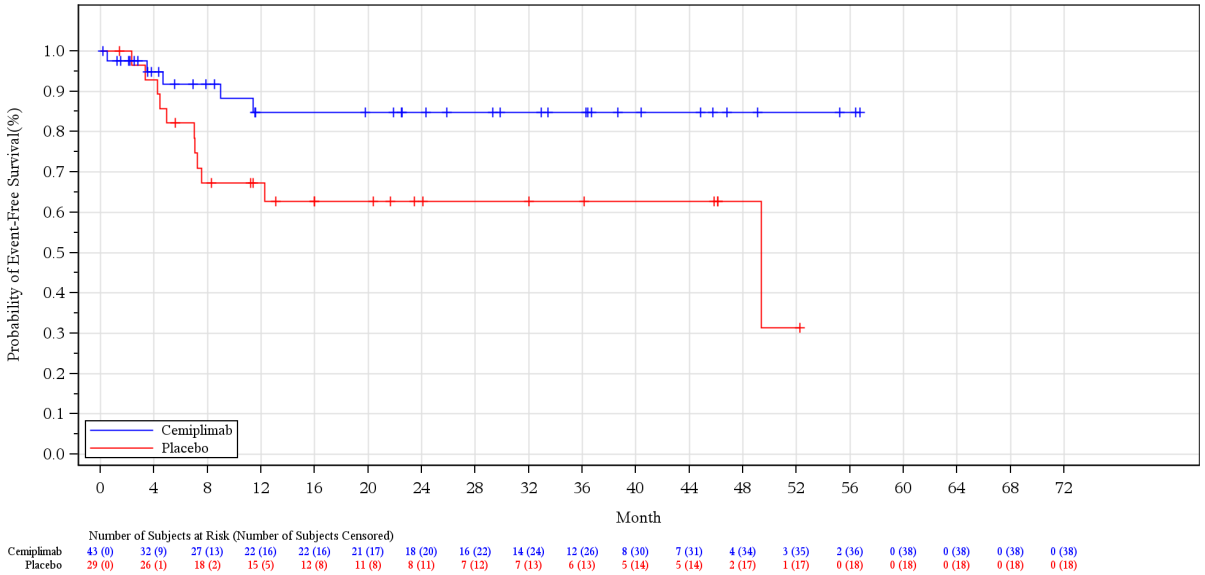
Cemiplimab	166 (0)	151 (13)	137 (25)	117 (44)	106 (54)	91 (69)	78 (79)	58 (95)	41 (111)	31 (121)	24 (128)	22 (130)	15 (138)	5 (147)	2 (150)	1 (151)	0 (152)	0 (152)	0 (152)
Placebo	177 (0)	155 (13)	118 (34)	91 (52)	76 (62)	66 (70)	54 (81)	45 (88)	35 (98)	31 (102)	23 (109)	21 (111)	15 (117)	6 (125)	3 (128)	1 (130)	0 (131)	0 (131)	0 (131)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

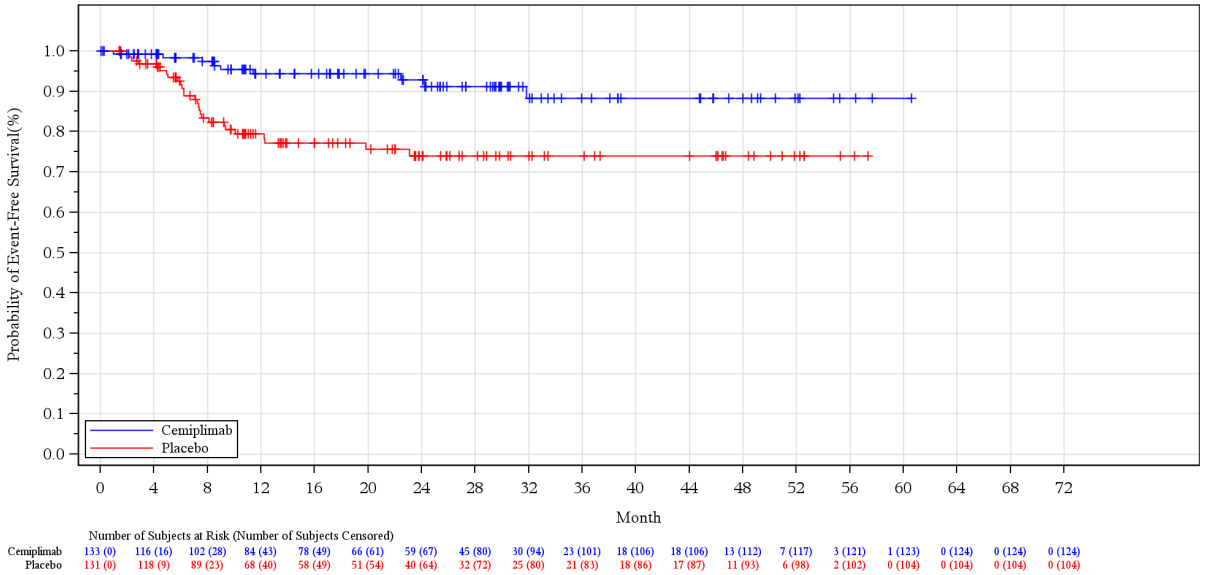
Cemiplimab	43 (0)	32 (9)	27 (13)	22 (16)	22 (16)	21 (17)	18 (20)	16 (22)	14 (24)	12 (26)	8 (30)	7 (31)	4 (34)	3 (35)	2 (36)	0 (38)	0 (38)	0 (38)	0 (38)
Placebo	29 (0)	26 (1)	18 (2)	15 (5)	12 (8)	11 (8)	8 (11)	7 (12)	7 (13)	6 (13)	5 (14)	5 (14)	2 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0



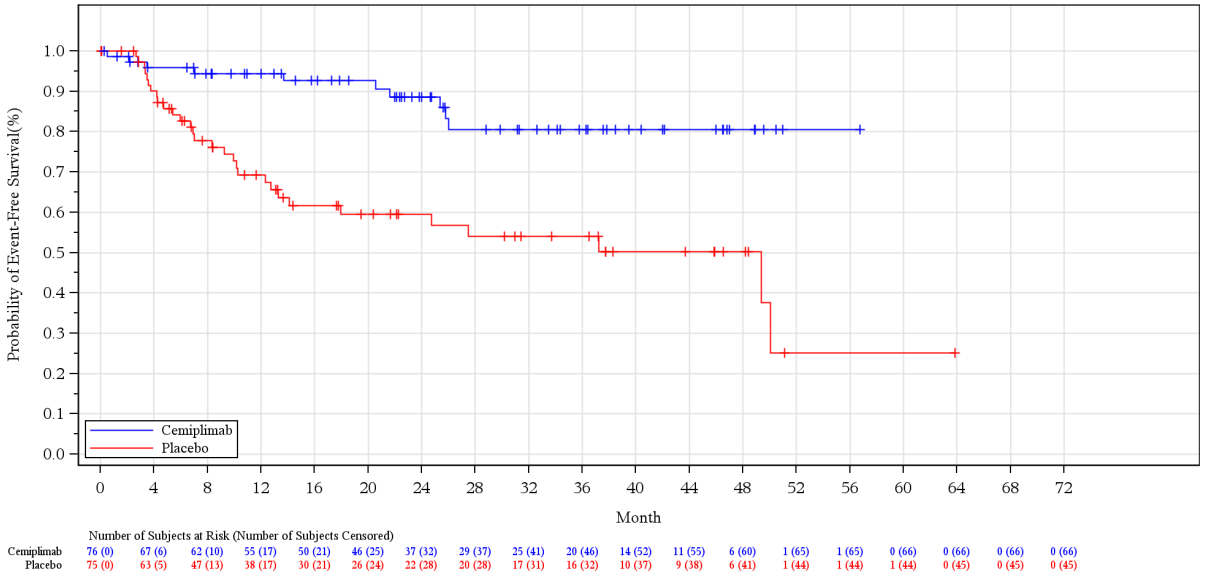
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	116 (16)	102 (28)	84 (43)	78 (49)	66 (61)	59 (67)	45 (80)	30 (94)	23 (101)	18 (106)	18 (106)	13 (112)	7 (117)	3 (121)	1 (123)	0 (124)	0 (124)	0 (124)
Placebo	131 (0)	118 (9)	89 (23)	68 (40)	58 (49)	51 (54)	40 (64)	32 (72)	25 (80)	21 (83)	18 (86)	17 (87)	11 (93)	6 (98)	2 (102)	0 (104)	0 (104)	0 (104)	0 (104)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

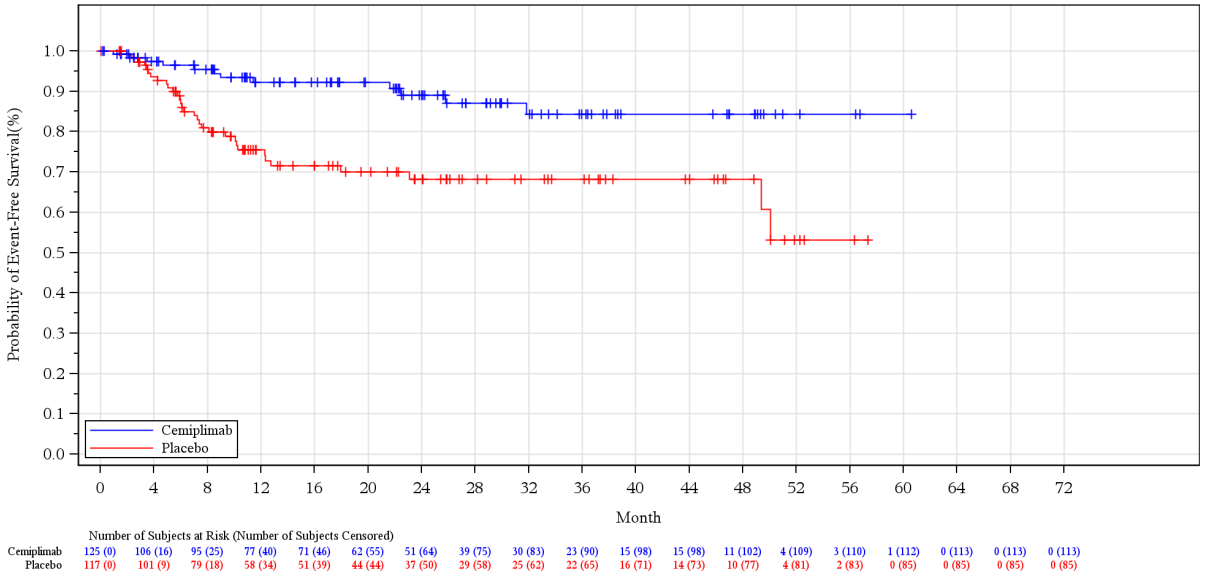
Cemiplimab	76 (0)	67 (6)	62 (10)	55 (17)	50 (21)	46 (25)	37 (32)	29 (37)	25 (41)	20 (46)	14 (52)	11 (55)	6 (60)	1 (65)	1 (65)	0 (66)	0 (66)	0 (66)	0 (66)
Placebo	75 (0)	63 (5)	47 (13)	38 (17)	30 (21)	26 (24)	22 (28)	20 (28)	17 (31)	16 (32)	10 (37)	9 (38)	6 (41)	1 (44)	1 (44)	1 (44)	0 (45)	0 (45)	0 (45)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

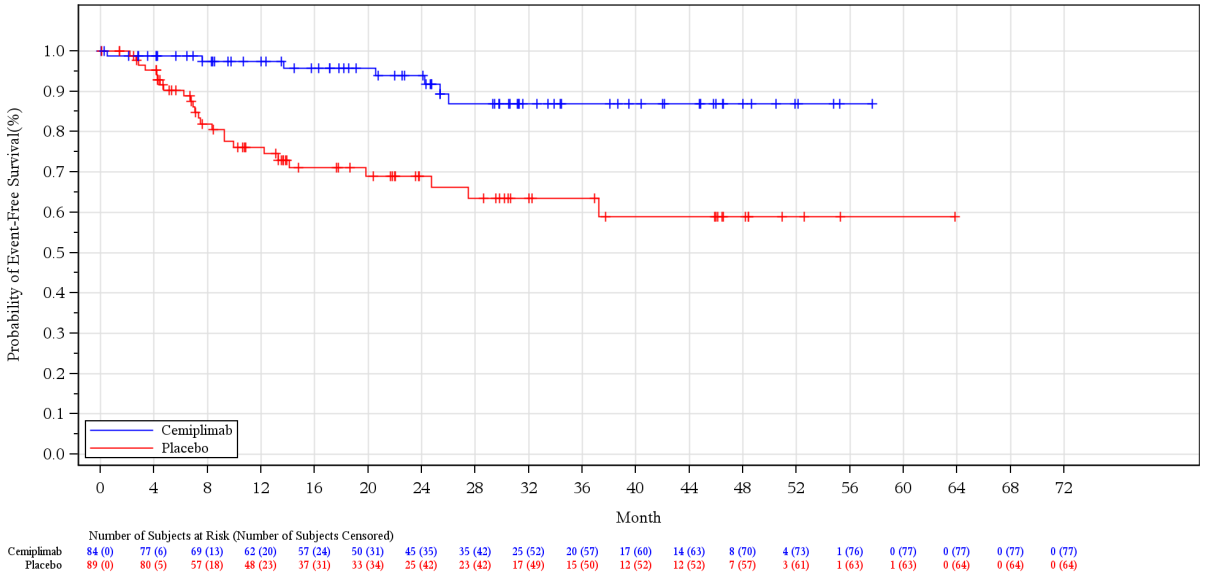
Cemiplimab	125 (0)	106 (16)	95 (25)	77 (40)	71 (46)	62 (55)	51 (64)	39 (75)	30 (83)	23 (90)	15 (98)	15 (98)	11 (102)	4 (109)	3 (110)	1 (112)	0 (113)	0 (113)	0 (113)
Placebo	117 (0)	101 (9)	79 (18)	58 (34)	51 (39)	44 (44)	37 (50)	29 (58)	25 (62)	22 (65)	16 (71)	14 (73)	10 (77)	4 (81)	2 (83)	0 (85)	0 (85)	0 (85)	0 (85)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	77 (6)	69 (13)	62 (20)	57 (24)	50 (31)	45 (35)	35 (42)	25 (52)	20 (57)	17 (60)	14 (63)	8 (70)	4 (73)	1 (76)	0 (77)	0 (77)	0 (77)	0 (77)
Placebo	89 (0)	80 (5)	57 (18)	48 (23)	37 (31)	33 (34)	25 (42)	23 (42)	17 (49)	15 (50)	12 (52)	12 (52)	7 (57)	3 (61)	1 (63)	1 (63)	0 (64)	0 (64)	0 (64)

Data cut-off as of October 4, 2024.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

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Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Number of censored participants, n (%)	52 (92.9%)	43 (66.2%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (28.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0004	
HR (95% CI) [c][d]	0.177 (0.060, 0.521)	
Heterogeneity p-value [c][e]	0.6809	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	92.3 (82.5, 96.7)
6 months	100 (100, 100)	87.7 (76.9, 93.6)
12 months	96.0 (84.9, 99.0)	70.1 (57.2, 79.8)
18 months	96.0 (84.9, 99.0)	66.3 (53.0, 76.7)
24 months	96.0 (84.9, 99.0)	66.3 (53.0, 76.7)
30 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
36 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
42 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
48 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
54 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
60 months	NE (NE, NE)	62.6 (48.0, 74.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	11 (7.2%)	39 (27.7%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	31 (22.0%)
Post Radiotherapy, n (%)	2 (1.3%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	8 (5.2%)	5 (3.5%)
Number of censored participants, n (%)	142 (92.8%)	102 (72.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	18.0 (9.3, 37.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.228 (0.116, 0.449)	
Heterogeneity p-value [c][e]	0.6809	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.3 (95.3, 99.9)	99.3 (95.0, 99.9)
6 months	98.0 (93.9, 99.3)	89.7 (83.3, 93.8)
12 months	96.5 (91.8, 98.5)	79.6 (71.7, 85.6)
18 months	96.5 (91.8, 98.5)	74.9 (66.2, 81.6)
24 months	93.4 (87.0, 96.7)	72.4 (63.4, 79.6)
30 months	92.3 (85.4, 96.0)	69.7 (60.2, 77.4)
36 months	90.6 (82.8, 95.0)	68.1 (58.2, 76.2)
42 months	88.7 (79.5, 93.9)	65.8 (55.2, 74.6)
48 months	88.7 (79.5, 93.9)	65.8 (55.2, 74.6)
54 months	88.7 (79.5, 93.9)	61.7 (48.6, 72.4)
60 months	88.7 (79.5, 93.9)	61.7 (48.6, 72.4)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Number of censored participants, n (%)	52 (92.9%)	43 (66.2%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (28.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0004	
HR (95% CI) [c][d]	0.177 (0.060, 0.521)	
Heterogeneity p-value [c][e]	0.5535	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	92.3 (82.5, 96.7)
6 months	100 (100, 100)	87.7 (76.9, 93.6)
12 months	96.0 (84.9, 99.0)	70.1 (57.2, 79.8)
18 months	96.0 (84.9, 99.0)	66.3 (53.0, 76.7)
24 months	96.0 (84.9, 99.0)	66.3 (53.0, 76.7)
30 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
36 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
42 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
48 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
54 months	89.7 (74.2, 96.1)	62.6 (48.0, 74.2)
60 months	NE (NE, NE)	62.6 (48.0, 74.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	7 (8.8%)	19 (27.5%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	6 (7.5%)	3 (4.3%)
Number of censored participants, n (%)	73 (91.3%)	50 (72.5%)
Q1 (95% CI), (months)[a]	NR (37.9, NE)	24.7 (10.3, 50.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0035	
HR (95% CI) [c][d]	0.289 (0.120, 0.699)	
Heterogeneity p-value [c][e]	0.5535	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.4, 99.8)	98.5 (90.0, 99.8)
6 months	96.2 (88.6, 98.7)	91.2 (81.4, 95.9)
12 months	94.8 (86.7, 98.0)	85.1 (74.0, 91.7)
18 months	94.8 (86.7, 98.0)	80.0 (67.9, 87.9)
24 months	92.8 (83.3, 97.0)	75.3 (61.9, 84.5)
30 months	90.7 (79.9, 95.8)	70.3 (56.0, 80.8)
36 months	90.7 (79.9, 95.8)	70.3 (56.0, 80.8)
42 months	86.9 (72.5, 94.0)	66.6 (51.0, 78.3)
48 months	86.9 (72.5, 94.0)	66.6 (51.0, 78.3)
54 months	86.9 (72.5, 94.0)	58.3 (36.8, 74.7)
60 months	86.9 (72.5, 94.0)	58.3 (36.8, 74.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	4 (5.5%)	20 (27.8%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	17 (23.6%)
Post Radiotherapy, n (%)	1 (1.4%)	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	2 (2.8%)
Number of censored participants, n (%)	69 (94.5%)	52 (72.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.3 (7.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0003	
HR (95% CI) [c][d]	0.141 (0.042, 0.478)	
Heterogeneity p-value [c][e]	0.5535	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	88.2 (77.8, 93.9)
12 months	98.4 (89.3, 99.8)	74.0 (61.5, 83.0)
18 months	98.4 (89.3, 99.8)	69.7 (56.4, 79.6)
24 months	94.1 (82.5, 98.1)	69.7 (56.4, 79.6)
30 months	94.1 (82.5, 98.1)	69.7 (56.4, 79.6)
36 months	90.8 (76.6, 96.6)	66.0 (51.2, 77.2)
42 months	90.8 (76.6, 96.6)	66.0 (51.2, 77.2)
48 months	90.8 (76.6, 96.6)	66.0 (51.2, 77.2)
54 months	90.8 (76.6, 96.6)	66.0 (51.2, 77.2)
60 months	90.8 (76.6, 96.6)	66.0 (51.2, 77.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	13 (7.5%)	47 (27.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	38 (21.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.9%)
Post Other Systemic Therapy, n (%)	10 (5.7%)	4 (2.3%)
Number of censored participants, n (%)	161 (92.5%)	127 (73.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	18.0 (9.3, 50.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.233 (0.125, 0.431)	
Heterogeneity p-value [c][e]	0.3990	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (95.9, 99.9)	97.1 (93.1, 98.8)
6 months	98.8 (95.4, 99.7)	88.8 (83.1, 92.7)
12 months	97.0 (92.8, 98.7)	78.8 (71.7, 84.3)
18 months	97.0 (92.8, 98.7)	74.9 (67.3, 81.0)
24 months	94.4 (88.9, 97.2)	72.9 (65.0, 79.4)
30 months	91.5 (85.0, 95.3)	70.7 (62.3, 77.5)
36 months	90.2 (83.0, 94.4)	69.3 (60.7, 76.5)
42 months	88.3 (79.9, 93.4)	67.5 (58.2, 75.2)
48 months	88.3 (79.9, 93.4)	67.5 (58.2, 75.2)
54 months	88.3 (79.9, 93.4)	64.1 (52.8, 73.4)
60 months	88.3 (79.9, 93.4)	64.1 (52.8, 73.4)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	14 (43.8%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	2 (6.3%)
Number of censored participants, n (%)	33 (94.3%)	18 (56.3%)
Q1 (95% CI), (months)[a]	NR (11.4, NE)	7.1 (4.7, 12.3)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0039	
HR (95% CI) [c][d]	0.147 (0.033, 0.656)	
Heterogeneity p-value [c][e]	0.3990	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.9 (79.8, 99.6)
6 months	96.8 (79.2, 99.5)	90.5 (73.4, 96.8)
12 months	92.9 (74.3, 98.2)	64.7 (45.3, 78.6)
18 months	92.9 (74.3, 98.2)	58.2 (39.1, 73.2)
24 months	92.9 (74.3, 98.2)	58.2 (39.1, 73.2)
30 months	92.9 (74.3, 98.2)	50.9 (29.7, 68.7)
36 months	92.9 (74.3, 98.2)	50.9 (29.7, 68.7)
42 months	92.9 (74.3, 98.2)	50.9 (29.7, 68.7)
48 months	92.9 (74.3, 98.2)	50.9 (29.7, 68.7)
54 months	NE (NE, NE)	50.9 (29.7, 68.7)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	9 (29.0%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	3 (9.7%)
Number of censored participants, n (%)	36 (97.3%)	22 (71.0%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.3 (5.8, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (12.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0014	
HR (95% CI) [c][d]	0.074 (0.009, 0.589)	
Heterogeneity p-value [c][e]	0.4624	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	93.5 (76.6, 98.3)
6 months	97.2 (81.9, 99.6)	90.1 (72.3, 96.7)
12 months	97.2 (81.9, 99.6)	72.8 (52.8, 85.4)
18 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
24 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
30 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
36 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
42 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
48 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
54 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
60 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	7 (7.8%)	29 (32.2%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	23 (25.6%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Number of censored participants, n (%)	83 (92.2%)	61 (67.8%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.3 (7.1, 30.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.197 (0.086, 0.451)	
Heterogeneity p-value [c][e]	0.4624	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (92.0, 99.8)	96.6 (89.9, 98.9)
6 months	98.8 (92.0, 99.8)	87.6 (78.8, 93.0)
12 months	96.5 (89.4, 98.8)	76.6 (66.1, 84.3)
18 months	96.5 (89.4, 98.8)	70.8 (59.5, 79.5)
24 months	94.7 (86.3, 98.0)	69.1 (57.5, 78.1)
30 months	91.0 (80.6, 95.9)	67.0 (55.0, 76.5)
36 months	88.3 (76.2, 94.5)	64.6 (52.1, 74.7)
42 months	88.3 (76.2, 94.5)	61.6 (48.1, 72.5)
48 months	88.3 (76.2, 94.5)	61.6 (48.1, 72.5)
54 months	88.3 (76.2, 94.5)	56.0 (39.5, 69.6)
60 months	88.3 (76.2, 94.5)	56.0 (39.5, 69.6)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	7 (8.5%)	23 (27.1%)
Received Cemiplimab in Part 2, n (%)	0	21 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.2%)
Post Other Systemic Therapy, n (%)	5 (6.1%)	1 (1.2%)
Number of censored participants, n (%)	75 (91.5%)	62 (72.9%)
Q1 (95% CI), (months)[a]	NR (37.9, NE)	16.2 (7.4, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0018	
HR (95% CI) [c][d]	0.282 (0.121, 0.658)	
Heterogeneity p-value [c][e]	0.4624	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	98.8 (91.8, 99.8)
6 months	98.7 (91.1, 99.8)	90.4 (81.7, 95.1)
12 months	95.6 (87.0, 98.6)	78.0 (67.3, 85.5)
18 months	95.6 (87.0, 98.6)	74.9 (63.7, 83.1)
24 months	91.2 (79.7, 96.3)	72.7 (60.9, 81.5)
30 months	88.8 (76.3, 94.9)	67.5 (54.2, 77.7)
36 months	88.8 (76.3, 94.9)	67.5 (54.2, 77.7)
42 months	84.1 (67.2, 92.8)	67.5 (54.2, 77.7)
48 months	84.1 (67.2, 92.8)	67.5 (54.2, 77.7)
54 months	84.1 (67.2, 92.8)	67.5 (54.2, 77.7)
60 months	84.1 (67.2, 92.8)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	14 (7.4%)	55 (29.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	45 (23.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.6%)
Post Other Systemic Therapy, n (%)	11 (5.8%)	5 (2.6%)
Number of censored participants, n (%)	175 (92.6%)	134 (70.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.3 (8.3, 30.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.211 (0.117, 0.381)	
Heterogeneity p-value [c][e]	0.6696	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.5 (96.2, 99.9)	96.8 (93.0, 98.5)
6 months	98.4 (95.0, 99.5)	88.1 (82.5, 92.0)
12 months	96.0 (91.8, 98.1)	76.6 (69.7, 82.2)
18 months	96.0 (91.8, 98.1)	73.1 (65.8, 79.1)
24 months	94.4 (89.3, 97.1)	71.3 (63.7, 77.6)
30 months	91.6 (85.5, 95.2)	68.2 (60.1, 75.0)
36 months	90.4 (83.7, 94.5)	67.0 (58.6, 74.0)
42 months	88.8 (81.1, 93.5)	65.3 (56.5, 72.8)
48 months	88.8 (81.1, 93.5)	65.3 (56.5, 72.8)
54 months	88.8 (81.1, 93.5)	62.4 (51.9, 71.2)
60 months	88.8 (81.1, 93.5)	62.4 (51.9, 71.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	6 (35.3%)
Received Cemiplimab in Part 2, n (%)	0	5 (29.4%)
Post Radiotherapy, n (%)	1 (5.0%)	0
Post Other Systemic Therapy, n (%)	0	1 (5.9%)
Number of censored participants, n (%)	19 (95.0%)	11 (64.7%)
Q1 (95% CI), (months)[a]	NR (20.9, NE)	12.3 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.6, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0329	
HR (95% CI) [c][d]	0.114 (0.012, 1.095)	
Heterogeneity p-value [c][e]	0.6696	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	100 (100, 100)
6 months	100 (100, 100)	100 (100, 100)
12 months	100 (100, 100)	76.5 (48.8, 90.4)
18 months	100 (100, 100)	62.3 (34.0, 81.3)
24 months	91.7 (53.9, 98.8)	62.3 (34.0, 81.3)
30 months	91.7 (53.9, 98.8)	62.3 (34.0, 81.3)
36 months	91.7 (53.9, 98.8)	62.3 (34.0, 81.3)
42 months	91.7 (53.9, 98.8)	62.3 (34.0, 81.3)
48 months	91.7 (53.9, 98.8)	62.3 (34.0, 81.3)
54 months	91.7 (53.9, 98.8)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	10 (6.0%)	52 (29.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	41 (23.2%)
Post Radiotherapy, n (%)	2 (1.2%)	5 (2.8%)
Post Other Systemic Therapy, n (%)	7 (4.2%)	6 (3.4%)
Number of censored participants, n (%)	156 (94.0%)	125 (70.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	13.3 (9.3, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.171 (0.087, 0.338)	
Heterogeneity p-value [c][e]	0.2862	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.4 (95.7, 99.9)	97.1 (93.2, 98.8)
6 months	99.4 (95.7, 99.9)	89.6 (84.0, 93.3)
12 months	98.1 (94.2, 99.4)	77.5 (70.3, 83.1)
18 months	98.1 (94.2, 99.4)	72.9 (65.3, 79.2)
24 months	95.4 (89.8, 97.9)	71.0 (63.0, 77.5)
30 months	93.3 (86.8, 96.6)	67.5 (58.9, 74.7)
36 months	91.8 (84.3, 95.8)	66.2 (57.4, 73.6)
42 months	89.7 (80.6, 94.6)	64.4 (55.0, 72.3)
48 months	89.7 (80.6, 94.6)	64.4 (55.0, 72.3)
54 months	89.7 (80.6, 94.6)	61.2 (50.1, 70.5)
60 months	89.7 (80.6, 94.6)	61.2 (50.1, 70.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	5 (11.6%)	9 (31.0%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	4 (9.3%)	0
Number of censored participants, n (%)	38 (88.4%)	20 (69.0%)
Q1 (95% CI), (months)[a]	NR (11.4, NE)	7.2 (4.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (12.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0534	
HR (95% CI) [c][d]	0.354 (0.118, 1.063)	
Heterogeneity p-value [c][e]	0.2862	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.6 (77.9, 99.5)
6 months	94.9 (81.0, 98.7)	85.8 (66.5, 94.4)
12 months	88.5 (72.0, 95.6)	70.9 (50.1, 84.3)
18 months	88.5 (72.0, 95.6)	67.0 (46.0, 81.3)
24 months	88.5 (72.0, 95.6)	67.0 (46.0, 81.3)
30 months	84.3 (65.7, 93.3)	67.0 (46.0, 81.3)
36 months	84.3 (65.7, 93.3)	67.0 (46.0, 81.3)
42 months	84.3 (65.7, 93.3)	67.0 (46.0, 81.3)
48 months	84.3 (65.7, 93.3)	67.0 (46.0, 81.3)
54 months	84.3 (65.7, 93.3)	67.0 (46.0, 81.3)
60 months	84.3 (65.7, 93.3)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	10 (7.5%)	32 (24.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	26 (19.8%)
Post Radiotherapy, n (%)	2 (1.5%)	1 (0.8%)
Post Other Systemic Therapy, n (%)	7 (5.3%)	5 (3.8%)
Number of censored participants, n (%)	123 (92.5%)	99 (75.6%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	23.1 (9.3, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.259 (0.127, 0.530)	
Heterogeneity p-value [c][e]	0.1890	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.9 (92.1, 98.8)
6 months	99.2 (94.5, 99.9)	91.6 (85.4, 95.3)
12 months	96.6 (91.1, 98.7)	80.4 (72.4, 86.3)
18 months	96.6 (91.1, 98.7)	77.7 (69.3, 84.0)
24 months	94.1 (87.0, 97.3)	75.0 (65.9, 81.9)
30 months	91.3 (83.2, 95.7)	73.3 (63.7, 80.7)
36 months	89.5 (80.2, 94.6)	71.4 (61.3, 79.3)
42 months	86.7 (75.3, 93.1)	71.4 (61.3, 79.3)
48 months	86.7 (75.3, 93.1)	71.4 (61.3, 79.3)
54 months	86.7 (75.3, 93.1)	71.4 (61.3, 79.3)
60 months	86.7 (75.3, 93.1)	71.4 (61.3, 79.3)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	5 (6.6%)	29 (38.7%)
Received Cemiplimab in Part 2, n (%)	0	24 (32.0%)
Post Radiotherapy, n (%)	1 (1.3%)	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	1 (1.3%)
Number of censored participants, n (%)	71 (93.4%)	46 (61.3%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	9.3 (5.9, 16.2)
Median (95% CI), (months)[a]	NR (NE, NE)	50.1 (18.0, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.122 (0.047, 0.319)	
Heterogeneity p-value [c][e]	0.1890	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (90.7, 99.8)	97.2 (89.3, 99.3)
6 months	97.3 (89.5, 99.3)	84.3 (73.5, 91.0)
12 months	95.9 (87.7, 98.6)	69.5 (57.1, 78.9)
18 months	95.9 (87.7, 98.6)	62.2 (49.1, 72.8)
24 months	94.0 (84.5, 97.7)	62.2 (49.1, 72.8)
30 months	91.8 (81.0, 96.6)	57.4 (43.8, 68.9)
36 months	91.8 (81.0, 96.6)	57.4 (43.8, 68.9)
42 months	91.8 (81.0, 96.6)	54.2 (40.0, 66.5)
48 months	91.8 (81.0, 96.6)	54.2 (40.0, 66.5)
54 months	91.8 (81.0, 96.6)	47.5 (29.9, 63.2)
60 months	NE (NE, NE)	47.5 (29.9, 63.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	11 (8.8%)	34 (29.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	28 (23.9%)
Post Radiotherapy, n (%)	1 (0.8%)	4 (3.4%)
Post Other Systemic Therapy, n (%)	9 (7.2%)	2 (1.7%)
Number of censored participants, n (%)	114 (91.2%)	83 (70.9%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.3 (7.2, 50.1)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.274 (0.138, 0.543)	
Heterogeneity p-value [c][e]	0.2059	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.2, 99.9)	97.4 (92.2, 99.2)
6 months	97.5 (92.4, 99.2)	87.8 (80.3, 92.6)
12 months	93.8 (87.5, 97.0)	76.1 (67.1, 83.0)
18 months	93.8 (87.5, 97.0)	71.6 (62.0, 79.2)
24 months	91.2 (83.5, 95.4)	70.1 (60.2, 78.0)
30 months	89.7 (81.3, 94.4)	70.1 (60.2, 78.0)
36 months	87.6 (78.0, 93.2)	68.2 (57.7, 76.6)
42 months	87.6 (78.0, 93.2)	68.2 (57.7, 76.6)
48 months	87.6 (78.0, 93.2)	68.2 (57.7, 76.6)
54 months	87.6 (78.0, 93.2)	62.9 (48.3, 74.5)
60 months	87.6 (78.0, 93.2)	62.9 (48.3, 74.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	4 (4.8%)	27 (30.3%)
Received Cemiplimab in Part 2, n (%)	0	22 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	2 (2.4%)	4 (4.5%)
Number of censored participants, n (%)	80 (95.2%)	62 (69.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.2 (7.5, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.119 (0.041, 0.341)	
Heterogeneity p-value [c][e]	0.2059	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.4.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	96.6 (89.7, 98.9)
6 months	100 (100, 100)	90.7 (82.3, 95.3)
12 months	100 (100, 100)	77.2 (66.5, 84.8)
18 months	100 (100, 100)	72.9 (61.7, 81.3)
24 months	98.2 (88.2, 99.8)	71.0 (59.4, 79.8)
30 months	94.4 (83.6, 98.2)	63.9 (50.7, 74.5)
36 months	94.4 (83.6, 98.2)	63.9 (50.7, 74.5)
42 months	91.0 (76.9, 96.7)	60.4 (46.0, 72.1)
48 months	91.0 (76.9, 96.7)	60.4 (46.0, 72.1)
54 months	91.0 (76.9, 96.7)	60.4 (46.0, 72.1)
60 months	91.0 (76.9, 96.7)	60.4 (46.0, 72.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Number of censored participants, n (%)	52 (92.9%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.0746	
Hazard ratio(interaction)	0.132 (0.014, 1.223)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	11 (7.2%)	39 (27.7%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	31 (22.0%)
Post Radiotherapy, n (%)	2 (1.3%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	8 (5.2%)	5 (3.5%)
Number of censored participants, n (%)	142 (92.8%)	102 (72.3%)
Proportionality Test p-value[a][b]	0.1846	
Hazard ratio(interaction)	0.550 (0.227, 1.331)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	4 (7.1%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Number of censored participants, n (%)	52 (92.9%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.0746	
Hazard ratio(interaction)	0.132 (0.014, 1.223)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	7 (8.8%)	19 (27.5%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	6 (7.5%)	3 (4.3%)
Number of censored participants, n (%)	73 (91.3%)	50 (72.5%)
Proportionality Test p-value[a][b]	0.8309	
Hazard ratio(interaction)	1.118 (0.403, 3.100)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	4 (5.5%)	20 (27.8%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	17 (23.6%)
Post Radiotherapy, n (%)	1 (1.4%)	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	2 (2.8%)
Number of censored participants, n (%)	69 (94.5%)	52 (72.2%)
Proportionality Test p-value[a][b]	0.0823	
Hazard ratio(interaction)	0.011 (0.000, 1.785)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	13 (7.5%)	47 (27.0%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	38 (21.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.9%)
Post Other Systemic Therapy, n (%)	10 (5.7%)	4 (2.3%)
Number of censored participants, n (%)	161 (92.5%)	127 (73.0%)
Proportionality Test p-value[a][b]	0.0411	
Hazard ratio(interaction)	0.417 (0.180, 0.965)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	2 (5.7%)	14 (43.8%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	2 (6.3%)
Number of censored participants, n (%)	33 (94.3%)	18 (56.3%)
Proportionality Test p-value[a][b]	0.9166	
Hazard ratio(interaction)	0.870 (0.063, 11.914)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	1 (2.7%)	9 (29.0%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	3 (9.7%)
Number of censored participants, n (%)	36 (97.3%)	22 (71.0%)
Proportionality Test p-value[a][b]	0.3985	
Hazard ratio(interaction)	5.222 (0.113, 242.25)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	7 (7.8%)	29 (32.2%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	23 (25.6%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Number of censored participants, n (%)	83 (92.2%)	61 (67.8%)
Proportionality Test p-value[a][b]	0.2698	
Hazard ratio(interaction)	0.551 (0.191, 1.589)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	7 (8.5%)	23 (27.1%)
Received Cemiplimab in Part 2, n (%)	0	21 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.2%)
Post Other Systemic Therapy, n (%)	5 (6.1%)	1 (1.2%)
Number of censored participants, n (%)	75 (91.5%)	62 (72.9%)
Proportionality Test p-value[a][b]	0.0535	
Hazard ratio(interaction)	0.249 (0.061, 1.021)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	14 (7.4%)	55 (29.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	45 (23.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.6%)
Post Other Systemic Therapy, n (%)	11 (5.8%)	5 (2.6%)
Number of censored participants, n (%)	175 (92.6%)	134 (70.9%)
Proportionality Test p-value[a][b]	0.0536	
Hazard ratio(interaction)	0.464 (0.213, 1.012)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	1 (5.0%)	6 (35.3%)
Received Cemiplimab in Part 2, n (%)	0	5 (29.4%)
Post Radiotherapy, n (%)	1 (5.0%)	0
Post Other Systemic Therapy, n (%)	0	1 (5.9%)
Number of censored participants, n (%)	19 (95.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	NE	
Hazard ratio(interaction)	NE (NE, NE)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	10 (6.0%)	52 (29.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	41 (23.2%)
Post Radiotherapy, n (%)	2 (1.2%)	5 (2.8%)
Post Other Systemic Therapy, n (%)	7 (4.2%)	6 (3.4%)
Number of censored participants, n (%)	156 (94.0%)	125 (70.6%)
Proportionality Test p-value[a][b]	0.0358	
Hazard ratio(interaction)	0.349 (0.131, 0.933)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	5 (11.6%)	9 (31.0%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	4 (9.3%)	0
Number of censored participants, n (%)	38 (88.4%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.2465	
Hazard ratio(interaction)	0.277 (0.031, 2.432)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	10 (7.5%)	32 (24.4%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	26 (19.8%)
Post Radiotherapy, n (%)	2 (1.5%)	1 (0.8%)
Post Other Systemic Therapy, n (%)	7 (5.3%)	5 (3.8%)
Number of censored participants, n (%)	123 (92.5%)	99 (75.6%)
Proportionality Test p-value[a][b]	0.0062	
Hazard ratio(interaction)	0.166 (0.046, 0.600)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	5 (6.6%)	29 (38.7%)
Received Cemiplimab in Part 2, n (%)	0	24 (32.0%)
Post Radiotherapy, n (%)	1 (1.3%)	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	1 (1.3%)
Number of censored participants, n (%)	71 (93.4%)	46 (61.3%)
Proportionality Test p-value[a][b]	0.6493	
Hazard ratio(interaction)	1.322 (0.397, 4.398)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	11 (8.8%)	34 (29.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	28 (23.9%)
Post Radiotherapy, n (%)	1 (0.8%)	4 (3.4%)
Post Other Systemic Therapy, n (%)	9 (7.2%)	2 (1.7%)
Number of censored participants, n (%)	114 (91.2%)	83 (70.9%)
Proportionality Test p-value[a][b]	0.1551	
Hazard ratio(interaction)	0.507 (0.199, 1.293)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.5.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

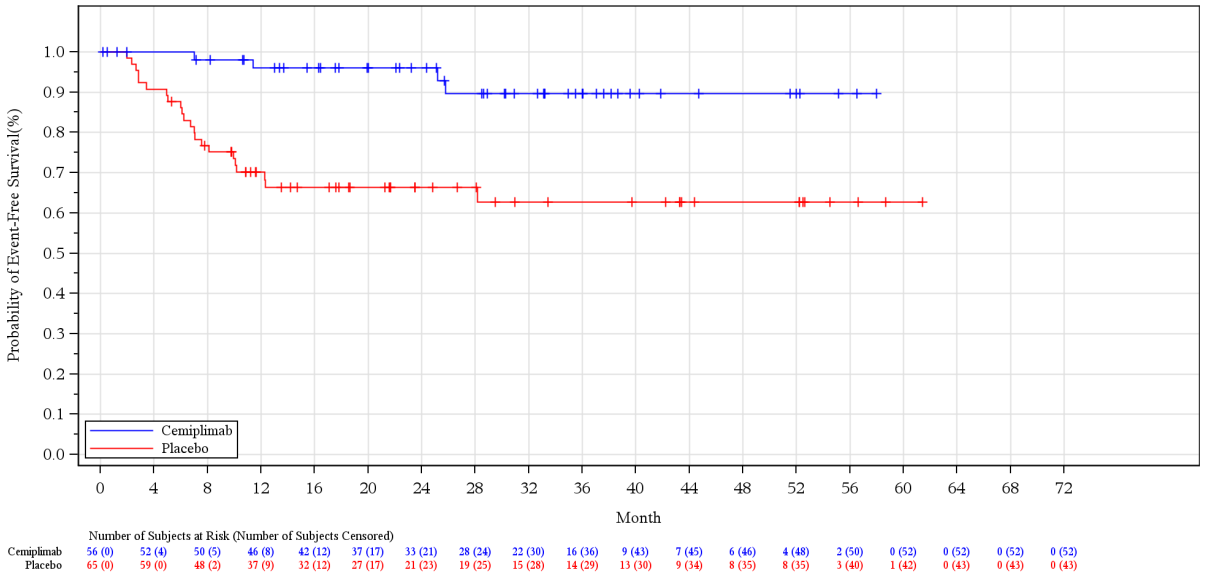
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	4 (4.8%)	27 (30.3%)
Received Cemiplimab in Part 2, n (%)	0	22 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	2 (2.4%)	4 (4.5%)
Number of censored participants, n (%)	80 (95.2%)	62 (69.7%)
Proportionality Test p-value[a][b]	0.0700	
Hazard ratio(interaction)	0.051 (0.002, 1.276)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	52 (4)	50 (5)	46 (8)	42 (12)	37 (17)	33 (21)	28 (24)	22 (30)	16 (36)	9 (43)	7 (45)	6 (46)	4 (48)	2 (50)	0 (52)	0 (52)	0 (52)	0 (52)
Placebo	65 (0)	59 (0)	48 (2)	37 (9)	32 (12)	27 (17)	21 (23)	19 (25)	15 (28)	14 (29)	13 (30)	9 (34)	8 (35)	8 (35)	3 (40)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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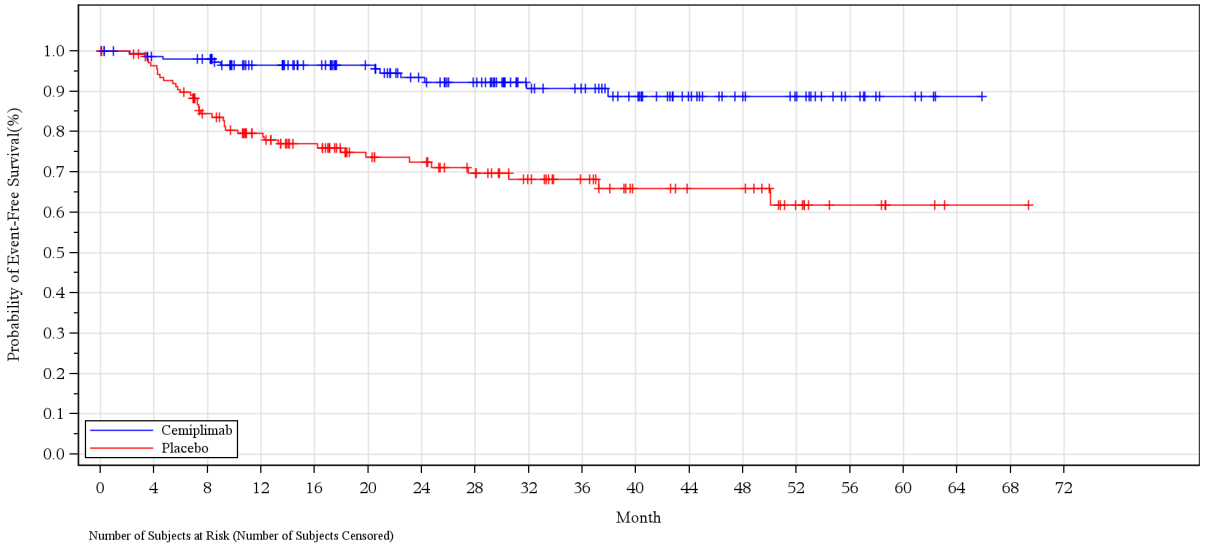
Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

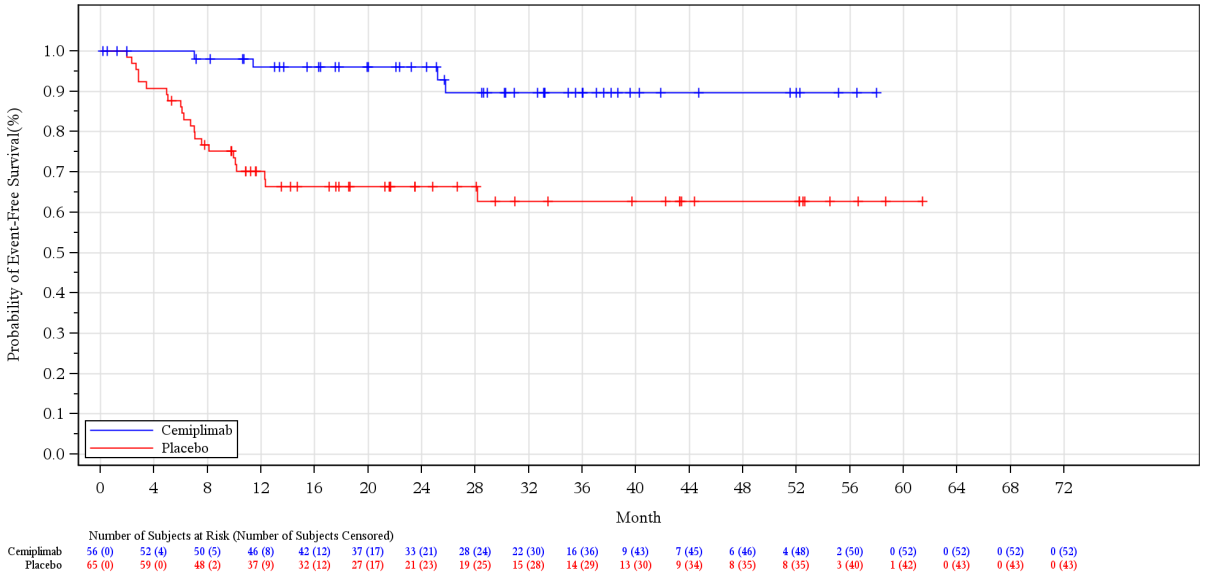
Cemiplimab	153 (0)	145 (6)	142 (8)	120 (28)	107 (41)	96 (52)	83 (62)	75 (69)	56 (87)	51 (92)	42 (100)	30 (112)	23 (120)	19 (123)	10 (132)	5 (137)	1 (141)	0 (142)	0 (142)
Placebo	141 (0)	131 (5)	108 (12)	91 (23)	78 (33)	62 (46)	58 (49)	50 (55)	40 (64)	33 (71)	23 (80)	20 (83)	20 (83)	11 (91)	6 (96)	3 (99)	1 (101)	1 (101)	0 (102)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

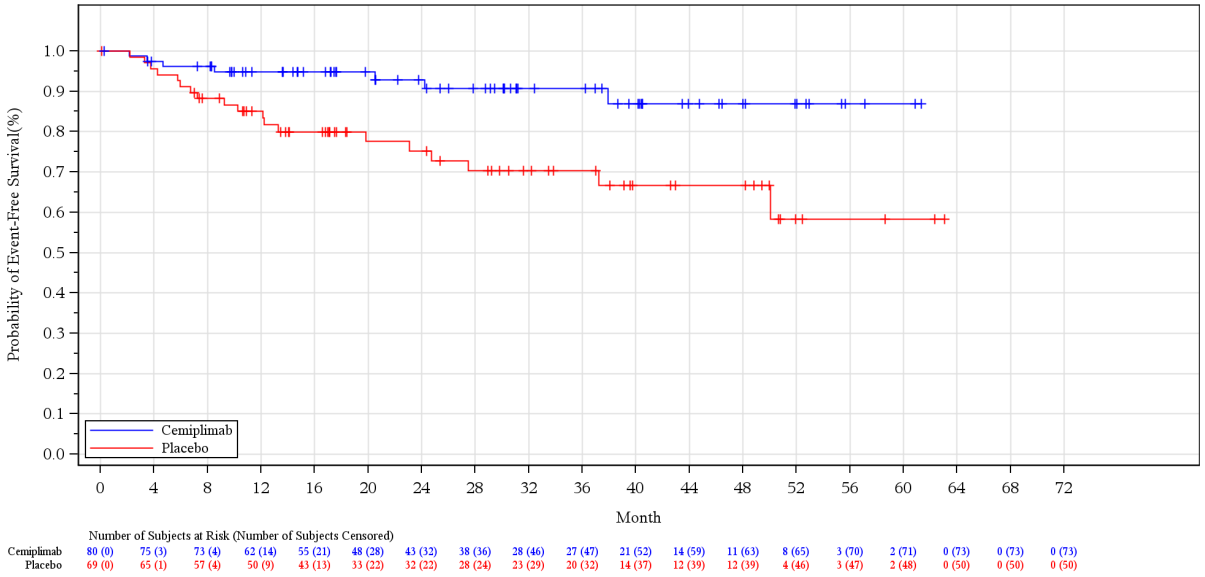
Cemiplimab	56 (0)	52 (4)	50 (5)	46 (8)	42 (12)	37 (17)	33 (21)	28 (24)	22 (30)	16 (36)	9 (43)	7 (45)	6 (46)	4 (48)	2 (50)	0 (52)	0 (52)	0 (52)	0 (52)
Placebo	65 (0)	59 (0)	48 (2)	37 (9)	32 (12)	27 (17)	21 (23)	19 (25)	15 (28)	14 (29)	13 (30)	9 (34)	8 (35)	8 (35)	3 (40)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

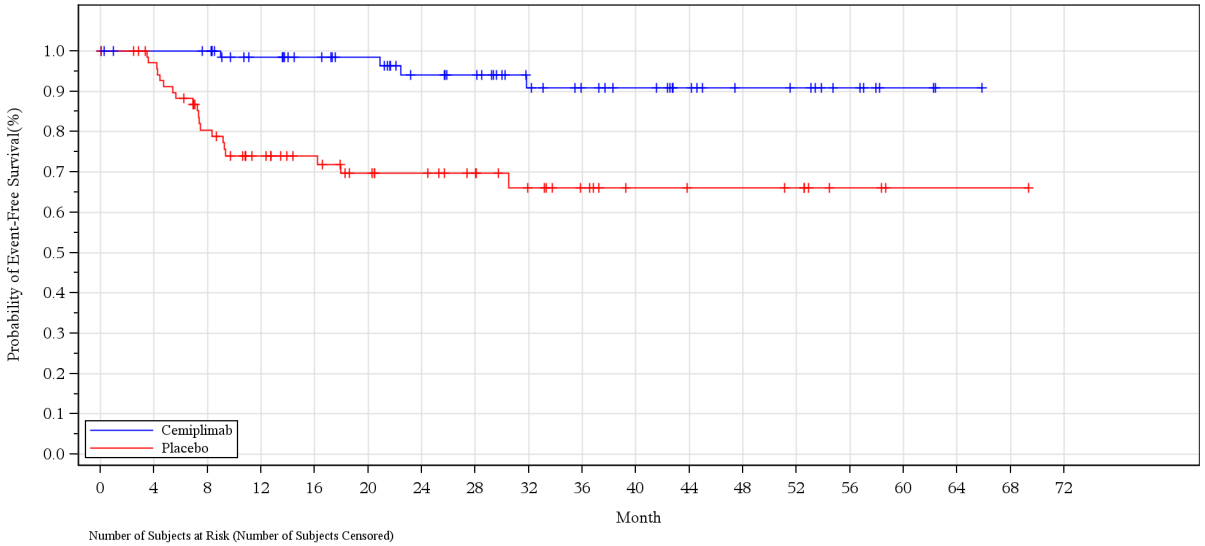
Cemiplimab	80 (0)	75 (3)	73 (4)	62 (14)	55 (21)	48 (28)	43 (32)	38 (36)	28 (46)	27 (47)	21 (52)	14 (59)	11 (63)	8 (65)	3 (70)	2 (71)	0 (73)	0 (73)	0 (73)
Placebo	69 (0)	65 (1)	57 (4)	50 (9)	43 (13)	33 (22)	32 (22)	28 (24)	23 (29)	20 (32)	14 (37)	12 (39)	12 (39)	4 (46)	3 (47)	2 (48)	0 (50)	0 (50)	0 (50)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

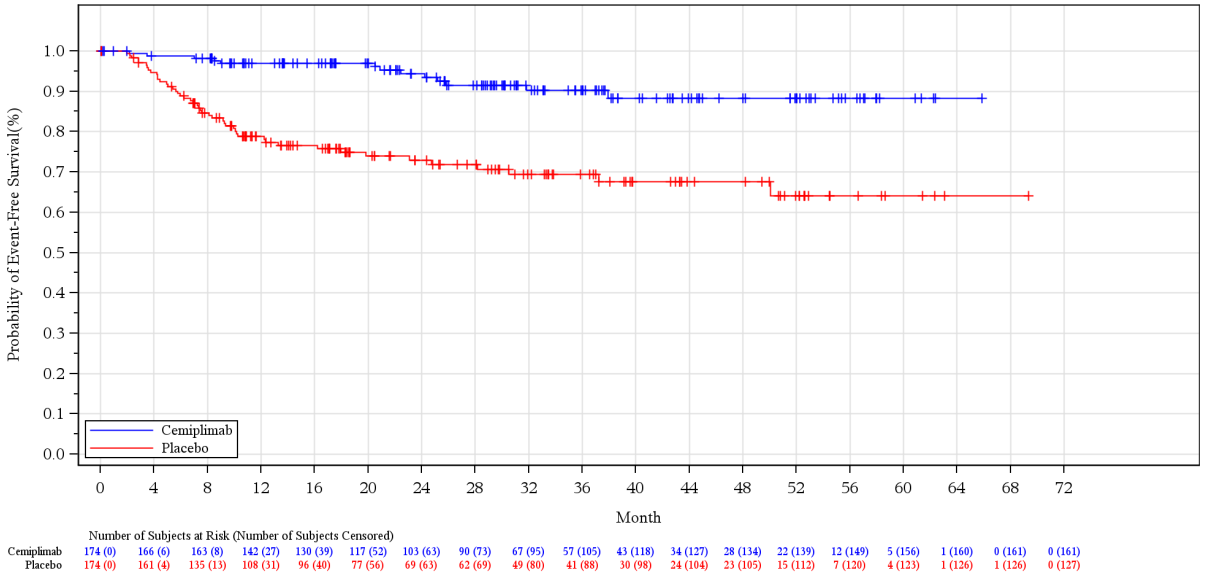
Cemiplimab	73 (0)	70 (3)	69 (4)	58 (14)	52 (20)	48 (24)	40 (30)	37 (33)	28 (41)	24 (45)	21 (48)	16 (53)	12 (57)	11 (58)	7 (62)	3 (66)	1 (68)	0 (69)	0 (69)
Placebo	72 (0)	66 (4)	51 (8)	41 (14)	35 (20)	29 (24)	26 (27)	22 (31)	17 (35)	13 (39)	9 (43)	8 (44)	8 (44)	7 (45)	3 (49)	1 (51)	1 (51)	1 (51)	0 (52)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

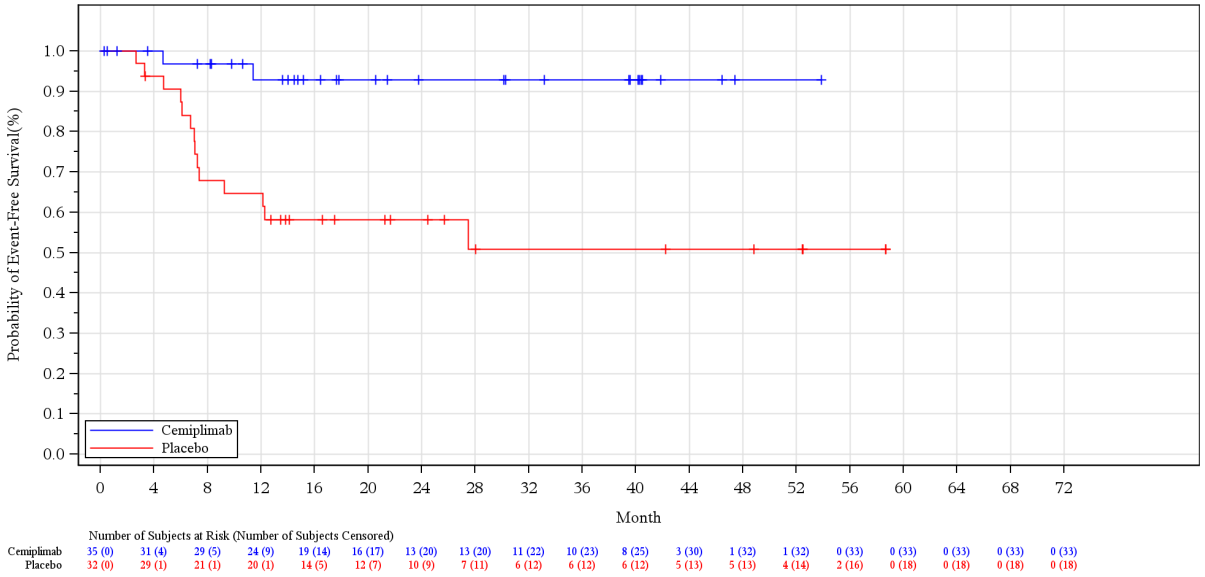
Cemiplimab	174 (0)	166 (6)	163 (8)	142 (27)	130 (39)	117 (52)	103 (63)	90 (73)	67 (95)	57 (105)	43 (118)	34 (127)	28 (134)	22 (139)	12 (149)	5 (156)	1 (160)	0 (161)	0 (161)
Placebo	174 (0)	161 (4)	135 (13)	108 (31)	96 (40)	77 (56)	69 (63)	62 (69)	49 (80)	41 (88)	30 (98)	24 (104)	23 (105)	15 (112)	7 (120)	4 (123)	1 (126)	1 (126)	0 (127)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

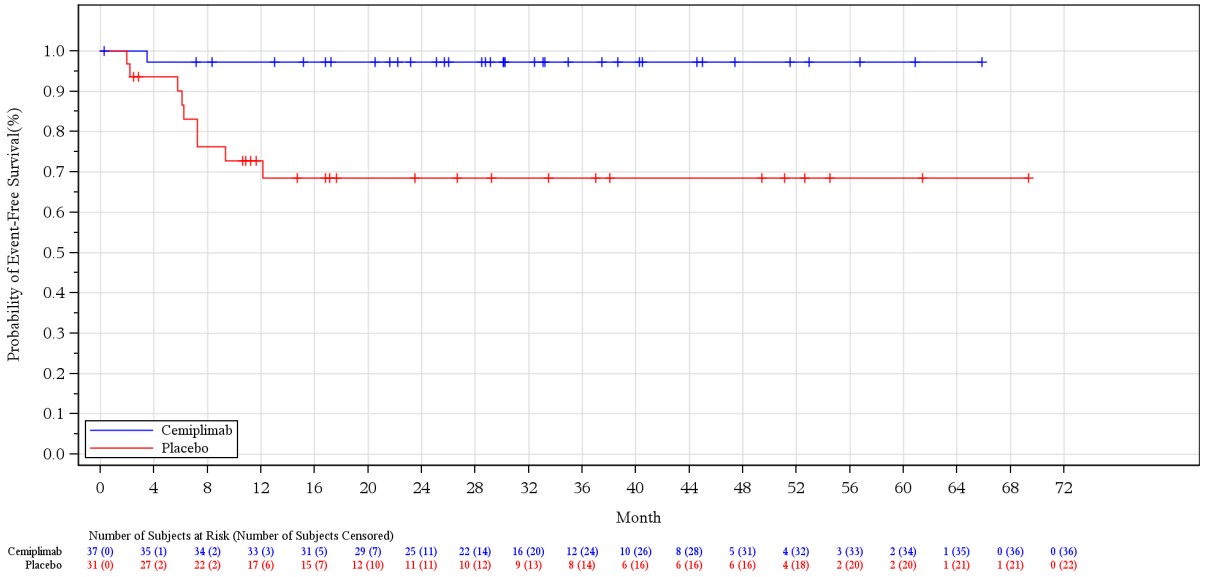
Cemiplimab	35 (0)	31 (4)	29 (5)	24 (9)	19 (14)	16 (17)	13 (20)	13 (20)	11 (22)	10 (23)	8 (25)	3 (30)	1 (32)	1 (32)	0 (33)	0 (33)	0 (33)	0 (33)	0 (33)
Placebo	32 (0)	29 (1)	21 (1)	20 (1)	14 (5)	12 (7)	10 (9)	7 (11)	6 (12)	6 (12)	6 (12)	5 (13)	5 (13)	4 (14)	2 (16)	0 (18)	0 (18)	0 (18)	0 (18)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

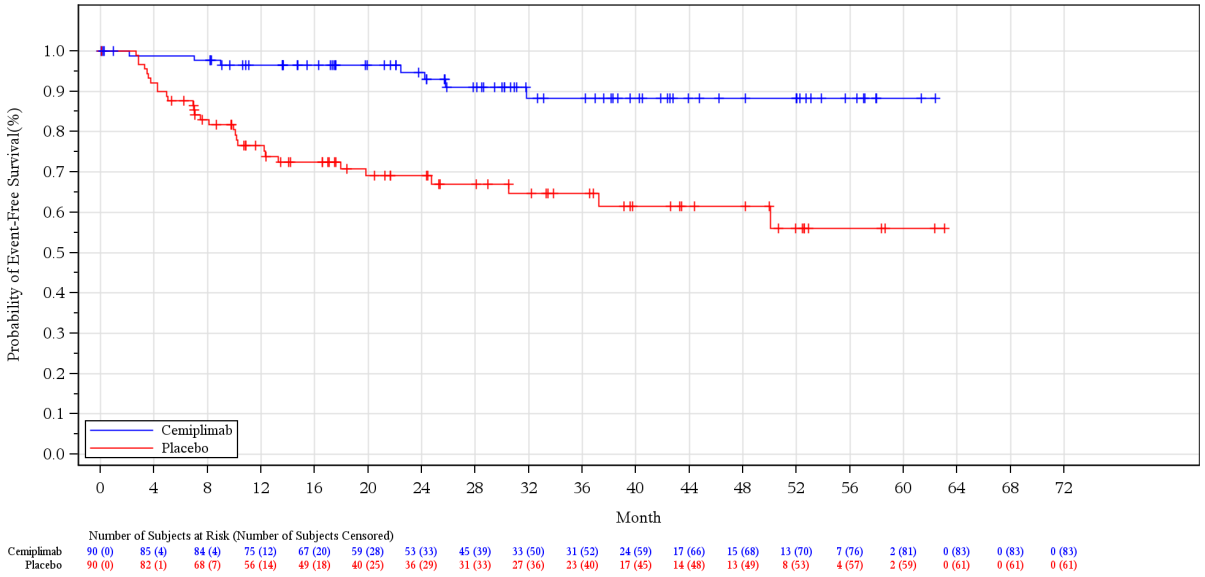
Cemiplimab	37 (0)	35 (1)	34 (2)	33 (3)	31 (5)	29 (7)	25 (11)	22 (14)	16 (20)	12 (24)	10 (26)	8 (28)	5 (31)	4 (32)	3 (33)	2 (34)	1 (35)	0 (36)	0 (36)
Placebo	31 (0)	27 (2)	22 (2)	17 (6)	15 (7)	12 (10)	11 (11)	10 (12)	9 (13)	8 (14)	6 (16)	6 (16)	6 (16)	4 (18)	2 (20)	2 (20)	1 (21)	1 (21)	0 (22)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

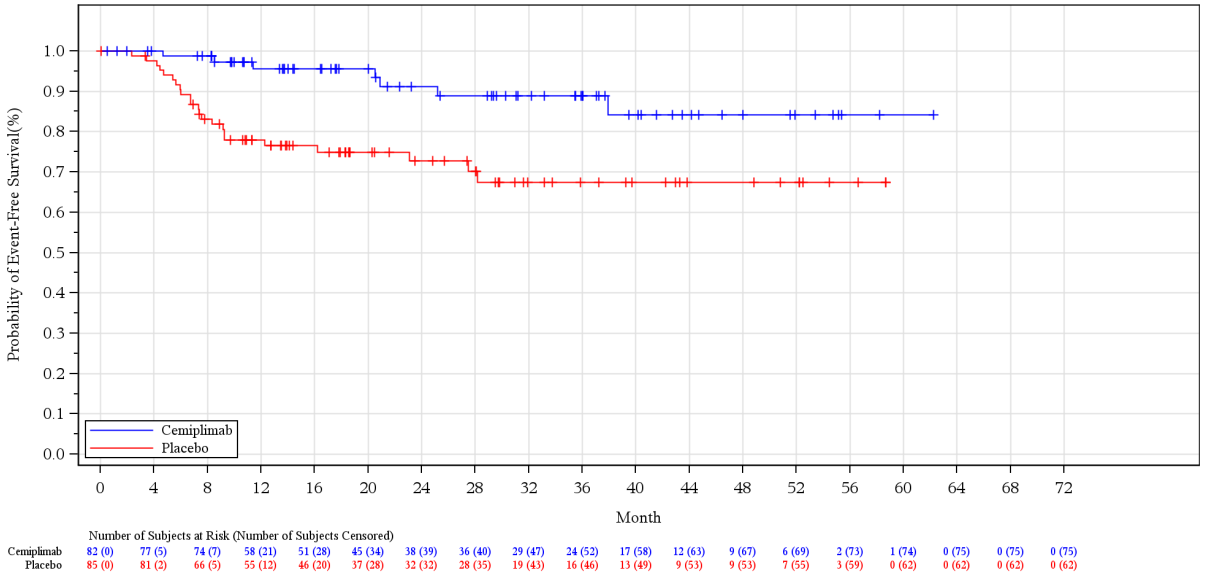
Cemiplimab	90 (0)	85 (4)	84 (4)	75 (12)	67 (20)	59 (28)	53 (33)	45 (39)	33 (50)	31 (52)	24 (59)	17 (66)	15 (68)	13 (70)	7 (76)	2 (81)	0 (83)	0 (83)	0 (83)
Placebo	90 (0)	82 (1)	68 (7)	56 (14)	49 (18)	40 (25)	36 (29)	31 (33)	27 (36)	23 (40)	17 (45)	14 (48)	13 (49)	8 (53)	4 (57)	2 (59)	0 (61)	0 (61)	0 (61)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

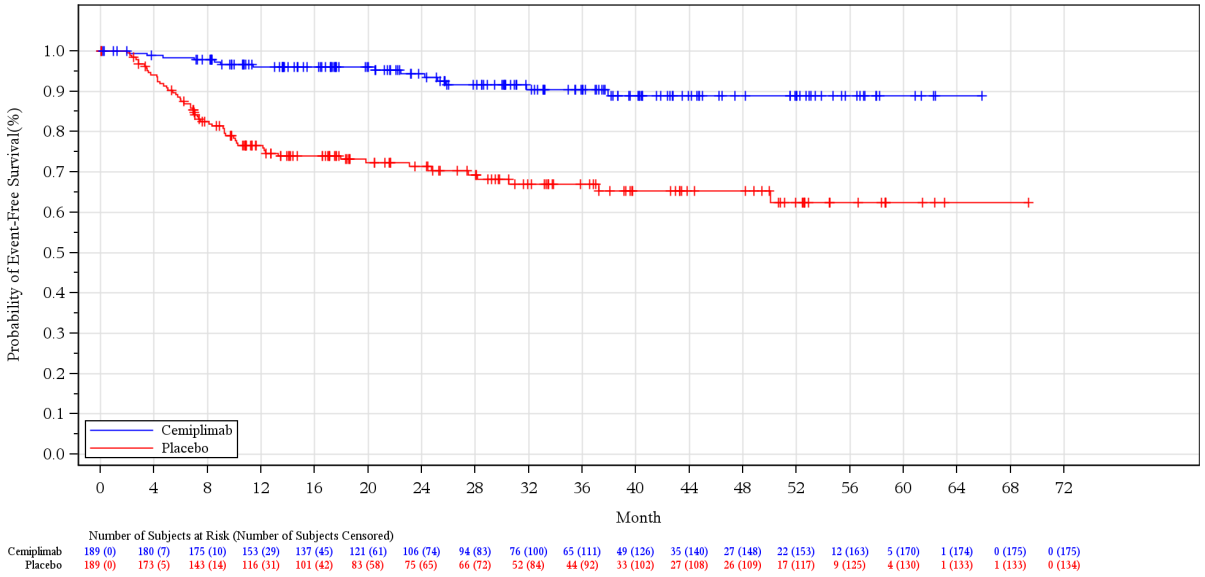
Cemiplimab	82 (0)	77 (5)	74 (7)	58 (21)	51 (28)	45 (34)	38 (39)	36 (40)	29 (47)	24 (52)	17 (58)	12 (63)	9 (67)	6 (69)	2 (73)	1 (74)	0 (75)	0 (75)	0 (75)
Placebo	85 (0)	81 (2)	66 (5)	55 (12)	46 (20)	37 (28)	32 (32)	28 (35)	19 (43)	16 (46)	13 (49)	9 (53)	9 (53)	7 (55)	3 (59)	0 (62)	0 (62)	0 (62)	0 (62)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

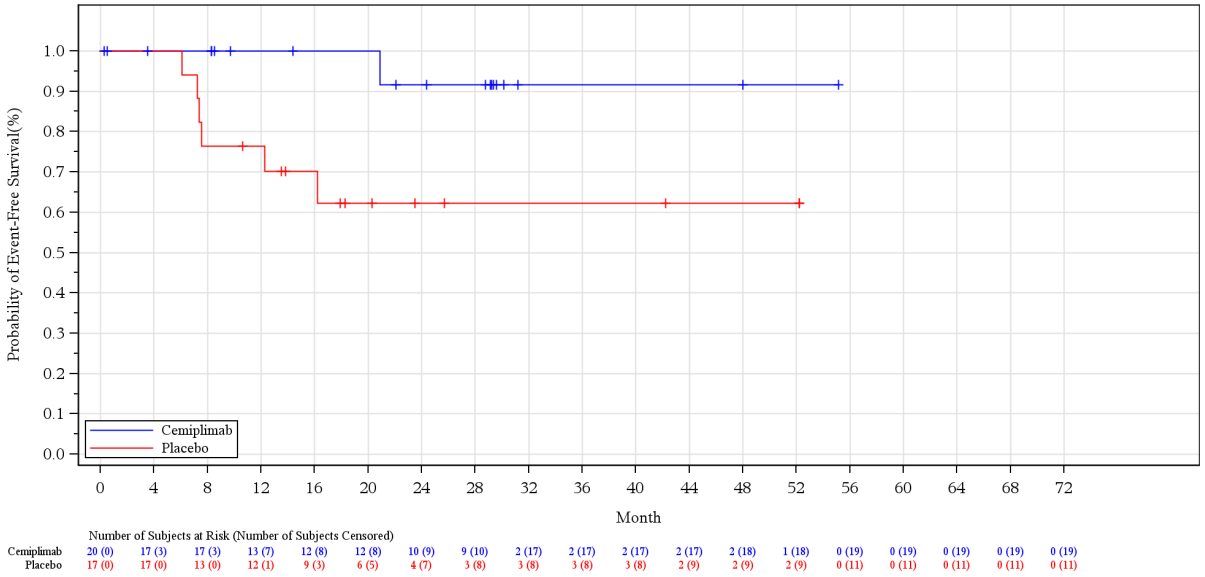
Cemiplimab	189 (0)	180 (7)	175 (10)	153 (29)	137 (45)	121 (61)	106 (74)	94 (83)	76 (100)	65 (111)	49 (126)	35 (140)	27 (148)	22 (153)	12 (163)	5 (170)	1 (174)	0 (175)	0 (175)
Placebo	189 (0)	173 (5)	143 (14)	116 (31)	101 (42)	83 (58)	75 (65)	66 (72)	52 (84)	44 (92)	33 (102)	27 (108)	26 (109)	17 (117)	9 (125)	4 (130)	1 (133)	1 (133)	0 (134)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

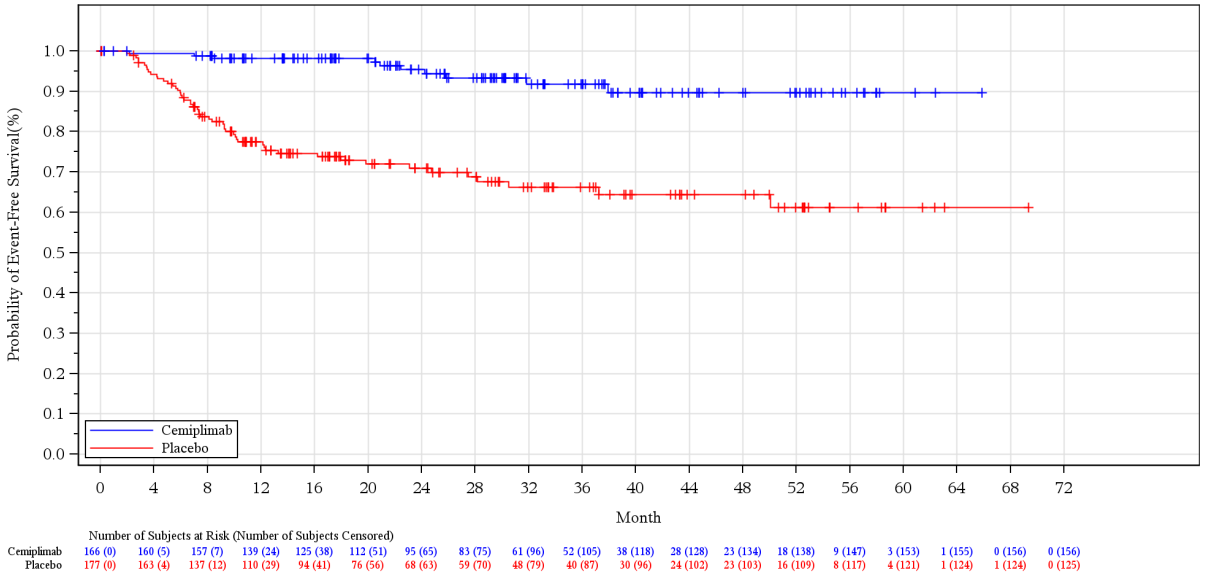
Cemiplimab	20 (0)	17 (3)	17 (3)	13 (7)	12 (8)	12 (8)	10 (9)	9 (10)	2 (17)	2 (17)	2 (17)	2 (17)	2 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	17 (0)	17 (0)	13 (0)	12 (1)	9 (3)	6 (5)	4 (7)	3 (8)	3 (8)	3 (8)	3 (8)	2 (9)	2 (9)	2 (9)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

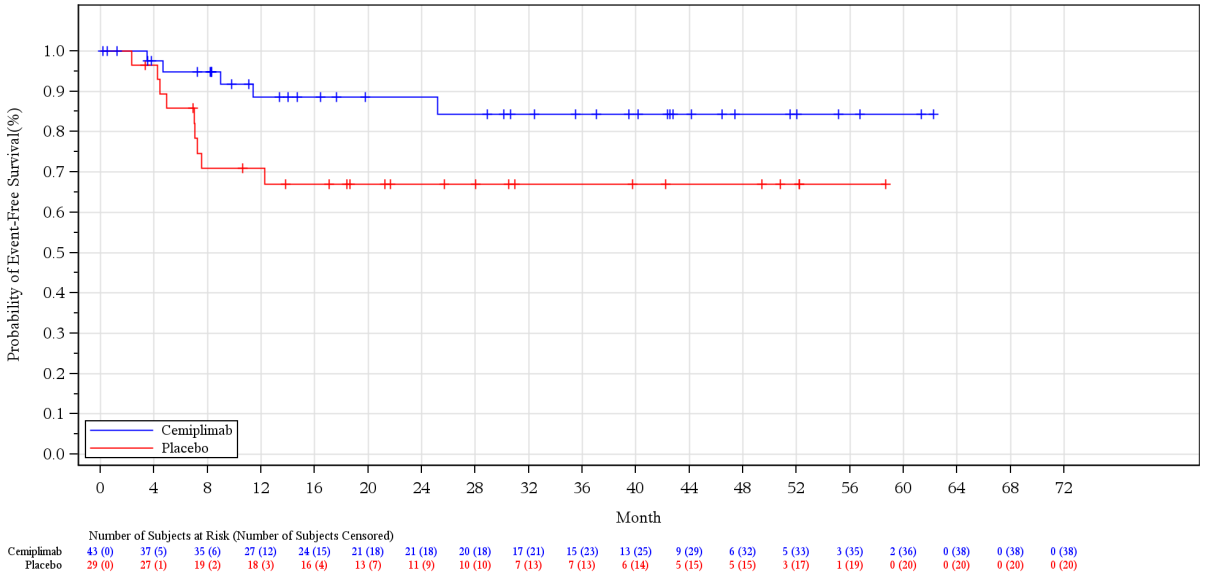
Cemiplimab	166 (0)	160 (5)	157 (7)	139 (24)	125 (38)	112 (51)	95 (65)	83 (75)	61 (96)	52 (105)	38 (118)	28 (128)	23 (134)	18 (138)	9 (147)	3 (153)	1 (155)	0 (156)	0 (156)
Placebo	177 (0)	163 (4)	137 (12)	110 (29)	94 (41)	76 (56)	68 (63)	59 (70)	48 (79)	40 (87)	30 (96)	24 (102)	23 (103)	16 (109)	8 (117)	4 (121)	1 (124)	1 (124)	0 (125)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

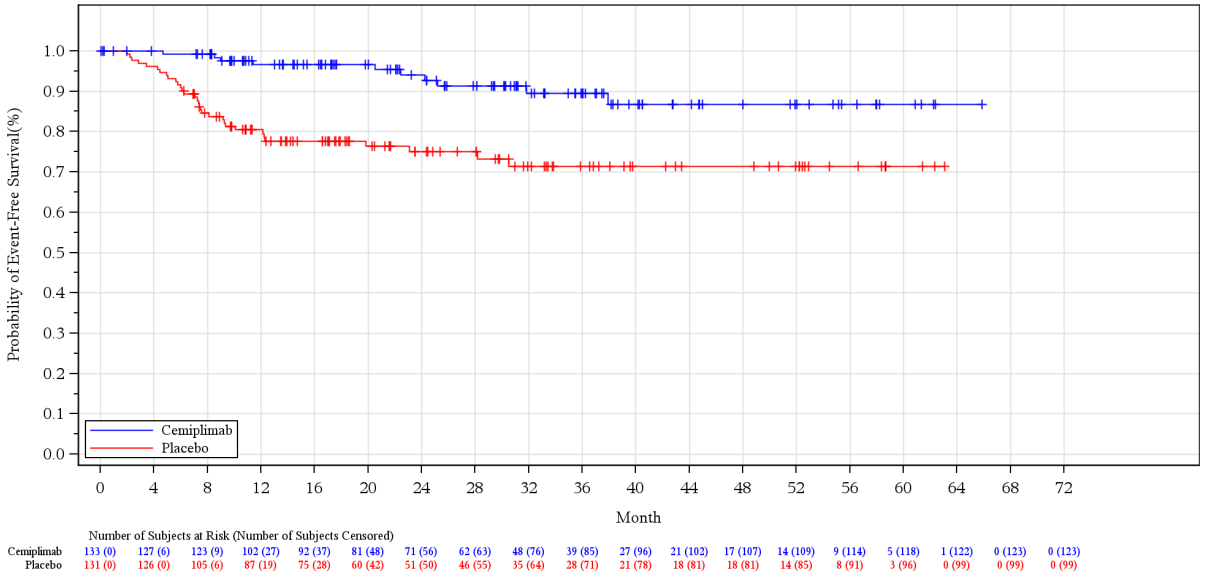
Cemiplimab	43 (0)	37 (5)	35 (6)	27 (12)	24 (15)	21 (18)	21 (18)	20 (18)	17 (21)	15 (23)	13 (25)	9 (29)	6 (32)	5 (33)	3 (35)	2 (36)	0 (38)	0 (38)	0 (38)
Placebo	29 (0)	27 (1)	19 (2)	18 (3)	16 (4)	13 (7)	11 (9)	10 (10)	7 (13)	7 (13)	6 (14)	5 (15)	5 (15)	3 (17)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

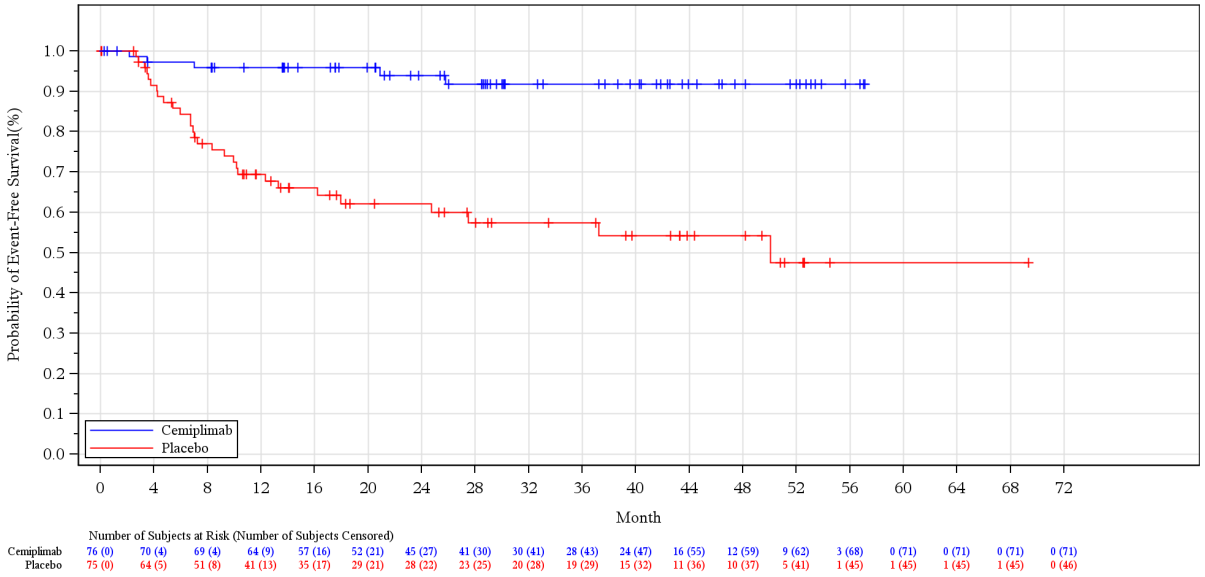
Cemiplimab	133 (0)	127 (6)	123 (9)	102 (27)	92 (37)	81 (48)	71 (56)	62 (63)	48 (76)	39 (85)	27 (96)	21 (102)	17 (107)	14 (109)	9 (114)	5 (118)	1 (122)	0 (123)	0 (123)
Placebo	131 (0)	126 (0)	105 (6)	87 (19)	75 (28)	60 (42)	51 (50)	46 (55)	35 (64)	28 (71)	21 (78)	18 (81)	18 (81)	14 (85)	8 (91)	3 (96)	0 (99)	0 (99)	0 (99)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

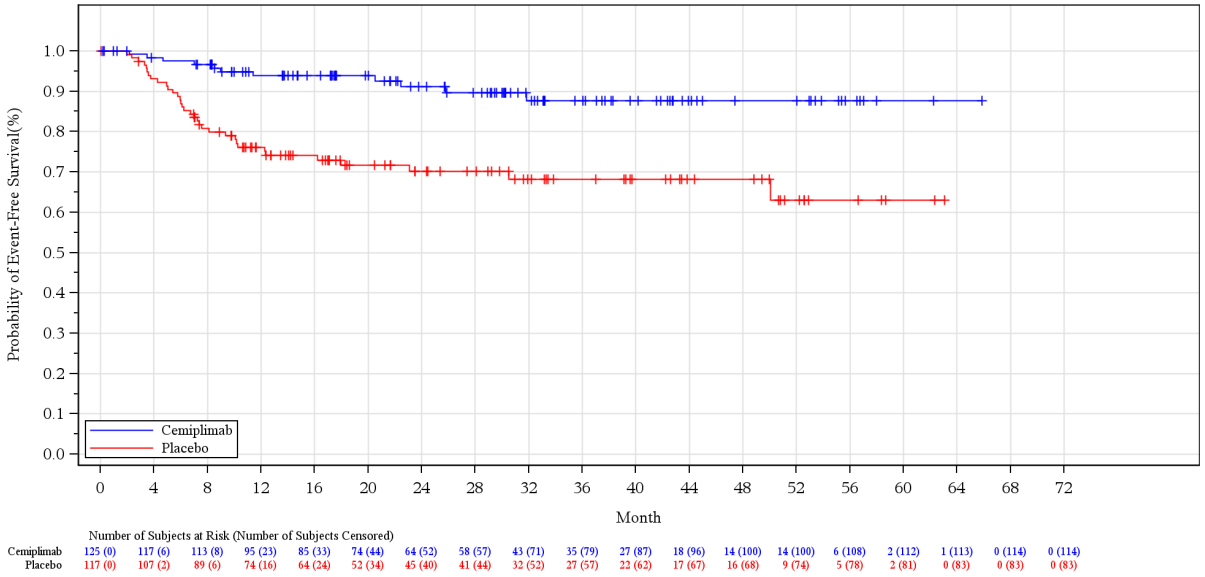
Cemiplimab	76 (0)	70 (4)	69 (4)	64 (9)	57 (16)	52 (21)	45 (27)	41 (30)	30 (41)	28 (43)	24 (47)	16 (55)	12 (59)	9 (62)	3 (68)	0 (71)	0 (71)	0 (71)	0 (71)
Placebo	75 (0)	64 (5)	51 (8)	41 (13)	35 (17)	29 (21)	28 (22)	23 (25)	20 (28)	19 (29)	15 (32)	11 (36)	10 (37)	5 (41)	1 (45)	1 (45)	1 (45)	1 (45)	0 (46)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

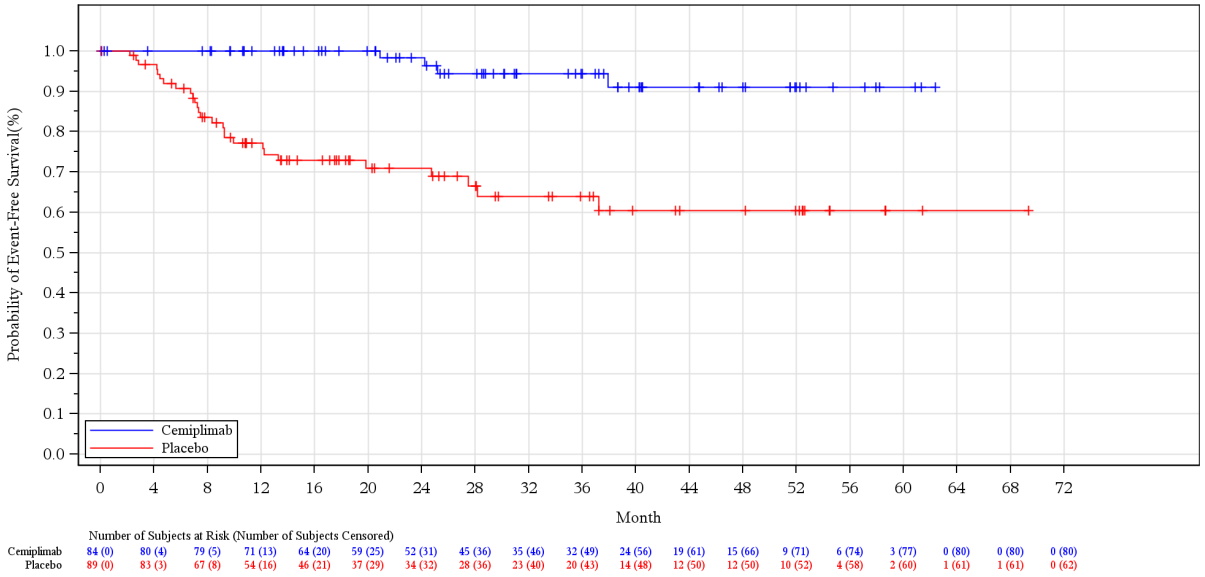
Cemiplimab	125 (0)	117 (6)	113 (8)	95 (23)	85 (33)	74 (44)	64 (52)	58 (57)	43 (71)	35 (79)	27 (87)	18 (96)	14 (100)	14 (100)	6 (108)	2 (112)	1 (113)	0 (114)	0 (114)
Placebo	117 (0)	107 (2)	89 (6)	74 (16)	64 (24)	52 (34)	45 (40)	41 (44)	32 (52)	27 (57)	22 (62)	17 (67)	16 (68)	9 (74)	5 (78)	2 (81)	0 (83)	0 (83)	0 (83)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.2.1 Time to First Subsequent Therapy by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	80 (4)	79 (5)	71 (13)	64 (20)	59 (25)	52 (31)	45 (36)	35 (46)	32 (49)	24 (56)	19 (61)	15 (66)	9 (71)	6 (74)	3 (77)	0 (80)	0 (80)	0 (80)
Placebo	89 (0)	83 (3)	67 (8)	54 (16)	46 (21)	37 (29)	34 (32)	28 (36)	23 (40)	20 (43)	14 (48)	12 (50)	12 (50)	10 (52)	4 (58)	2 (60)	1 (61)	1 (61)	0 (62)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfst-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	6 (10.7%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	50 (89.3%)	43 (66.2%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (28.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0028	
HR (95% CI) [c][d]	0.268 (0.107, 0.672)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Heterogeneity p-value [c][e]	0.7372	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (87.8, 99.7)	92.3 (82.5, 96.7)
6 months	98.2 (87.8, 99.7)	87.7 (76.9, 93.6)
12 months	94.2 (83.2, 98.1)	70.1 (57.2, 79.8)
18 months	92.1 (80.3, 97.0)	66.3 (53.0, 76.7)
24 months	92.1 (80.3, 97.0)	66.3 (53.0, 76.7)
30 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
36 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
42 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
48 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
54 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
60 months	NE (NE, NE)	62.6 (48.0, 74.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	18 (11.8%)	44 (31.2%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	31 (22.0%)
Post Radiotherapy, n (%)	2 (1.3%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	8 (5.2%)	5 (3.5%)
Death, n (%)	7 (4.6%)	5 (3.5%)
Number of censored participants, n (%)	135 (88.2%)	97 (68.8%)
Q1 (95% CI), (months)[a]	NR (37.9, NE)	13.3 (8.3, 27.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.321 (0.184, 0.559)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Heterogeneity p-value [c][e]	0.7372	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (94.8, 99.7)	99.3 (95.0, 99.9)
6 months	97.3 (93.0, 99.0)	89.1 (82.5, 93.3)
12 months	95.2 (90.2, 97.7)	78.4 (70.4, 84.5)
18 months	95.2 (90.2, 97.7)	72.0 (63.2, 79.0)
24 months	90.1 (83.0, 94.3)	69.6 (60.5, 77.0)
30 months	86.8 (78.8, 91.9)	67.0 (57.5, 74.9)
36 months	85.3 (76.6, 90.9)	65.5 (55.6, 73.6)
42 months	83.4 (74.0, 89.7)	63.3 (52.8, 72.1)
48 months	83.4 (74.0, 89.7)	63.3 (52.8, 72.1)
54 months	79.4 (66.4, 87.9)	56.0 (42.4, 67.7)
60 months	79.4 (66.4, 87.9)	56.0 (42.4, 67.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	6 (10.7%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	50 (89.3%)	43 (66.2%)
Q1 (95% CI), (months)[a]	NR (25.8, NE)	10.0 (6.1, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (28.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0028	
HR (95% CI) [c][d]	0.268 (0.107, 0.672)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Heterogeneity p-value [c][e]	0.7355	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.2 (87.8, 99.7)	92.3 (82.5, 96.7)
6 months	98.2 (87.8, 99.7)	87.7 (76.9, 93.6)
12 months	94.2 (83.2, 98.1)	70.1 (57.2, 79.8)
18 months	92.1 (80.3, 97.0)	66.3 (53.0, 76.7)
24 months	92.1 (80.3, 97.0)	66.3 (53.0, 76.7)
30 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
36 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
42 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
48 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
54 months	86.1 (70.9, 93.6)	62.6 (48.0, 74.2)
60 months	NE (NE, NE)	62.6 (48.0, 74.2)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	10 (12.5%)	21 (30.4%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	6 (7.5%)	3 (4.3%)
Death, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	70 (87.5%)	48 (69.6%)
Q1 (95% CI), (months)[a]	NR (25.4, NE)	23.1 (10.3, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0109	
HR (95% CI) [c][d]	0.379 (0.175, 0.822)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Heterogeneity p-value [c][e]	0.7355	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.7 (91.4, 99.8)	98.5 (90.0, 99.8)
6 months	96.2 (88.6, 98.7)	91.2 (81.4, 95.9)
12 months	94.8 (86.7, 98.0)	85.1 (74.0, 91.7)
18 months	94.8 (86.7, 98.0)	78.1 (65.8, 86.5)
24 months	90.8 (80.3, 95.9)	73.5 (60.1, 83.1)
30 months	84.4 (71.6, 91.7)	68.7 (54.4, 79.4)
36 months	84.4 (71.6, 91.7)	68.7 (54.4, 79.4)
42 months	80.8 (66.0, 89.7)	65.1 (49.6, 76.9)
48 months	80.8 (66.0, 89.7)	65.1 (49.6, 76.9)
54 months	80.8 (66.0, 89.7)	51.3 (30.0, 69.1)
60 months	80.8 (66.0, 89.7)	51.3 (30.0, 69.1)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	8 (11.0%)	23 (31.9%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	17 (23.6%)
Post Radiotherapy, n (%)	1 (1.4%)	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	2 (2.8%)
Death, n (%)	4 (5.5%)	3 (4.2%)
Number of censored participants, n (%)	65 (89.0%)	49 (68.1%)
Q1 (95% CI), (months)[a]	NR (31.8, NE)	9.2 (6.2, 30.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (30.5, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0015	
HR (95% CI) [c][d]	0.272 (0.115, 0.642)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Heterogeneity p-value [c][e]	0.7355	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.6 (90.4, 99.8)	100 (100, 100)
6 months	98.6 (90.4, 99.8)	87.0 (76.4, 93.0)
12 months	95.6 (87.1, 98.6)	71.7 (59.3, 81.0)
18 months	95.6 (87.1, 98.6)	65.8 (52.6, 76.2)
24 months	89.4 (77.5, 95.2)	65.8 (52.6, 76.2)
30 months	89.4 (77.5, 95.2)	65.8 (52.6, 76.2)
36 months	86.3 (72.5, 93.5)	62.4 (48.0, 73.8)
42 months	86.3 (72.5, 93.5)	62.4 (48.0, 73.8)
48 months	86.3 (72.5, 93.5)	62.4 (48.0, 73.8)
54 months	79.1 (56.9, 90.7)	62.4 (48.0, 73.8)
60 months	79.1 (56.9, 90.7)	62.4 (48.0, 73.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	20 (11.5%)	49 (28.2%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	38 (21.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.9%)
Post Other Systemic Therapy, n (%)	10 (5.7%)	4 (2.3%)
Death, n (%)	7 (4.0%)	2 (1.1%)
Number of censored participants, n (%)	154 (88.5%)	125 (71.8%)
Q1 (95% CI), (months)[a]	NR (51.5, NE)	18.0 (9.3, 37.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.344 (0.204, 0.581)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Heterogeneity p-value [c][e]	0.3207	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (95.4, 99.7)	97.1 (93.1, 98.8)
6 months	98.2 (94.6, 99.4)	88.8 (83.1, 92.7)
12 months	95.8 (91.4, 98.0)	78.3 (71.2, 83.8)
18 months	95.1 (90.4, 97.5)	74.4 (66.8, 80.5)
24 months	91.7 (85.8, 95.3)	72.4 (64.5, 78.9)
30 months	87.1 (79.9, 91.9)	70.2 (61.8, 77.1)
36 months	85.8 (78.1, 91.0)	68.9 (60.2, 76.0)
42 months	84.0 (75.4, 89.8)	67.1 (57.8, 74.7)
48 months	84.0 (75.4, 89.8)	67.1 (57.8, 74.7)
54 months	80.8 (69.5, 88.3)	60.8 (48.6, 71.0)
60 months	80.8 (69.5, 88.3)	60.8 (48.6, 71.0)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	4 (11.4%)	17 (53.1%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	2 (6.3%)
Death, n (%)	2 (5.7%)	3 (9.4%)
Number of censored participants, n (%)	31 (88.6%)	15 (46.9%)
Q1 (95% CI), (months)[a]	NR (11.4, NE)	7.0 (3.4, 12.1)
Median (95% CI), (months)[a]	NR (NE, NE)	14.1 (7.3, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (27.5, NE)
Stratified log-rank test p-value [b][c]	0.0035	
HR (95% CI) [c][d]	0.222 (0.074, 0.667)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Heterogeneity p-value [c][e]	0.3207	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.1 (80.9, 99.6)	96.9 (79.8, 99.6)
6 months	93.9 (77.8, 98.4)	87.5 (70.0, 95.1)
12 months	90.2 (72.3, 96.8)	62.5 (43.5, 76.7)
18 months	90.2 (72.3, 96.8)	49.6 (31.4, 65.4)
24 months	84.5 (62.5, 94.2)	49.6 (31.4, 65.4)
30 months	84.5 (62.5, 94.2)	43.4 (24.3, 61.0)
36 months	84.5 (62.5, 94.2)	43.4 (24.3, 61.0)
42 months	84.5 (62.5, 94.2)	43.4 (24.3, 61.0)
48 months	84.5 (62.5, 94.2)	43.4 (24.3, 61.0)
54 months	NE (NE, NE)	43.4 (24.3, 61.0)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	10 (32.3%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	3 (9.7%)
Death, n (%)	3 (8.1%)	1 (3.2%)
Number of censored participants, n (%)	33 (89.2%)	21 (67.7%)
Q1 (95% CI), (months)[a]	51.5 (26.0, NE)	9.3 (5.8, NE)
Median (95% CI), (months)[a]	NR (51.5, NE)	NR (12.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0195	
HR (95% CI) [c][d]	0.271 (0.084, 0.874)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Heterogeneity p-value [c][e]	0.4118	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	100 (100, 100)	93.5 (76.6, 98.3)
6 months	97.2 (81.9, 99.6)	90.1 (72.3, 96.7)
12 months	97.2 (81.9, 99.6)	72.8 (52.8, 85.4)
18 months	97.2 (81.9, 99.6)	68.5 (47.9, 82.3)
24 months	93.8 (77.0, 98.4)	68.5 (47.9, 82.3)
30 months	89.7 (70.9, 96.6)	68.5 (47.9, 82.3)
36 months	89.7 (70.9, 96.6)	68.5 (47.9, 82.3)
42 months	89.7 (70.9, 96.6)	68.5 (47.9, 82.3)
48 months	89.7 (70.9, 96.6)	68.5 (47.9, 82.3)
54 months	71.7 (27.0, 91.9)	57.1 (29.4, 77.3)
60 months	71.7 (27.0, 91.9)	57.1 (29.4, 77.3)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	30 (33.3%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	23 (25.6%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Death, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	82 (91.1%)	60 (66.7%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.2 (7.0, 30.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (37.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.220 (0.101, 0.482)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Heterogeneity p-value [c][e]	0.4118	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.7 (91.1, 99.4)	96.6 (89.9, 98.9)
6 months	97.7 (91.1, 99.4)	87.6 (78.8, 93.0)
12 months	95.4 (88.1, 98.2)	75.6 (65.0, 83.4)
18 months	95.4 (88.1, 98.2)	69.9 (58.6, 78.6)
24 months	93.6 (85.1, 97.3)	68.2 (56.6, 77.2)
30 months	89.9 (79.6, 95.2)	66.2 (54.2, 75.7)
36 months	87.3 (75.3, 93.7)	63.8 (51.3, 73.9)
42 months	87.3 (75.3, 93.7)	60.8 (47.4, 71.7)
48 months	87.3 (75.3, 93.7)	60.8 (47.4, 71.7)
54 months	87.3 (75.3, 93.7)	55.2 (38.9, 68.8)
60 months	87.3 (75.3, 93.7)	55.2 (38.9, 68.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	12 (14.6%)	26 (30.6%)
Received Cemiplimab in Part 2, n (%)	0	21 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.2%)
Post Other Systemic Therapy, n (%)	5 (6.1%)	1 (1.2%)
Death, n (%)	5 (6.1%)	3 (3.5%)
Number of censored participants, n (%)	70 (85.4%)	59 (69.4%)
Q1 (95% CI), (months)[a]	NR (20.9, NE)	12.7 (7.3, 28.2)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0111	
HR (95% CI) [c][d]	0.422 (0.213, 0.838)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Heterogeneity p-value [c][e]	0.4118	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	98.8 (91.8, 99.8)
6 months	97.5 (90.4, 99.4)	89.3 (80.4, 94.3)
12 months	93.2 (84.3, 97.1)	77.0 (66.4, 84.7)
18 months	91.5 (82.0, 96.1)	71.1 (59.7, 79.9)
24 months	85.3 (73.2, 92.2)	69.0 (57.1, 78.3)
30 months	80.8 (67.4, 89.1)	64.1 (51.0, 74.5)
36 months	80.8 (67.4, 89.1)	64.1 (51.0, 74.5)
42 months	76.5 (60.5, 86.7)	64.1 (51.0, 74.5)
48 months	76.5 (60.5, 86.7)	64.1 (51.0, 74.5)
54 months	76.5 (60.5, 86.7)	64.1 (51.0, 74.5)
60 months	76.5 (60.5, 86.7)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	22 (11.6%)	60 (31.7%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	45 (23.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.6%)
Post Other Systemic Therapy, n (%)	11 (5.8%)	5 (2.6%)
Death, n (%)	8 (4.2%)	5 (2.6%)
Number of censored participants, n (%)	167 (88.4%)	129 (68.3%)
Q1 (95% CI), (months)[a]	NR (51.5, NE)	12.2 (8.1, 24.7)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.307 (0.187, 0.502)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Heterogeneity p-value [c][e]	0.8817	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.9 (95.7, 99.7)	96.8 (93.0, 98.5)
6 months	97.8 (94.3, 99.2)	87.6 (81.9, 91.6)
12 months	95.0 (90.5, 97.3)	75.7 (68.8, 81.3)
18 months	94.3 (89.7, 96.9)	70.9 (63.5, 77.1)
24 months	91.1 (85.3, 94.7)	69.2 (61.5, 75.6)
30 months	86.7 (79.6, 91.4)	66.2 (58.0, 73.1)
36 months	85.5 (78.2, 90.6)	65.0 (56.6, 72.1)
42 months	84.0 (76.0, 89.5)	63.4 (54.6, 70.9)
48 months	84.0 (76.0, 89.5)	63.4 (54.6, 70.9)
54 months	80.8 (69.9, 88.1)	58.0 (46.9, 67.5)
60 months	80.8 (69.9, 88.1)	58.0 (46.9, 67.5)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	6 (35.3%)
Received Cemiplimab in Part 2, n (%)	0	5 (29.4%)
Post Radiotherapy, n (%)	1 (5.0%)	0
Post Other Systemic Therapy, n (%)	0	1 (5.9%)
Death, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	18 (90.0%)	11 (64.7%)
Q1 (95% CI), (months)[a]	NR (0.5, NE)	12.3 (6.1, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.6, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.1633	
HR (95% CI) [c][d]	0.295 (0.050, 1.744)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Heterogeneity p-value [c][e]	0.8817	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	94.7 (68.1, 99.2)	100 (100, 100)
6 months	94.7 (68.1, 99.2)	100 (100, 100)
12 months	94.7 (68.1, 99.2)	76.5 (48.8, 90.4)
18 months	94.7 (68.1, 99.2)	62.3 (34.0, 81.3)
24 months	86.8 (55.7, 96.7)	62.3 (34.0, 81.3)
30 months	86.8 (55.7, 96.7)	62.3 (34.0, 81.3)
36 months	86.8 (55.7, 96.7)	62.3 (34.0, 81.3)
42 months	86.8 (55.7, 96.7)	62.3 (34.0, 81.3)
48 months	86.8 (55.7, 96.7)	62.3 (34.0, 81.3)
54 months	86.8 (55.7, 96.7)	NE (NE, NE)
60 months	NE (NE, NE)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	18 (10.8%)	55 (31.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	41 (23.2%)
Post Radiotherapy, n (%)	2 (1.2%)	5 (2.8%)
Post Other Systemic Therapy, n (%)	7 (4.2%)	6 (3.4%)
Death, n (%)	8 (4.8%)	3 (1.7%)
Number of censored participants, n (%)	148 (89.2%)	122 (68.9%)
Q1 (95% CI), (months)[a]	NR (51.5, NE)	12.3 (9.2, 24.7)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.289 (0.169, 0.493)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Heterogeneity p-value [c][e]	0.7928	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (95.2, 99.7)	97.1 (93.2, 98.8)
6 months	98.8 (95.2, 99.7)	89.6 (84.0, 93.3)
12 months	96.9 (92.7, 98.7)	76.9 (69.8, 82.6)
18 months	96.2 (91.6, 98.3)	71.0 (63.3, 77.4)
24 months	91.7 (85.4, 95.4)	69.1 (61.1, 75.8)
30 months	87.7 (80.2, 92.5)	65.8 (57.2, 73.0)
36 months	86.3 (78.2, 91.5)	64.5 (55.7, 72.0)
42 months	84.3 (75.2, 90.3)	62.7 (53.5, 70.7)
48 months	84.3 (75.2, 90.3)	62.7 (53.5, 70.7)
54 months	80.3 (67.3, 88.6)	59.6 (48.7, 68.9)
60 months	80.3 (67.3, 88.6)	59.6 (48.7, 68.9)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	6 (14.0%)	11 (37.9%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	4 (9.3%)	0
Death, n (%)	1 (2.3%)	2 (6.9%)
Number of censored participants, n (%)	37 (86.0%)	18 (62.1%)
Q1 (95% CI), (months)[a]	NR (9.0, NE)	7.2 (4.3, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (7.6, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Stratified log-rank test p-value [b][c]	0.0382	
HR (95% CI) [c][d]	0.362 (0.133, 0.985)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Heterogeneity p-value [c][e]	0.7928	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.6 (84.3, 99.7)	96.6 (77.9, 99.5)
6 months	92.6 (78.8, 97.6)	82.8 (63.4, 92.4)
12 months	86.4 (70.1, 94.2)	68.4 (48.0, 82.1)
18 months	86.4 (70.1, 94.2)	64.6 (44.1, 79.2)
24 months	86.4 (70.1, 94.2)	64.6 (44.1, 79.2)
30 months	82.3 (64.1, 91.8)	64.6 (44.1, 79.2)
36 months	82.3 (64.1, 91.8)	64.6 (44.1, 79.2)
42 months	82.3 (64.1, 91.8)	64.6 (44.1, 79.2)
48 months	82.3 (64.1, 91.8)	64.6 (44.1, 79.2)
54 months	82.3 (64.1, 91.8)	51.7 (23.6, 73.9)
60 months	82.3 (64.1, 91.8)	NE (NE, NE)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	12 (9.0%)	33 (25.2%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	26 (19.8%)
Post Radiotherapy, n (%)	2 (1.5%)	1 (0.8%)
Post Other Systemic Therapy, n (%)	7 (5.3%)	5 (3.8%)
Death, n (%)	2 (1.5%)	1 (0.8%)
Number of censored participants, n (%)	121 (91.0%)	98 (74.8%)
Q1 (95% CI), (months)[a]	NR (37.9, NE)	23.1 (9.2, NE)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0002	
HR (95% CI) [c][d]	0.307 (0.158, 0.598)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Heterogeneity p-value [c][e]	0.7332	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	99.2 (94.7, 99.9)	96.9 (92.1, 98.8)
6 months	98.4 (93.9, 99.6)	91.6 (85.4, 95.3)
12 months	95.1 (89.3, 97.8)	79.8 (71.7, 85.7)
18 months	95.1 (89.3, 97.8)	77.0 (68.6, 83.4)
24 months	92.6 (85.5, 96.3)	74.3 (65.3, 81.4)
30 months	89.9 (81.7, 94.6)	72.6 (63.1, 80.1)
36 months	88.1 (78.9, 93.4)	70.8 (60.7, 78.7)
42 months	85.3 (74.1, 91.9)	70.8 (60.7, 78.7)
48 months	85.3 (74.1, 91.9)	70.8 (60.7, 78.7)
54 months	85.3 (74.1, 91.9)	70.8 (60.7, 78.7)
60 months	85.3 (74.1, 91.9)	70.8 (60.7, 78.7)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	12 (15.8%)	33 (44.0%)
Received Cemiplimab in Part 2, n (%)	0	24 (32.0%)
Post Radiotherapy, n (%)	1 (1.3%)	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	1 (1.3%)
Death, n (%)	7 (9.2%)	4 (5.3%)
Number of censored participants, n (%)	64 (84.2%)	42 (56.0%)
Q1 (95% CI), (months)[a]	51.5 (25.4, NE)	8.3 (5.4, 13.3)
Median (95% CI), (months)[a]	NR (NE, NE)	49.4 (14.1, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (50.1, NE)
Stratified log-rank test p-value [b][c]	<0.0001	
HR (95% CI) [c][d]	0.271 (0.139, 0.529)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Heterogeneity p-value [c][e]	0.7332	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	97.3 (89.7, 99.3)	97.2 (89.3, 99.3)
6 months	96.0 (88.0, 98.7)	83.1 (72.1, 90.0)
12 months	94.6 (86.2, 97.9)	68.5 (56.1, 78.0)
18 months	93.0 (84.1, 97.1)	58.0 (45.1, 69.0)
24 months	87.5 (76.4, 93.6)	58.0 (45.1, 69.0)
30 months	81.6 (68.9, 89.5)	53.6 (40.3, 65.2)
36 months	81.6 (68.9, 89.5)	53.6 (40.3, 65.2)
42 months	81.6 (68.9, 89.5)	50.7 (36.9, 62.9)
48 months	81.6 (68.9, 89.5)	50.7 (36.9, 62.9)
54 months	74.2 (53.2, 86.8)	39.4 (22.6, 55.8)
60 months	NE (NE, NE)	39.4 (22.6, 55.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	13 (10.4%)	36 (30.8%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	28 (23.9%)
Post Radiotherapy, n (%)	1 (0.8%)	4 (3.4%)
Post Other Systemic Therapy, n (%)	9 (7.2%)	2 (1.7%)
Death, n (%)	2 (1.6%)	2 (1.7%)
Number of censored participants, n (%)	112 (89.6%)	81 (69.2%)
Q1 (95% CI), (months)[a]	NR (NE, NE)	12.3 (7.2, 49.4)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (49.4, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0001	
HR (95% CI) [c][d]	0.302 (0.159, 0.572)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Heterogeneity p-value [c][e]	0.9398	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.4 (93.6, 99.6)	97.4 (92.2, 99.2)
6 months	96.7 (91.4, 98.7)	87.8 (80.3, 92.6)
12 months	93.1 (86.6, 96.5)	76.1 (67.1, 83.0)
18 months	93.1 (86.6, 96.5)	70.6 (60.9, 78.3)
24 months	89.2 (81.0, 93.9)	69.1 (59.2, 77.1)
30 months	87.7 (79.0, 92.9)	69.1 (59.2, 77.1)
36 months	85.7 (76.0, 91.7)	67.2 (56.8, 75.7)
42 months	85.7 (76.0, 91.7)	67.2 (56.8, 75.7)
48 months	85.7 (76.0, 91.7)	67.2 (56.8, 75.7)
54 months	85.7 (76.0, 91.7)	57.9 (42.1, 70.8)
60 months	85.7 (76.0, 91.7)	57.9 (42.1, 70.8)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	11 (13.1%)	30 (33.7%)
Received Cemiplimab in Part 2, n (%)	0	22 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	2 (2.4%)	4 (4.5%)
Death, n (%)	7 (8.3%)	3 (3.4%)
Number of censored participants, n (%)	73 (86.9%)	59 (66.3%)
Q1 (95% CI), (months)[a]	NR (26.0, NE)	12.1 (7.3, 27.5)
Median (95% CI), (months)[a]	NR (NE, NE)	NR (28.2, NE)
Q3 (95% CI), (months)[a]	NR (NE, NE)	NR (NE, NE)
Stratified log-rank test p-value [b][c]	0.0005	
HR (95% CI) [c][d]	0.310 (0.154, 0.623)	

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.6.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Heterogeneity p-value [c][e]	0.9398	
Estimated Event-Free Probability, % (95% CI) [a]		
3 months	98.8 (91.7, 99.8)	96.6 (89.7, 98.9)
6 months	98.8 (91.7, 99.8)	89.7 (81.1, 94.5)
12 months	97.5 (90.5, 99.4)	75.3 (64.6, 83.1)
18 months	96.1 (88.3, 98.7)	69.6 (58.3, 78.4)
24 months	92.8 (83.4, 97.0)	67.8 (56.1, 76.9)
30 months	85.4 (73.5, 92.2)	61.1 (48.1, 71.7)
36 months	85.4 (73.5, 92.2)	61.1 (48.1, 71.7)
42 months	82.3 (68.8, 90.4)	57.7 (43.7, 69.3)
48 months	82.3 (68.8, 90.4)	57.7 (43.7, 69.3)
54 months	76.0 (56.4, 87.7)	57.7 (43.7, 69.3)
60 months	76.0 (56.4, 87.7)	57.7 (43.7, 69.3)

Data cut-off as of April 07, 2025.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value. Significance threshold is set to 0.00455 using the OBrien Fleming alpha spending function.
[c] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[d] Based on stratified proportional hazards model (cemiplimab vs placebo).
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Non-white includes not reported and unknown values. Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	6 (10.7%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	50 (89.3%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.6009	
Hazard ratio(interaction)	0.736 (0.233, 2.323)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	18 (11.8%)	44 (31.2%)
Received Cemiplimab in Part 2, n (%)	1 (0.7%)	31 (22.0%)
Post Radiotherapy, n (%)	2 (1.3%)	3 (2.1%)
Post Other Systemic Therapy, n (%)	8 (5.2%)	5 (3.5%)
Death, n (%)	7 (4.6%)	5 (3.5%)
Number of censored participants, n (%)	135 (88.2%)	97 (68.8%)
Proportionality Test p-value[a][b]	0.1823	
Hazard ratio(interaction)	0.627 (0.316, 1.245)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	6 (10.7%)	22 (33.8%)
Received Cemiplimab in Part 2, n (%)	0	19 (29.2%)
Post Radiotherapy, n (%)	1 (1.8%)	2 (3.1%)
Post Other Systemic Therapy, n (%)	3 (5.4%)	1 (1.5%)
Death, n (%)	2 (3.6%)	0
Number of censored participants, n (%)	50 (89.3%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.6009	
Hazard ratio(interaction)	0.736 (0.233, 2.323)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	10 (12.5%)	21 (30.4%)
Received Cemiplimab in Part 2, n (%)	0	14 (20.3%)
Post Radiotherapy, n (%)	1 (1.3%)	2 (2.9%)
Post Other Systemic Therapy, n (%)	6 (7.5%)	3 (4.3%)
Death, n (%)	3 (3.8%)	2 (2.9%)
Number of censored participants, n (%)	70 (87.5%)	48 (69.6%)
Proportionality Test p-value[a][b]	0.6336	
Hazard ratio(interaction)	0.799 (0.317, 2.014)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	8 (11.0%)	23 (31.9%)
Received Cemiplimab in Part 2, n (%)	1 (1.4%)	17 (23.6%)
Post Radiotherapy, n (%)	1 (1.4%)	1 (1.4%)
Post Other Systemic Therapy, n (%)	2 (2.7%)	2 (2.8%)
Death, n (%)	4 (5.5%)	3 (4.2%)
Number of censored participants, n (%)	65 (89.0%)	49 (68.1%)
Proportionality Test p-value[a][b]	0.1350	
Hazard ratio(interaction)	0.388 (0.112, 1.343)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	20 (11.5%)	49 (28.2%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	38 (21.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.9%)
Post Other Systemic Therapy, n (%)	10 (5.7%)	4 (2.3%)
Death, n (%)	7 (4.0%)	2 (1.1%)
Number of censored participants, n (%)	154 (88.5%)	125 (71.8%)
Proportionality Test p-value[a][b]	0.0437	
Hazard ratio(interaction)	0.508 (0.263, 0.981)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	4 (11.4%)	17 (53.1%)
Received Cemiplimab in Part 2, n (%)	0	12 (37.5%)
Post Radiotherapy, n (%)	1 (2.9%)	0
Post Other Systemic Therapy, n (%)	1 (2.9%)	2 (6.3%)
Death, n (%)	2 (5.7%)	3 (9.4%)
Number of censored participants, n (%)	31 (88.6%)	15 (46.9%)
Proportionality Test p-value[a][b]	0.5362	
Hazard ratio(interaction)	1.470 (0.434, 4.980)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	10 (32.3%)
Received Cemiplimab in Part 2, n (%)	0	6 (19.4%)
Post Radiotherapy, n (%)	0	0
Post Other Systemic Therapy, n (%)	1 (2.7%)	3 (9.7%)
Death, n (%)	3 (8.1%)	1 (3.2%)
Number of censored participants, n (%)	33 (89.2%)	21 (67.7%)
Proportionality Test p-value[a][b]	0.1161	
Hazard ratio(interaction)	0.320 (0.077, 1.325)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	8 (8.9%)	30 (33.3%)
Received Cemiplimab in Part 2, n (%)	1 (1.1%)	23 (25.6%)
Post Radiotherapy, n (%)	1 (1.1%)	4 (4.4%)
Post Other Systemic Therapy, n (%)	5 (5.6%)	2 (2.2%)
Death, n (%)	1 (1.1%)	1 (1.1%)
Number of censored participants, n (%)	82 (91.1%)	60 (66.7%)
Proportionality Test p-value[a][b]	0.8618	
Hazard ratio(interaction)	0.923 (0.373, 2.285)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	12 (14.6%)	26 (30.6%)
Received Cemiplimab in Part 2, n (%)	0	21 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.2%)
Post Other Systemic Therapy, n (%)	5 (6.1%)	1 (1.2%)
Death, n (%)	5 (6.1%)	3 (3.5%)
Number of censored participants, n (%)	70 (85.4%)	59 (69.4%)
Proportionality Test p-value[a][b]	0.2202	
Hazard ratio(interaction)	0.555 (0.216, 1.423)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	22 (11.6%)	60 (31.7%)
Received Cemiplimab in Part 2, n (%)	1 (0.5%)	45 (23.8%)
Post Radiotherapy, n (%)	2 (1.1%)	5 (2.6%)
Post Other Systemic Therapy, n (%)	11 (5.8%)	5 (2.6%)
Death, n (%)	8 (4.2%)	5 (2.6%)
Number of censored participants, n (%)	167 (88.4%)	129 (68.3%)
Proportionality Test p-value[a][b]	0.0233	
Hazard ratio(interaction)	0.485 (0.259, 0.906)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	6 (35.3%)
Received Cemiplimab in Part 2, n (%)	0	5 (29.4%)
Post Radiotherapy, n (%)	1 (5.0%)	0
Post Other Systemic Therapy, n (%)	0	1 (5.9%)
Death, n (%)	1 (5.0%)	0
Number of censored participants, n (%)	18 (90.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	0.1056	
Hazard ratio(interaction)	3.600 (0.763, 16.979)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	18 (10.8%)	55 (31.1%)
Received Cemiplimab in Part 2, n (%)	1 (0.6%)	41 (23.2%)
Post Radiotherapy, n (%)	2 (1.2%)	5 (2.8%)
Post Other Systemic Therapy, n (%)	7 (4.2%)	6 (3.4%)
Death, n (%)	8 (4.8%)	3 (1.7%)
Number of censored participants, n (%)	148 (89.2%)	122 (68.9%)
Proportionality Test p-value[a][b]	0.0230	
Hazard ratio(interaction)	0.419 (0.198, 0.887)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	6 (14.0%)	11 (37.9%)
Received Cemiplimab in Part 2, n (%)	0	9 (31.0%)
Post Radiotherapy, n (%)	1 (2.3%)	0
Post Other Systemic Therapy, n (%)	4 (9.3%)	0
Death, n (%)	1 (2.3%)	2 (6.9%)
Number of censored participants, n (%)	37 (86.0%)	18 (62.1%)
Proportionality Test p-value[a][b]	0.6838	
Hazard ratio(interaction)	1.255 (0.421, 3.746)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	12 (9.0%)	33 (25.2%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	26 (19.8%)
Post Radiotherapy, n (%)	2 (1.5%)	1 (0.8%)
Post Other Systemic Therapy, n (%)	7 (5.3%)	5 (3.8%)
Death, n (%)	2 (1.5%)	1 (0.8%)
Number of censored participants, n (%)	121 (91.0%)	98 (74.8%)
Proportionality Test p-value[a][b]	0.0656	
Hazard ratio(interaction)	0.399 (0.150, 1.061)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	12 (15.8%)	33 (44.0%)
Received Cemiplimab in Part 2, n (%)	0	24 (32.0%)
Post Radiotherapy, n (%)	1 (1.3%)	4 (5.3%)
Post Other Systemic Therapy, n (%)	4 (5.3%)	1 (1.3%)
Death, n (%)	7 (9.2%)	4 (5.3%)
Number of censored participants, n (%)	64 (84.2%)	42 (56.0%)
Proportionality Test p-value[a][b]	0.6245	
Hazard ratio(interaction)	0.832 (0.399, 1.735)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	13 (10.4%)	36 (30.8%)
Received Cemiplimab in Part 2, n (%)	1 (0.8%)	28 (23.9%)
Post Radiotherapy, n (%)	1 (0.8%)	4 (3.4%)
Post Other Systemic Therapy, n (%)	9 (7.2%)	2 (1.7%)
Death, n (%)	2 (1.6%)	2 (1.7%)
Number of censored participants, n (%)	112 (89.6%)	81 (69.2%)
Proportionality Test p-value[a][b]	0.5798	
Hazard ratio(interaction)	0.800 (0.363, 1.762)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.7.1 Test of Proportional Hazards Assumption for Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

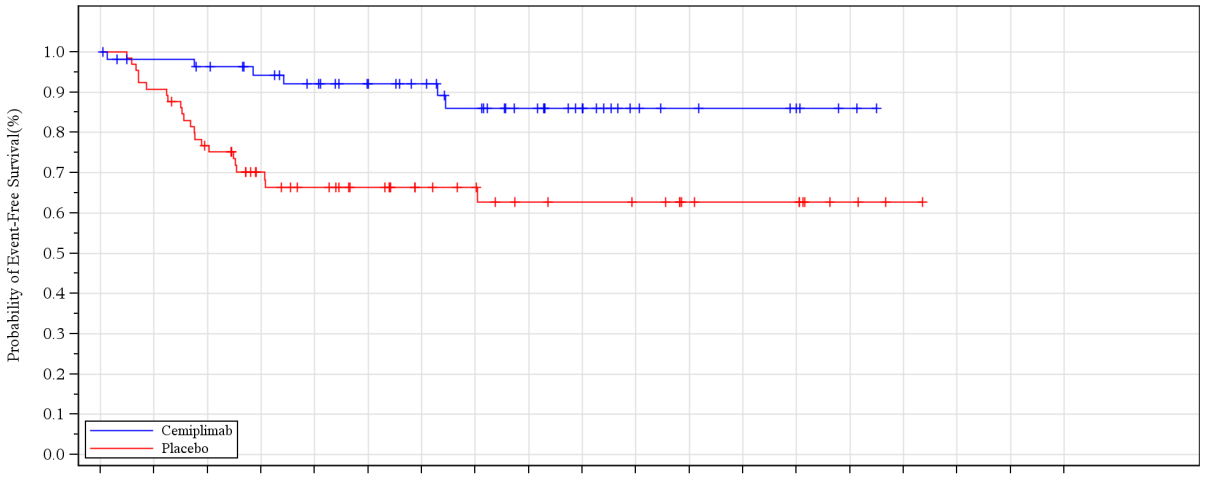
High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	11 (13.1%)	30 (33.7%)
Received Cemiplimab in Part 2, n (%)	0	22 (24.7%)
Post Radiotherapy, n (%)	2 (2.4%)	1 (1.1%)
Post Other Systemic Therapy, n (%)	2 (2.4%)	4 (4.5%)
Death, n (%)	7 (8.3%)	3 (3.4%)
Number of censored participants, n (%)	73 (86.9%)	59 (66.3%)
Proportionality Test p-value[a][b]	0.0810	
Hazard ratio(interaction)	0.411 (0.152, 1.116)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: <65



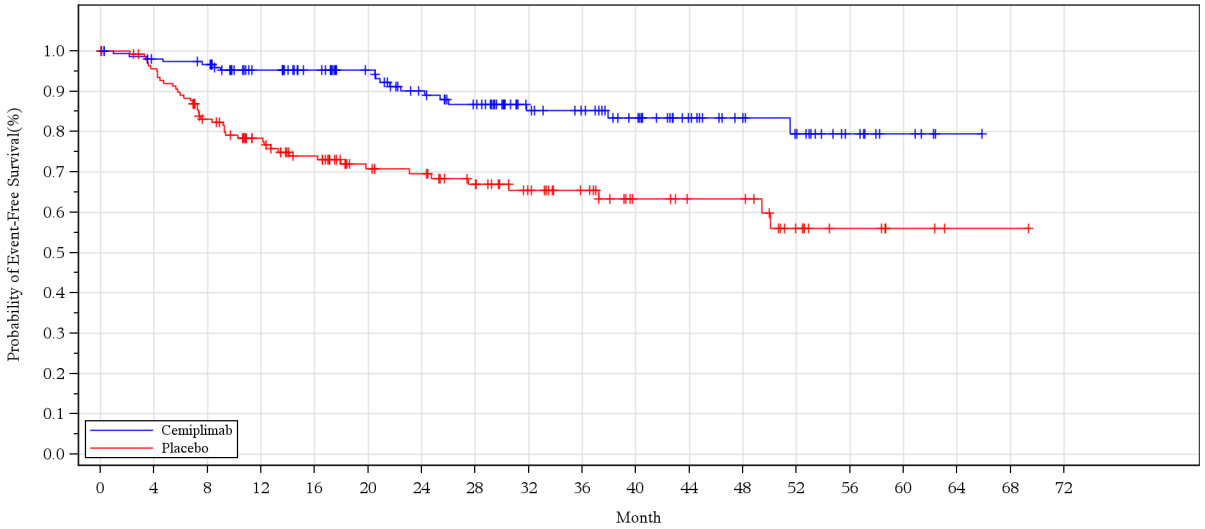
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	52 (3)	50 (4)	46 (7)	42 (10)	37 (15)	33 (19)	28 (22)	22 (28)	16 (34)	9 (41)	7 (43)	6 (44)	4 (46)	2 (48)	0 (50)	0 (50)	0 (50)	0 (50)
Placebo	65 (0)	59 (0)	48 (2)	37 (9)	32 (12)	27 (17)	21 (23)	19 (25)	15 (28)	14 (29)	13 (30)	9 (34)	8 (35)	8 (35)	3 (40)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

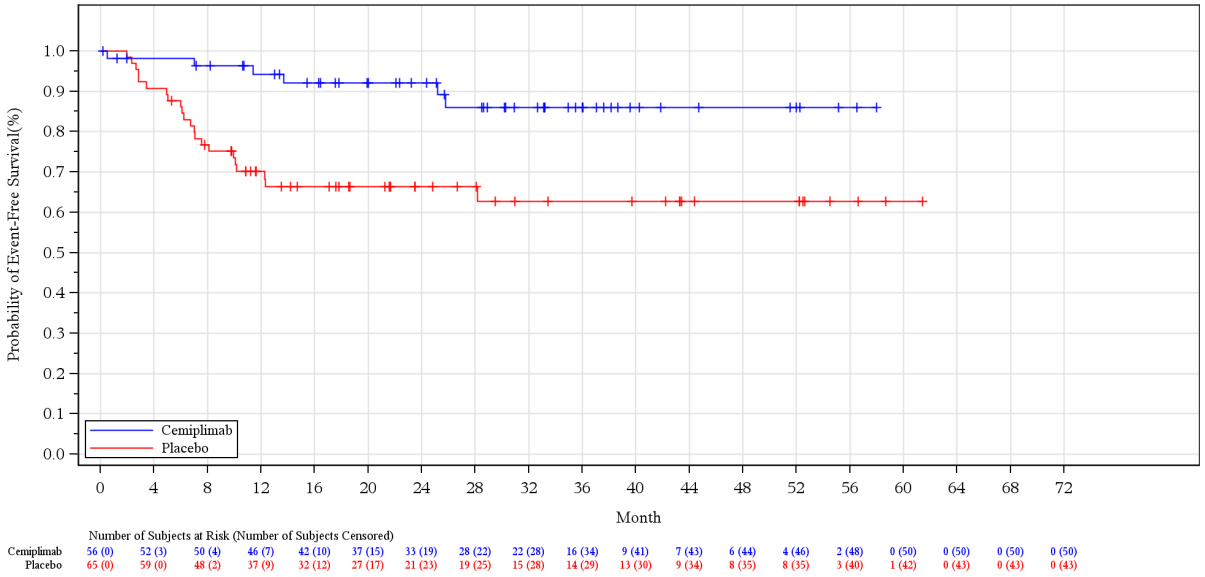
Cemiplimab	153 (0)	145 (5)	142 (6)	120 (26)	107 (39)	96 (50)	83 (58)	75 (63)	56 (81)	51 (86)	42 (94)	30 (106)	23 (114)	19 (116)	10 (125)	5 (130)	1 (134)	0 (135)	0 (135)
Placebo	141 (0)	131 (4)	108 (10)	91 (21)	78 (29)	62 (42)	58 (45)	50 (51)	40 (60)	33 (67)	23 (76)	20 (79)	20 (79)	11 (86)	6 (91)	3 (94)	1 (96)	1 (96)	0 (97)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

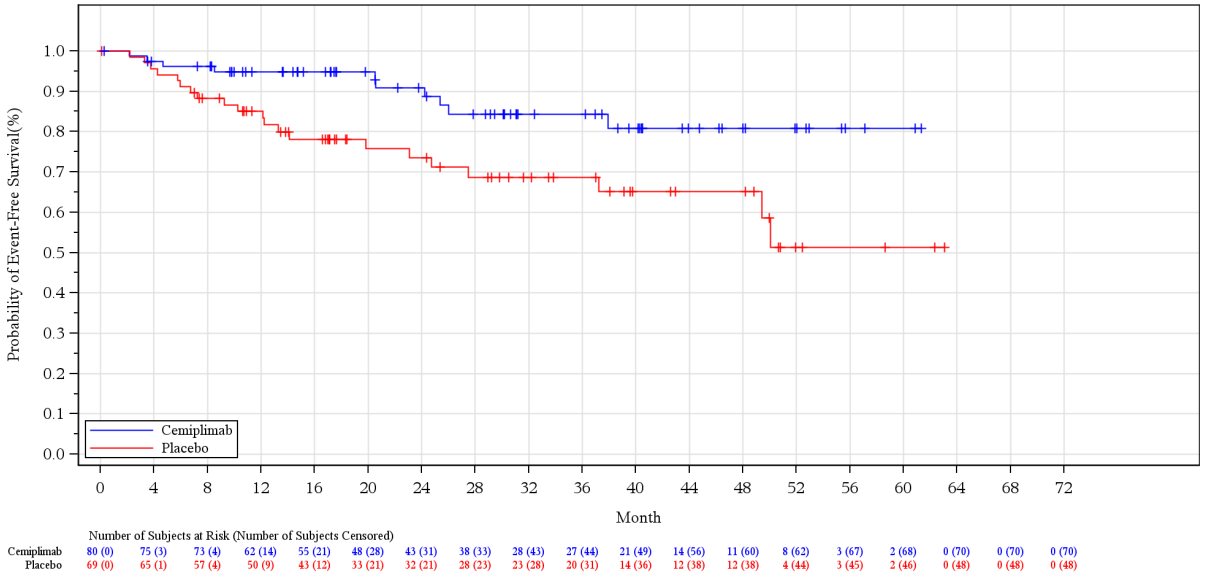
Cemiplimab	56 (0)	52 (3)	50 (4)	46 (7)	42 (10)	37 (15)	33 (19)	28 (22)	22 (28)	16 (34)	9 (41)	7 (43)	6 (44)	4 (46)	2 (48)	0 (50)	0 (50)	0 (50)	0 (50)
Placebo	65 (0)	59 (0)	48 (2)	37 (9)	32 (12)	27 (17)	21 (23)	19 (25)	15 (28)	14 (29)	13 (30)	9 (34)	8 (35)	8 (35)	3 (40)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

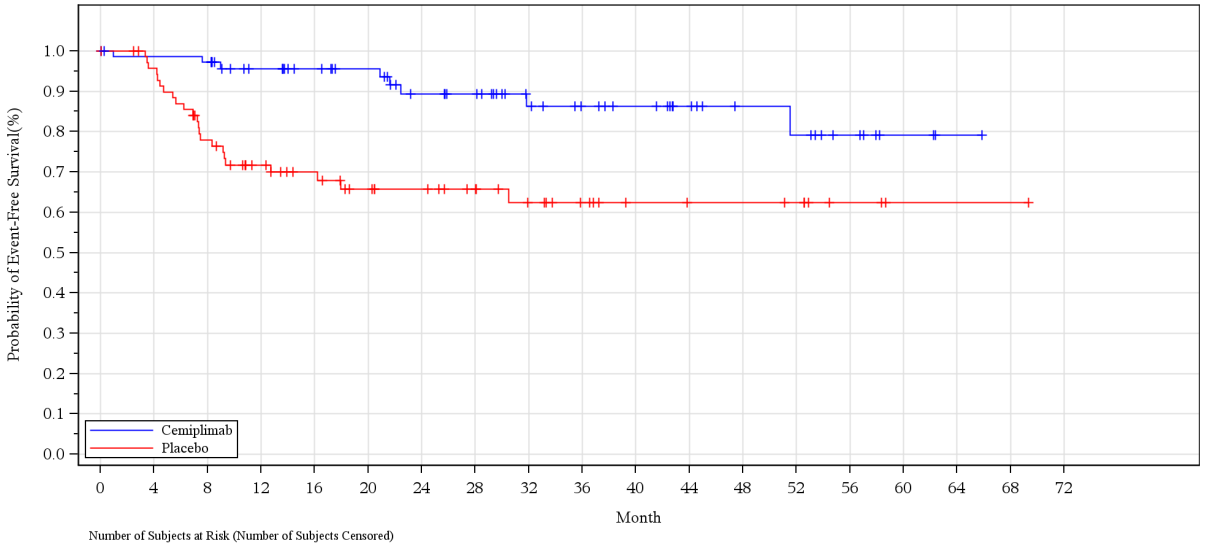
Cemiplimab	80 (0)	75 (3)	73 (4)	62 (14)	55 (21)	48 (28)	43 (31)	38 (33)	28 (43)	27 (44)	21 (49)	14 (56)	11 (60)	8 (62)	3 (67)	2 (68)	0 (70)	0 (70)	0 (70)
Placebo	69 (0)	65 (1)	57 (4)	50 (9)	43 (12)	33 (21)	32 (21)	28 (23)	23 (28)	20 (31)	14 (36)	12 (38)	12 (38)	4 (44)	3 (45)	2 (46)	0 (48)	0 (48)	0 (48)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

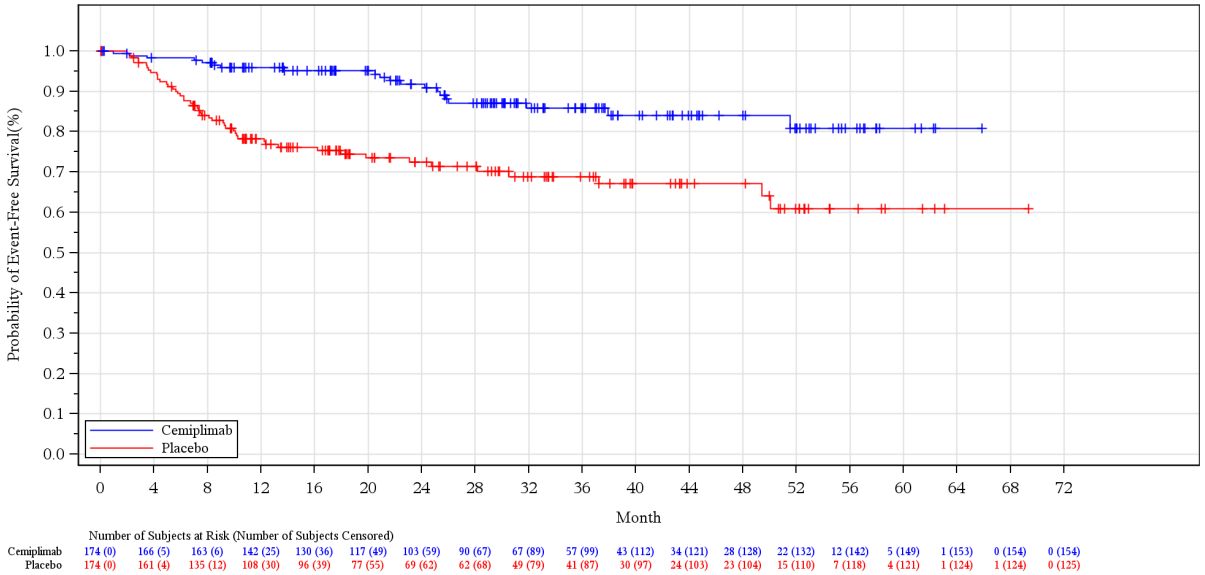
Cemiplimab	73 (0)	70 (2)	69 (2)	58 (12)	52 (18)	48 (22)	40 (27)	37 (30)	28 (38)	24 (42)	21 (45)	16 (50)	12 (54)	11 (54)	7 (58)	3 (62)	1 (64)	0 (65)	0 (65)
Placebo	72 (0)	66 (3)	51 (6)	41 (12)	35 (17)	29 (21)	26 (24)	22 (28)	17 (32)	13 (36)	9 (40)	8 (41)	8 (41)	7 (42)	3 (46)	1 (48)	1 (48)	1 (48)	0 (49)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

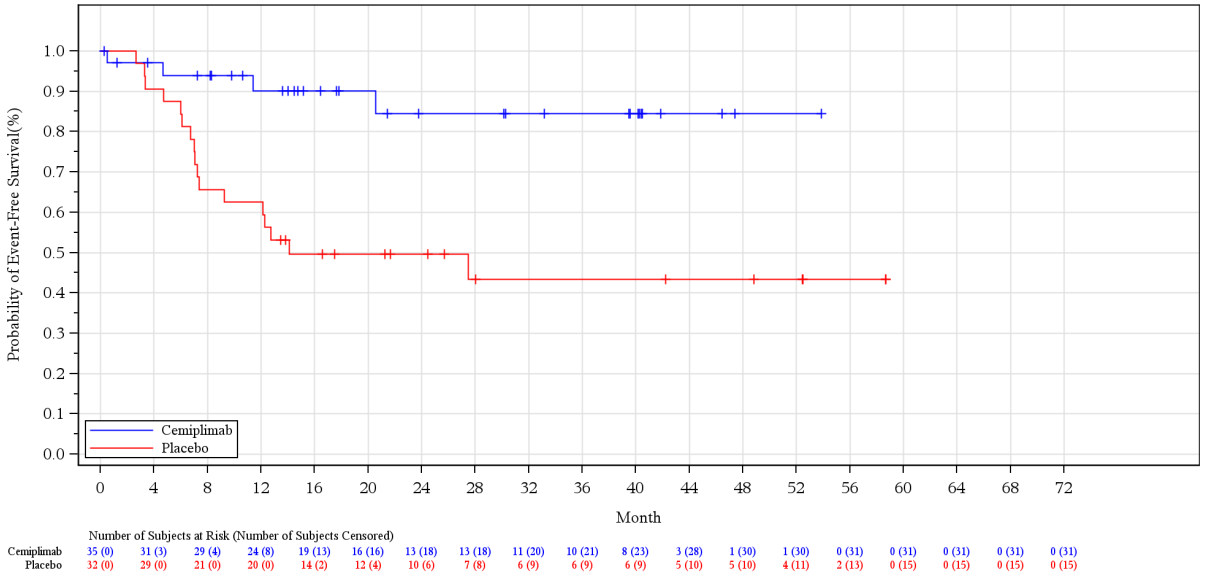
Cemiplimab	174 (0)	166 (5)	163 (6)	142 (25)	130 (36)	117 (49)	103 (59)	90 (67)	67 (89)	57 (99)	43 (112)	34 (121)	28 (128)	22 (132)	12 (142)	5 (149)	1 (153)	0 (154)	0 (154)
Placebo	174 (0)	161 (4)	135 (12)	108 (30)	96 (39)	77 (55)	69 (62)	62 (68)	49 (79)	41 (87)	30 (97)	24 (103)	23 (104)	15 (110)	7 (118)	4 (121)	1 (124)	1 (124)	0 (125)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

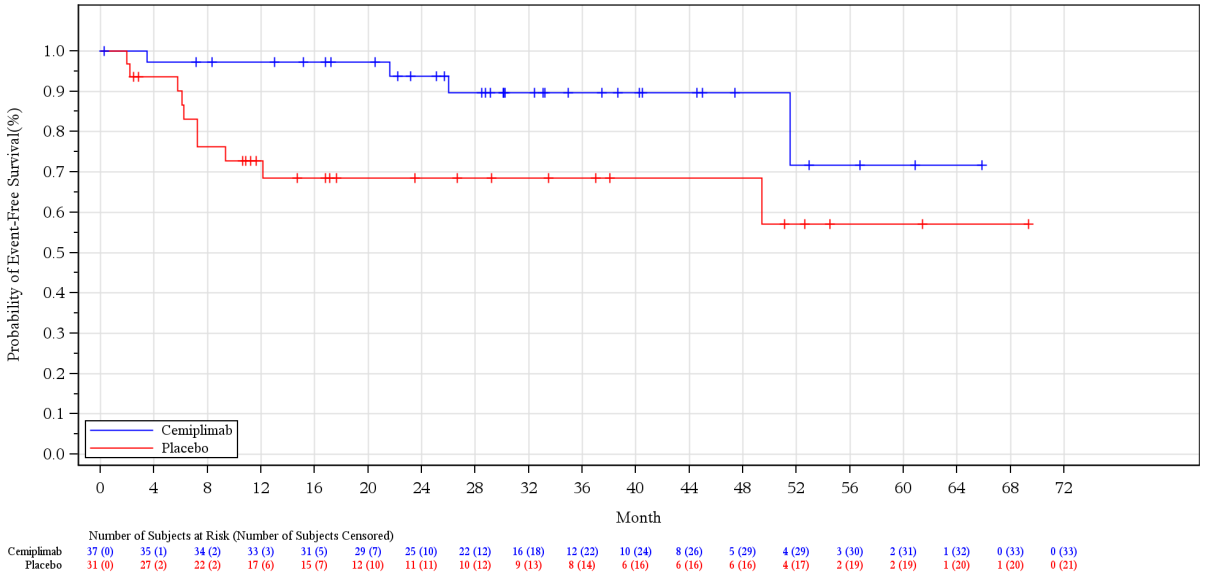
Cemiplimab	35 (0)	31 (3)	29 (4)	24 (8)	19 (13)	16 (16)	13 (18)	13 (18)	11 (20)	10 (21)	8 (23)	3 (28)	1 (30)	1 (30)	0 (31)	0 (31)	0 (31)	0 (31)	0 (31)
Placebo	32 (0)	29 (0)	21 (0)	20 (0)	14 (2)	12 (4)	10 (6)	7 (8)	6 (9)	6 (9)	6 (9)	5 (10)	5 (10)	4 (11)	2 (13)	0 (15)	0 (15)	0 (15)	0 (15)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

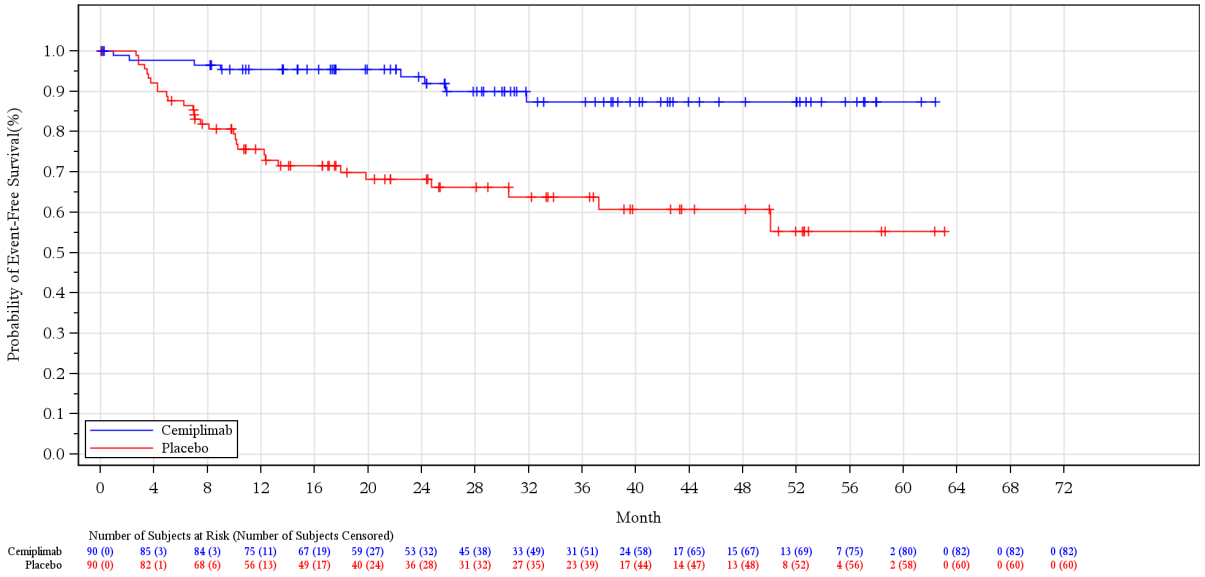
Cemiplimab	37 (0)	35 (1)	34 (2)	33 (3)	31 (5)	29 (7)	25 (10)	22 (12)	16 (18)	12 (22)	10 (24)	8 (26)	5 (29)	4 (29)	3 (30)	2 (31)	1 (32)	0 (33)	0 (33)
Placebo	31 (0)	27 (2)	22 (2)	17 (6)	15 (7)	12 (10)	11 (11)	10 (12)	9 (13)	8 (14)	6 (16)	6 (16)	6 (16)	4 (17)	2 (19)	2 (19)	1 (20)	1 (20)	0 (21)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

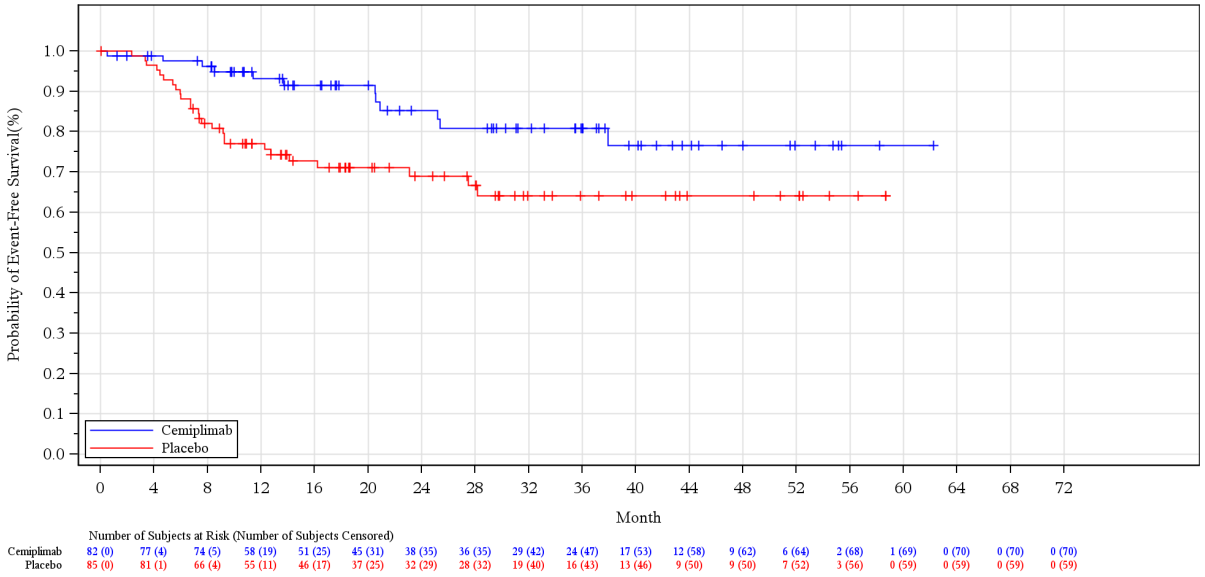
Cemiplimab	90 (0)	85 (3)	84 (3)	75 (11)	67 (19)	59 (27)	53 (32)	45 (38)	33 (49)	31 (51)	24 (58)	17 (65)	15 (67)	13 (69)	7 (75)	2 (80)	0 (82)	0 (82)	0 (82)
Placebo	90 (0)	82 (1)	68 (6)	56 (13)	49 (17)	40 (24)	36 (28)	31 (32)	27 (35)	23 (39)	17 (44)	14 (47)	13 (48)	8 (52)	4 (56)	2 (58)	0 (60)	0 (60)	0 (60)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

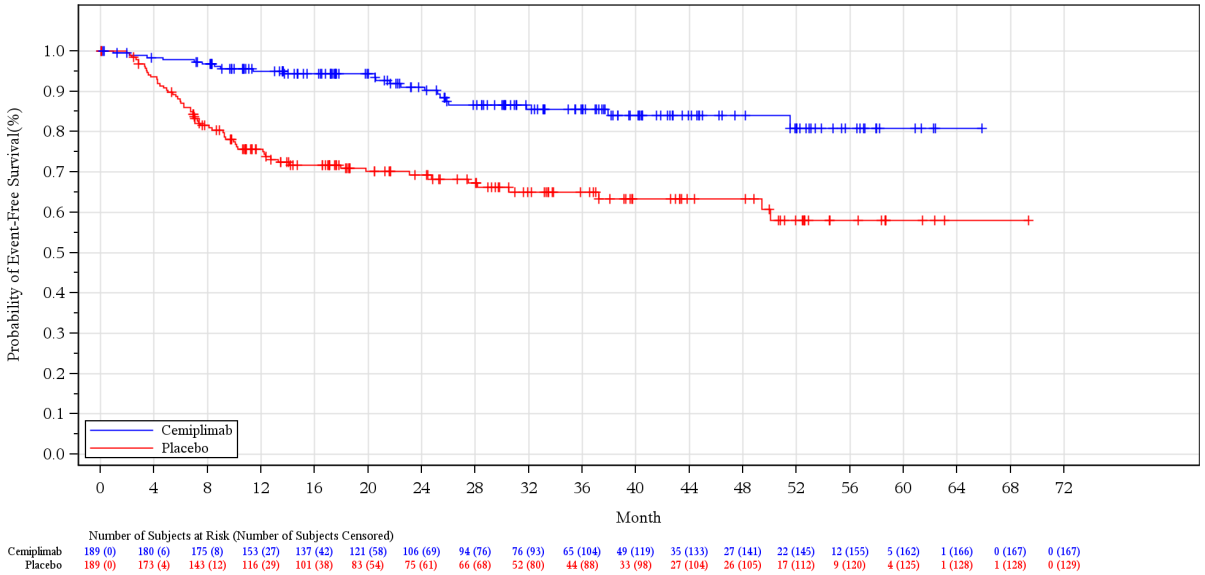
Cemiplimab	82 (0)	77 (4)	74 (5)	58 (19)	51 (25)	45 (31)	38 (35)	36 (35)	29 (42)	24 (47)	17 (53)	12 (58)	9 (62)	6 (64)	2 (68)	1 (69)	0 (70)	0 (70)	0 (70)
Placebo	85 (0)	81 (1)	66 (4)	55 (11)	46 (17)	37 (25)	32 (29)	28 (32)	19 (40)	16 (43)	13 (46)	9 (50)	9 (50)	7 (52)	3 (56)	0 (59)	0 (59)	0 (59)	0 (59)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

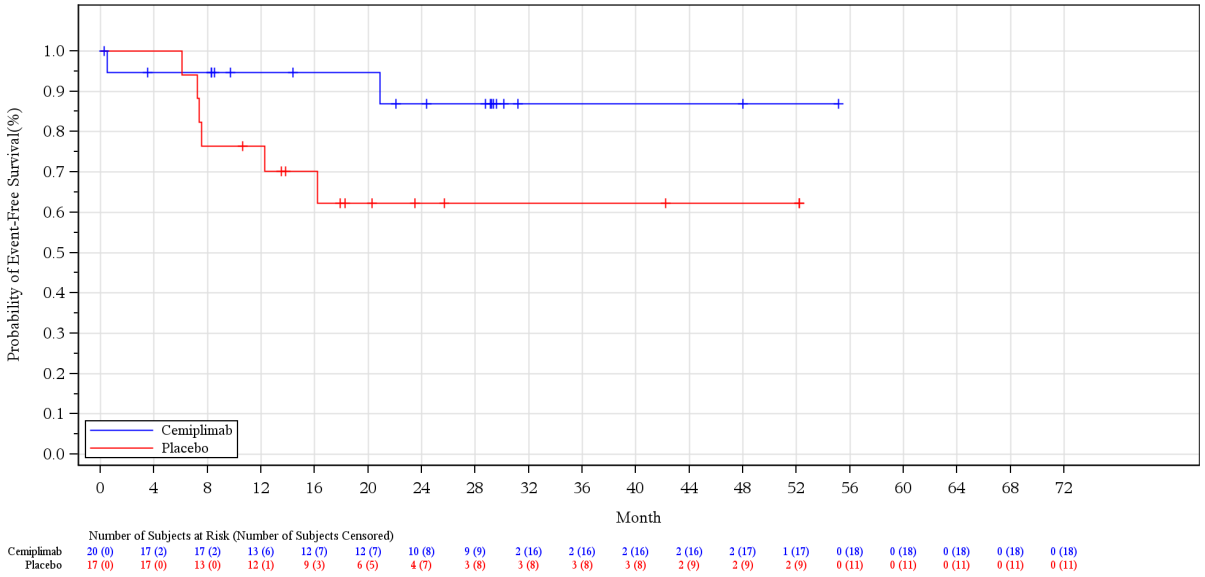
Cemiplimab	189 (0)	180 (6)	175 (8)	153 (27)	137 (42)	121 (58)	106 (69)	94 (76)	76 (93)	65 (104)	49 (119)	35 (133)	27 (141)	22 (145)	12 (155)	5 (162)	1 (166)	0 (167)	0 (167)
Placebo	189 (0)	173 (4)	143 (12)	116 (29)	101 (38)	83 (54)	75 (61)	66 (68)	52 (80)	44 (88)	33 (98)	27 (104)	26 (105)	17 (112)	9 (120)	4 (125)	1 (128)	1 (128)	0 (129)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

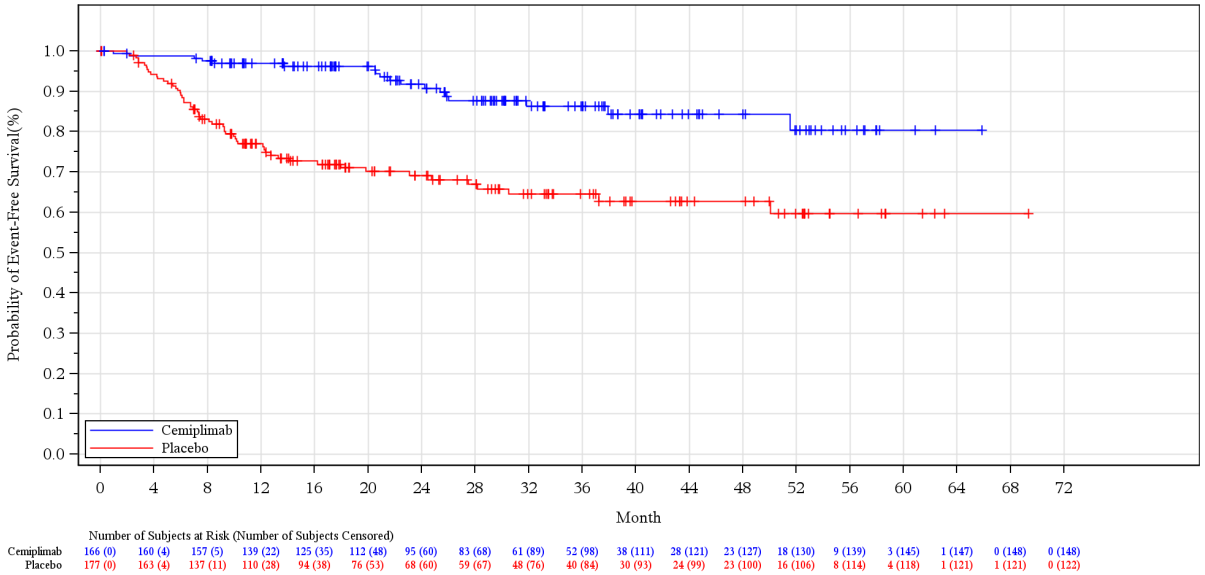
Cemiplimab	20 (0)	17 (2)	17 (2)	13 (6)	12 (7)	12 (7)	10 (8)	9 (9)	2 (16)	2 (16)	2 (16)	2 (16)	2 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	17 (0)	17 (0)	13 (0)	12 (1)	9 (3)	6 (5)	4 (7)	3 (8)	3 (8)	3 (8)	3 (8)	2 (9)	2 (9)	2 (9)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

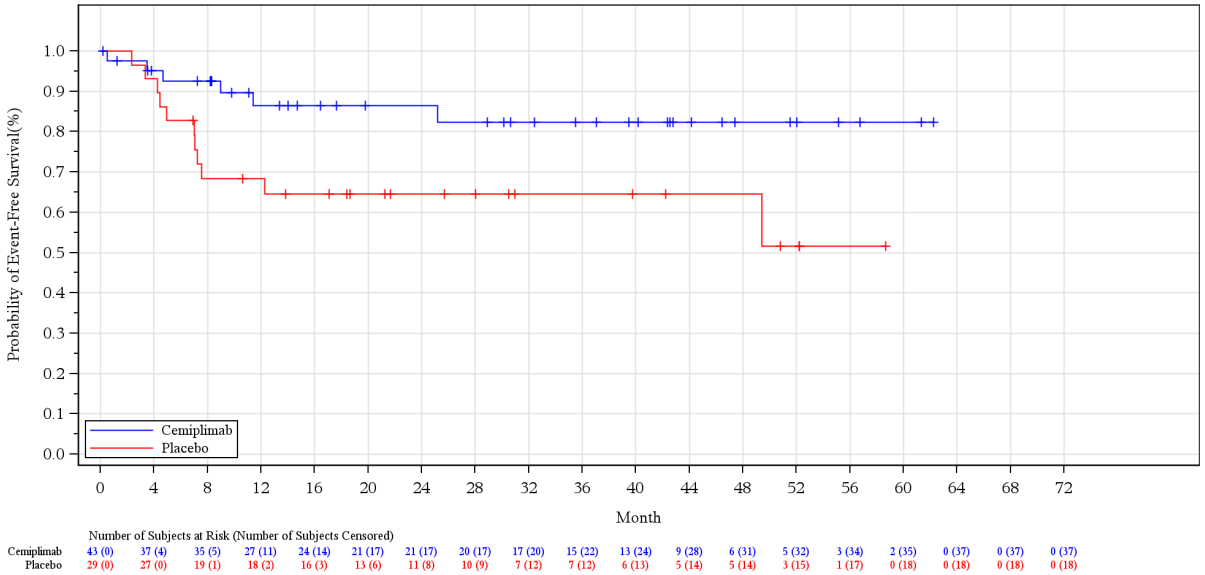
Cemiplimab	166 (0)	160 (4)	157 (5)	139 (22)	125 (35)	112 (48)	95 (60)	83 (68)	61 (89)	52 (98)	38 (111)	28 (121)	23 (127)	18 (130)	9 (139)	3 (145)	1 (147)	0 (148)	0 (148)
Placebo	177 (0)	163 (4)	137 (11)	110 (28)	94 (38)	76 (53)	68 (60)	59 (67)	48 (76)	40 (84)	30 (93)	24 (99)	23 (100)	16 (106)	8 (114)	4 (118)	1 (121)	1 (121)	0 (122)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

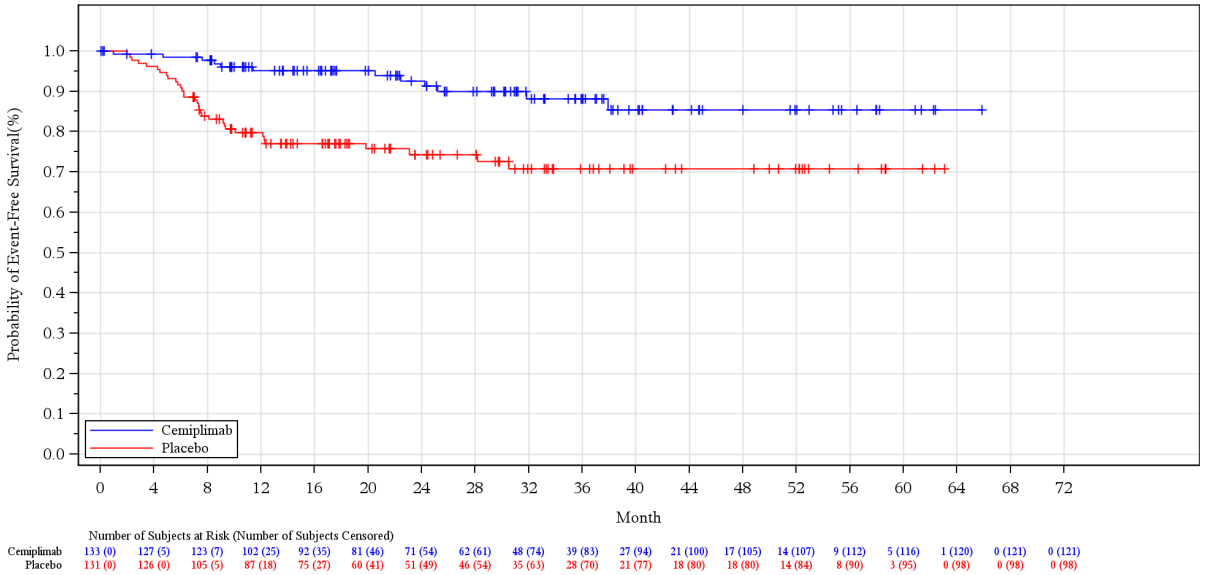
Cemiplimab	43 (0)	37 (4)	35 (5)	27 (11)	24 (14)	21 (17)	21 (17)	20 (17)	17 (20)	15 (22)	13 (24)	9 (28)	6 (31)	5 (32)	3 (34)	2 (35)	0 (37)	0 (37)	0 (37)
Placebo	29 (0)	27 (0)	19 (1)	18 (2)	16 (3)	13 (6)	11 (8)	10 (9)	7 (12)	7 (12)	6 (13)	5 (14)	5 (14)	3 (15)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

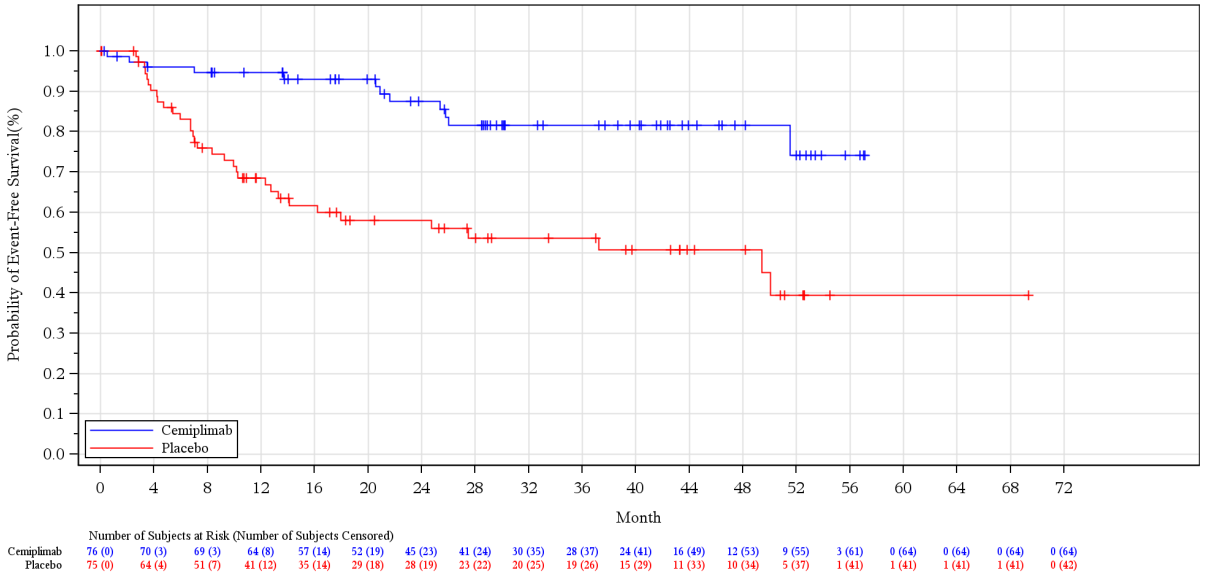
Cemiplimab	133 (0)	127 (5)	123 (7)	102 (25)	92 (35)	81 (46)	71 (54)	62 (61)	48 (74)	39 (83)	27 (94)	21 (100)	17 (105)	14 (107)	9 (112)	5 (116)	1 (120)	0 (121)	0 (121)
Placebo	131 (0)	126 (0)	105 (5)	87 (18)	75 (27)	60 (41)	51 (49)	46 (54)	35 (63)	28 (70)	21 (77)	18 (80)	18 (80)	14 (84)	8 (90)	3 (95)	0 (98)	0 (98)	0 (98)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

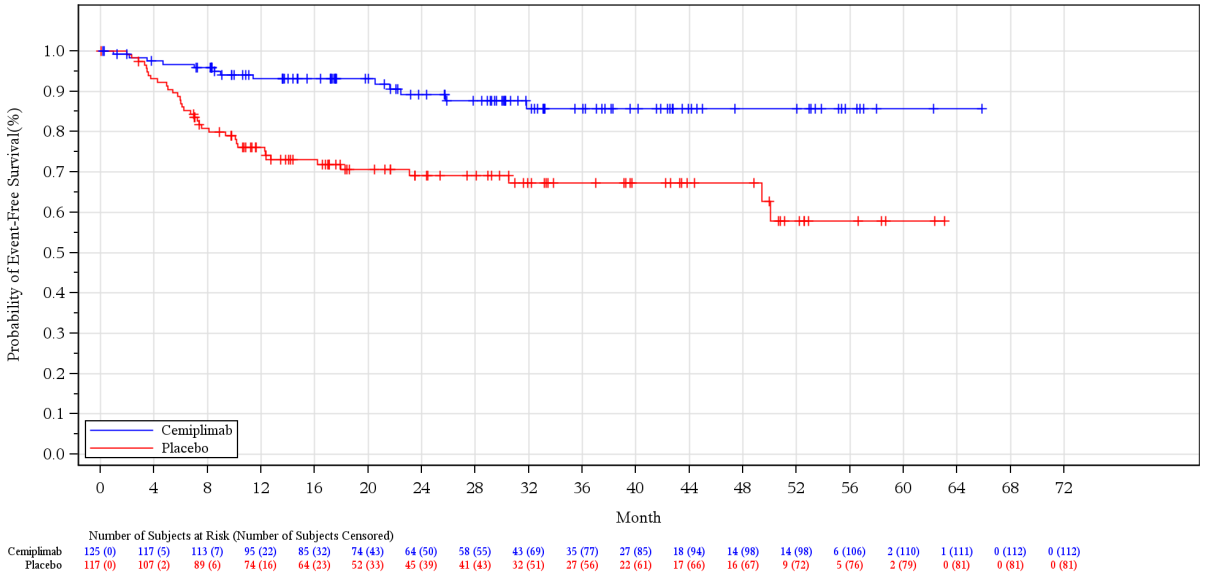
Cemiplimab	76 (0)	70 (3)	69 (3)	64 (8)	57 (14)	52 (19)	45 (23)	41 (24)	30 (35)	28 (37)	24 (41)	16 (49)	12 (53)	9 (55)	3 (61)	0 (64)	0 (64)	0 (64)	0 (64)
Placebo	75 (0)	64 (4)	51 (7)	41 (12)	35 (14)	29 (18)	28 (19)	23 (22)	20 (25)	19 (26)	15 (29)	11 (33)	10 (34)	5 (37)	1 (41)	1 (41)	1 (41)	1 (41)	0 (42)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

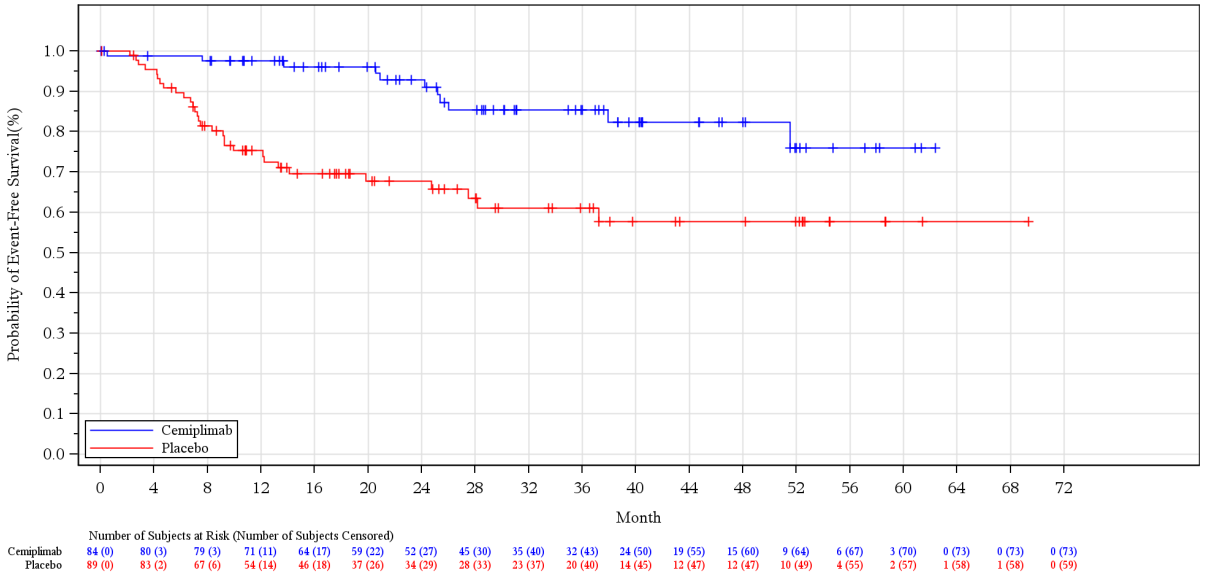
Cemiplimab	125 (0)	117 (5)	113 (7)	95 (22)	85 (32)	74 (43)	64 (50)	58 (55)	43 (69)	35 (77)	27 (85)	18 (94)	14 (98)	14 (98)	6 (106)	2 (110)	1 (111)	0 (112)	0 (112)
Placebo	117 (0)	107 (2)	89 (6)	74 (16)	64 (23)	52 (33)	45 (39)	41 (43)	32 (51)	27 (56)	22 (61)	17 (66)	16 (67)	9 (72)	5 (76)	2 (79)	0 (81)	0 (81)	0 (81)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.3.3.1 Time to First Subsequent Therapy or Death by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	80 (3)	79 (3)	71 (11)	64 (17)	59 (22)	52 (27)	45 (30)	35 (40)	32 (43)	24 (50)	19 (55)	15 (60)	9 (64)	6 (67)	3 (70)	0 (73)	0 (73)	0 (73)
Placebo	89 (0)	83 (2)	67 (6)	54 (14)	46 (18)	37 (26)	34 (29)	28 (33)	23 (37)	20 (40)	14 (45)	12 (47)	12 (47)	10 (49)	4 (55)	2 (57)	1 (58)	1 (58)	0 (59)

Data cut-off as of April 07, 2025.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-km-tfstd-sub.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

2.6 Kumulative Auftretenshäufigkeit von Sekundärtumoren

2.6.1 1. Datenschnitt

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of participants with at least one SPT, n(%)	5 (8.9%)	6 (9.2%)
Odds ratio (95% CI)	0.954 (0.267, 3.404)	
P-value for Odds Ratio	0.9419	
Relative Risk (95% CI)	0.98 (0.32, 2.98)	
P-value for Relative Risk	0.9761	
Heterogeneity p-value of RR	0.6649	
Risk difference (95% CI)	-0.44 (-17.43, 16.55)	
P-value for Risk Difference	0.9592	
Participants by number of SPTs, n(%)		
1	5 (8.9%)	3 (4.6%)
2	0	1 (1.5%)
3	0	1 (1.5%)
6	0	1 (1.5%)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Location of SPT		
Head and Neck	4 (7.1%)	6 (9.2%)
Non Head and Neck	1 (1.8%)	1 (1.5%)
Total number of SPTs	5	14
Total patient-years followed	110.2	100.5
Unadjusted SPT rate [1]	0.0	0.1
Adjusted annualized SPT rate [2] (95% CI)	0.350 (0.112,1.094)	0.981 (0.502,1.920)
SPT rate ratio [2] (95% CI)	2.803 (0.711,11.048)	
P-value [2]	0.1407	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of participants with at least one SPT, n(%)	26 (17.0%)	31 (22.0%)
Odds ratio (95% CI)	0.702 (0.383, 1.289)	
P-value for Odds Ratio	0.2540	
Relative Risk (95% CI)	0.78 (0.49, 1.22)	
P-value for Relative Risk	0.2705	
Heterogeneity p-value of RR	0.6649	
Risk difference (95% CI)	-5.38 (-13.84, 3.09)	
P-value for Risk Difference	0.2130	
Participants by number of SPTs, n(%)		
1	12 (7.8%)	22 (15.6%)
2	6 (3.9%)	3 (2.1%)
3	2 (1.3%)	0
4	1 (0.7%)	2 (1.4%)
5	4 (2.6%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Participants by number of SPTs, n(%)		
7	0	2 (1.4%)
9	1 (0.7%)	0
16	0	1 (0.7%)
43	0	1 (0.7%)
Location of SPT		
Head and Neck	17 (11.1%)	27 (19.1%)
Non Head and Neck	14 (9.2%)	11 (7.8%)
Total number of SPTs	63	109
Total patient-years followed	302.3	230.5
Unadjusted SPT rate [1]	0.2	0.5
Adjusted annualized SPT rate [2] (95% CI)	0.687 (0.381,1.238)	1.148 (0.525,2.512)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
SPT rate ratio [2] (95% CI)	1.671 (0.813,3.435)	
P-value [2]	0.1628	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of participants with at least one SPT, n(%)	5 (8.9%)	6 (9.2%)
Odds ratio (95% CI)	0.954 (0.267, 3.404)	
P-value for Odds Ratio	0.9419	
Relative Risk (95% CI)	0.98 (0.32, 2.98)	
P-value for Relative Risk	0.9761	
Heterogeneity p-value of RR	0.4857	
Risk difference (95% CI)	-0.44 (-17.43, 16.55)	
P-value for Risk Difference	0.9592	
Participants by number of SPTs, n(%)		
1	5 (8.9%)	3 (4.6%)
2	0	1 (1.5%)
3	0	1 (1.5%)
6	0	1 (1.5%)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Location of SPT		
Head and Neck	4 (7.1%)	6 (9.2%)
Non Head and Neck	1 (1.8%)	1 (1.5%)
Total number of SPTs	5	14
Total patient-years followed	110.2	100.5
Unadjusted SPT rate [1]	0.0	0.1
Adjusted annualized SPT rate [2] (95% CI)	0.350 (0.112,1.094)	0.981 (0.502,1.920)
SPT rate ratio [2] (95% CI)	2.803 (0.711,11.048)	
P-value [2]	0.1407	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of participants with at least one SPT, n(%)	8 (10.0%)	14 (20.3%)
Odds ratio (95% CI)	0.488 (0.183, 1.304)	
P-value for Odds Ratio	0.1524	
Relative Risk (95% CI)	0.56 (0.26, 1.22)	
P-value for Relative Risk	0.1459	
Heterogeneity p-value of RR	0.4857	
Risk difference (95% CI)	-5.76 (-22.92, 11.39)	
P-value for Risk Difference	0.5104	
Participants by number of SPTs, n(%)		
1	5 (6.3%)	11 (15.9%)
2	2 (2.5%)	1 (1.4%)
4	0	1 (1.4%)
5	1 (1.3%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Participants by number of SPTs, n(%)		
7	0	1 (1.4%)
Location of SPT		
Head and Neck	4 (5.0%)	11 (15.9%)
Non Head and Neck	5 (6.3%)	6 (8.7%)
Total number of SPTs	14	24
Total patient-years followed	153.6	128.1
Unadjusted SPT rate [1]	0.1	0.2
Adjusted annualized SPT rate [2] (95% CI)	0.583 (0.293,1.162)	0.318 (0.111,0.915)
SPT rate ratio [2] (95% CI)	0.545 (0.211,1.407)	
P-value [2]	0.2097	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of participants with at least one SPT, n(%)	18 (24.7%)	17 (23.6%)
Odds ratio (95% CI)	0.875 (0.385, 1.989)	
P-value for Odds Ratio	0.7495	
Relative Risk (95% CI)	0.91 (0.52, 1.60)	
P-value for Relative Risk	0.7524	
Heterogeneity p-value of RR	0.4857	
Risk difference (95% CI)	-2.50 (-16.84, 11.84)	
P-value for Risk Difference	0.7325	
Participants by number of SPTs, n(%)		
1	7 (9.6%)	11 (15.3%)
2	4 (5.5%)	2 (2.8%)
3	2 (2.7%)	0
4	1 (1.4%)	1 (1.4%)
5	3 (4.1%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Participants by number of SPTs, n(%)		
7	0	1 (1.4%)
9	1 (1.4%)	0
16	0	1 (1.4%)
43	0	1 (1.4%)
Location of SPT		
Head and Neck	13 (17.8%)	16 (22.2%)
Non Head and Neck	9 (12.3%)	5 (6.9%)
Total number of SPTs	49	85
Total patient-years followed	148.6	102.4
Unadjusted SPT rate [1]	0.3	0.8
Adjusted annualized SPT rate [2] (95% CI)	0.649 (0.295,1.424)	1.879 (0.669,5.278)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
SPT rate ratio [2] (95% CI)	2.897 (1.201,6.989)	
P-value [2]	0.0179	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of participants with at least one SPT, n(%)	30 (17.2%)	36 (20.7%)
Odds ratio (95% CI)	0.789 (0.453, 1.374)	
P-value for Odds Ratio	0.4022	
Relative Risk (95% CI)	0.85 (0.55, 1.29)	
P-value for Relative Risk	0.4413	
Heterogeneity p-value of RR	0.9416	
Risk difference (95% CI)	-4.28 (-12.23, 3.66)	
P-value for Risk Difference	0.2908	
Participants by number of SPTs, n(%)		
1	16 (9.2%)	24 (13.8%)
2	6 (3.4%)	4 (2.3%)
3	2 (1.1%)	1 (0.6%)
4	1 (0.6%)	2 (1.1%)
5	4 (2.3%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Participants by number of SPTs, n(%)		
6	0	1 (0.6%)
7	0	2 (1.1%)
9	1 (0.6%)	0
16	0	1 (0.6%)
43	0	1 (0.6%)
Location of SPT		
Head and Neck	21 (12.1%)	32 (18.4%)
Non Head and Neck	14 (8.0%)	12 (6.9%)
Total number of SPTs	67	122
Total patient-years followed	356.1	282.9
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Adjusted annualized SPT rate [2] (95% CI)	0.636 (0.347,1.166)	1.204 (0.564,2.574)
SPT rate ratio [2] (95% CI)	1.893 (0.991,3.613)	
P-value [2]	0.0531	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of participants with at least one SPT, n(%)	1 (2.9%)	1 (3.1%)
Odds ratio (95% CI)	0.546 (0.022, 13.598)	
P-value for Odds Ratio	0.7123	
Relative Risk (95% CI)	0.44 (0.44, 0.44)*	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.9416	
Risk difference (95% CI)	-2.13 (-43.95, 39.69)	
P-value for Risk Difference	0.9204	
Participants by number of SPTs, n(%)		
1	1 (2.9%)	1 (3.1%)
Location of SPT		
Head and Neck	0	1 (3.1%)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Location of SPT		
Non Head and Neck	1 (2.9%)	0
Total number of SPTs	1	1
Total patient-years followed	56.4	48.2
Unadjusted SPT rate [1]	0.0	0.0
Adjusted annualized SPT rate [2] (95% CI)	0	
SPT rate ratio [2] (95% CI)	0	
P-value [2]	NE	.

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of participants with at least one SPT, n(%)	6 (16.2%)	5 (16.1%)
Odds ratio (95% CI)	1.018 (0.276, 3.751)	
P-value for Odds Ratio	0.9789	
Relative Risk (95% CI)	1.01 (0.34, 3.01)	
P-value for Relative Risk	0.9826	
Heterogeneity p-value of RR	0.3002	
Risk difference (95% CI)	0.46 (-17.91, 18.82)	
P-value for Risk Difference	0.9611	
Participants by number of SPTs, n(%)		
1	3 (8.1%)	4 (12.9%)
2	2 (5.4%)	1 (3.2%)
5	1 (2.7%)	0
Location of SPT		

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Location of SPT		
Head and Neck	2 (5.4%)	4 (12.9%)
Non Head and Neck	4 (10.8%)	1 (3.2%)
Total number of SPTs	12	6
Total patient-years followed	82.1	54.1
Unadjusted SPT rate [1]	0.1	0.1
Adjusted annualized SPT rate [2] (95% CI)	0.422 (0.152,1.174)	0.390 (0.106,1.432)
SPT rate ratio [2] (95% CI)	0.926 (0.342,2.503)	
P-value [2]	0.8790	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of participants with at least one SPT, n(%)	22 (24.4%)	23 (25.6%)
Odds ratio (95% CI)	0.948 (0.482, 1.865)	
P-value for Odds Ratio	0.8771	
Relative Risk (95% CI)	0.95 (0.58, 1.58)	
P-value for Relative Risk	0.8583	
Heterogeneity p-value of RR	0.3002	
Risk difference (95% CI)	-0.70 (-13.90, 12.50)	
P-value for Risk Difference	0.9175	
Participants by number of SPTs, n(%)		
1	13 (14.4%)	15 (16.7%)
2	4 (4.4%)	2 (2.2%)
3	2 (2.2%)	1 (1.1%)
4	1 (1.1%)	1 (1.1%)
5	1 (1.1%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Participants by number of SPTs, n(%)		
7	0	2 (2.2%)
9	1 (1.1%)	0
16	0	1 (1.1%)
43	0	1 (1.1%)
Location of SPT		
Head and Neck	16 (17.8%)	20 (22.2%)
Non Head and Neck	10 (11.1%)	9 (10.0%)
Total number of SPTs	45	99
Total patient-years followed	184.7	148.5
Unadjusted SPT rate [1]	0.2	0.7
Adjusted annualized SPT rate [2] (95% CI)	0.756 (0.371,1.541)	2.055 (0.854,4.942)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
SPT rate ratio [2] (95% CI)	2.719 (1.195,6.184)	
P-value [2]	0.0171	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of participants with at least one SPT, n(%)	3 (3.7%)	9 (10.6%)
Odds ratio (95% CI)	0.346 (0.090, 1.337)	
P-value for Odds Ratio	0.1239	
Relative Risk (95% CI)	0.37 (0.10, 1.31)	
P-value for Relative Risk	0.1241	
Heterogeneity p-value of RR	0.3002	
Risk difference (95% CI)	-5.47 (-14.84, 3.91)	
P-value for Risk Difference	0.2531	
Participants by number of SPTs, n(%)		
1	1 (1.2%)	6 (7.1%)
2	0	1 (1.2%)
4	0	1 (1.2%)
5	2 (2.4%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Participants by number of SPTs, n(%)		
6	0	1 (1.2%)
Location of SPT		
Head and Neck	3 (3.7%)	9 (10.6%)
Non Head and Neck	1 (1.2%)	2 (2.4%)
Total number of SPTs	11	18
Total patient-years followed	145.7	128.4
Unadjusted SPT rate [1]	0.1	0.1
Adjusted annualized SPT rate [2] (95% CI)	1.412 (0.689,2.893)	0.800 (0.321,1.997)
SPT rate ratio [2] (95% CI)	0.567 (0.187,1.714)	
P-value [2]	0.3147	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of participants with at least one SPT, n(%)	31 (16.4%)	37 (19.6%)
Odds ratio (95% CI)	0.819 (0.477, 1.406)	
P-value for Odds Ratio	0.4694	
Relative Risk (95% CI)	0.86 (0.56, 1.32)	
P-value for Relative Risk	0.4903	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-3.38 (-11.39, 4.64)	
P-value for Risk Difference	0.4091	
Participants by number of SPTs, n(%)		
1	17 (9.0%)	25 (13.2%)
2	6 (3.2%)	4 (2.1%)
3	2 (1.1%)	1 (0.5%)
4	1 (0.5%)	2 (1.1%)
5	4 (2.1%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Participants by number of SPTs, n(%)		
6	0	1 (0.5%)
7	0	2 (1.1%)
9	1 (0.5%)	0
16	0	1 (0.5%)
43	0	1 (0.5%)
Location of SPT		
Head and Neck	21 (11.1%)	33 (17.5%)
Non Head and Neck	15 (7.9%)	12 (6.3%)
Total number of SPTs	68	123
Total patient-years followed	383.3	306.6
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Adjusted annualized SPT rate [2] (95% CI)	0.633 (0.361,1.110)	1.202 (0.592,2.442)
SPT rate ratio [2] (95% CI)	1.900 (1.002,3.600)	
P-value [2]	0.0491	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of participants with at least one SPT, n(%)	0	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of participants with at least one SPT, n(%)	24 (14.5%)	37 (20.9%)
Odds ratio (95% CI)	0.614 (0.345, 1.092)	
P-value for Odds Ratio	0.0966	
Relative Risk (95% CI)	0.69 (0.44, 1.10)	
P-value for Relative Risk	0.1166	
Heterogeneity p-value of RR	0.0016	
Risk difference (95% CI)	-7.67 (-14.82, -0.53)	
P-value for Risk Difference	0.0353	
Participants by number of SPTs, n(%)		
1	13 (7.8%)	25 (14.1%)
2	4 (2.4%)	4 (2.3%)
3	2 (1.2%)	1 (0.6%)
4	1 (0.6%)	2 (1.1%)
5	3 (1.8%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Participants by number of SPTs, n(%)		
6	0	1 (0.6%)
7	0	2 (1.1%)
9	1 (0.6%)	0
16	0	1 (0.6%)
43	0	1 (0.6%)
Location of SPT		
Head and Neck	18 (10.8%)	33 (18.6%)
Non Head and Neck	9 (5.4%)	12 (6.8%)
Total number of SPTs	55	123
Total patient-years followed	330.8	285.1
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Adjusted annualized SPT rate [2] (95% CI)	0.856 (0.492,1.490)	1.641 (1.018,2.643)
SPT rate ratio [2] (95% CI)	1.917 (0.993,3.701)	
P-value [2]	0.0525	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of participants with at least one SPT, n(%)	7 (16.3%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.0016	
Risk difference (95% CI)	10.87 (-25.66, 47.40)	
P-value for Risk Difference	0.5598	
Participants by number of SPTs, n(%)		
1	4 (9.3%)	0
2	2 (4.7%)	0
5	1 (2.3%)	0

Location of SPT

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Location of SPT		
Head and Neck	3 (7.0%)	0
Non Head and Neck	6 (14.0%)	0
Total number of SPTs	13	0
Total patient-years followed	81.6	45.9
Unadjusted SPT rate [1]	0.2	0
Adjusted annualized SPT rate [2] (95% CI)	0.495 (0.232,1.055)	
SPT rate ratio [2] (95% CI)	0	
P-value [2]	NE	.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of participants with at least one SPT, n(%)	19 (14.3%)	21 (16.0%)
Odds ratio (95% CI)	0.898 (0.449, 1.799)	
P-value for Odds Ratio	0.7623	

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Relative Risk (95% CI)	0.90 (0.52, 1.57)	
P-value for Relative Risk	0.7195	
Heterogeneity p-value of RR	0.7133	
Risk difference (95% CI)	0.52 (-8.99, 10.03)	
P-value for Risk Difference	0.9143	
Participants by number of SPTs, n(%)		
1	8 (6.0%)	12 (9.2%)
2	5 (3.8%)	4 (3.1%)
3	1 (0.8%)	1 (0.8%)
4	1 (0.8%)	2 (1.5%)
5	4 (3.0%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Participants by number of SPTs, n(%)		
7	0	1 (0.8%)
16	0	1 (0.8%)
Location of SPT		
Head and Neck	12 (9.0%)	18 (13.7%)
Non Head and Neck	10 (7.5%)	8 (6.1%)
Total number of SPTs	45	54
Total patient-years followed	251.8	212.9
Unadjusted SPT rate [1]	0.2	0.3
Adjusted annualized SPT rate [2] (95% CI)	0.807 (0.442,1.474)	0.871 (0.384,1.976)
SPT rate ratio [2] (95% CI)	1.079 (0.527,2.212)	
P-value [2]	0.8349	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of participants with at least one SPT, n(%)	12 (15.8%)	16 (21.3%)
Odds ratio (95% CI)	0.662 (0.282, 1.553)	
P-value for Odds Ratio	0.3433	
Relative Risk (95% CI)	0.77 (0.40, 1.50)	
P-value for Relative Risk	0.4464	
Heterogeneity p-value of RR	0.7133	
Risk difference (95% CI)	-10.70 (-26.60, 5.21)	
P-value for Risk Difference	0.1876	
Participants by number of SPTs, n(%)		
1	9 (11.8%)	13 (17.3%)
2	1 (1.3%)	0
3	1 (1.3%)	0
6	0	1 (1.3%)
7	0	1 (1.3%)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Participants by number of SPTs, n(%)		
9	1 (1.3%)	0
43	0	1 (1.3%)
Location of SPT		
Head and Neck	9 (11.8%)	15 (20.0%)
Non Head and Neck	5 (6.6%)	4 (5.3%)
Total number of SPTs	23	69
Total patient-years followed	160.6	118.2
Unadjusted SPT rate [1]	0.1	0.6
Adjusted annualized SPT rate [2] (95% CI)	0.306 (0.099,0.948)	1.381 (0.422,4.514)
SPT rate ratio [2] (95% CI)	4.514 (1.451,14.038)	
P-value [2]	0.0092	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of participants with at least one SPT, n(%)	26 (20.8%)	23 (19.7%)
Odds ratio (95% CI)	1.141 (0.593, 2.194)	
P-value for Odds Ratio	0.6926	
Relative Risk (95% CI)	1.11 (0.68, 1.79)	
P-value for Relative Risk	0.6852	
Heterogeneity p-value of RR	0.0342	
Risk difference (95% CI)	2.43 (-8.91, 13.77)	
P-value for Risk Difference	0.6747	
Participants by number of SPTs, n(%)		
1	13 (10.4%)	15 (12.8%)
2	5 (4.0%)	3 (2.6%)
3	2 (1.6%)	1 (0.9%)
4	1 (0.8%)	1 (0.9%)
5	4 (3.2%)	0

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Participants by number of SPTs, n(%)		
6	0	1 (0.9%)
7	0	1 (0.9%)
9	1 (0.8%)	0
43	0	1 (0.9%)
Location of SPT		
Head and Neck	17 (13.6%)	19 (16.2%)
Non Head and Neck	13 (10.4%)	9 (7.7%)
Total number of SPTs	62	84
Total patient-years followed	233.8	189.4
Unadjusted SPT rate [1]	0.3	0.4
Adjusted annualized SPT rate [2] (95% CI)	0.681 (0.371,1.251)	1.255 (0.553,2.846)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
SPT rate ratio [2] (95% CI)	1.843 (0.882,3.849)	
P-value [2]	0.1039	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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(zheyuan.zhang 13AUG2025 13:56 SAS Linux 9.4)

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of participants with at least one SPT, n(%)	5 (6.0%)	14 (15.7%)
Odds ratio (95% CI)	0.318 (0.107, 0.947)	
P-value for Odds Ratio	0.0396	
Relative Risk (95% CI)	0.38 (0.14, 0.98)	
P-value for Relative Risk	0.0465	
Heterogeneity p-value of RR	0.0342	
Risk difference (95% CI)	-9.17 (-21.17, 2.84)	
P-value for Risk Difference	0.1344	
Participants by number of SPTs, n(%)		
1	4 (4.8%)	10 (11.2%)
2	1 (1.2%)	1 (1.1%)
4	0	1 (1.1%)
7	0	1 (1.1%)

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Participants by number of SPTs, n(%)		
16	0	1 (1.1%)
Location of SPT		
Head and Neck	4 (4.8%)	14 (15.7%)
Non Head and Neck	2 (2.4%)	3 (3.4%)
Total number of SPTs	6	39
Total patient-years followed	178.7	141.6
Unadjusted SPT rate [1]	0.0	0.3
Adjusted annualized SPT rate [2] (95% CI)	0.308 (0.064,1.482)	1.198 (0.249,5.776)
SPT rate ratio [2] (95% CI)	3.895 (0.768,19.760)	
P-value [2]	0.1008	

Data cut-off as of October 4, 2024.CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of participants with at least one SPT, n(%)	7 (12.5%)	9 (13.8%)
Odds ratio (95% CI)	0.885 (0.299, 2.616)	
P-value for Odds Ratio	0.8249	
Relative Risk (95% CI)	0.92 (0.37, 2.27)	
P-value for Relative Risk	0.8577	
Heterogeneity p-value of RR	0.8149	
Risk difference (95% CI)	-1.25 (-19.22, 16.73)	
P-value for Risk Difference	0.8919	
Participants by number of SPTs, n(%)		
1	7 (12.5%)	6 (9.2%)
2	0	1 (1.5%)
3	0	1 (1.5%)
6	0	1 (1.5%)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: <65

	Cemiplimab (N=56)	Placebo (N=65)
Location of SPT		
Head and Neck	6 (10.7%)	9 (13.8%)
Non Head and Neck	1 (1.8%)	1 (1.5%)
Total number of SPTs	7	17
Total patient-years followed	135.2	121.5
Unadjusted SPT rate [1]	0.1	0.1
Adjusted annualized SPT rate [2] (95% CI)	0.785 (0.233,2.648)	1.440 (0.434,4.781)
SPT rate ratio [2] (95% CI)	1.834 (0.605,5.563)	
P-value [2]	0.2841	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Number of participants with at least one SPT, n(%)	30 (19.6%)	33 (23.4%)
Odds ratio (95% CI)	0.795 (0.443, 1.427)	
P-value for Odds Ratio	0.4420	
Relative Risk (95% CI)	0.85 (0.56, 1.30)	
P-value for Relative Risk	0.4562	
Heterogeneity p-value of RR	0.8149	
Risk difference (95% CI)	-3.71 (-12.85, 5.43)	
P-value for Risk Difference	0.4265	
Participants by number of SPTs, n(%)		
1	14 (9.2%)	21 (14.9%)
2	5 (3.3%)	5 (3.5%)
3	4 (2.6%)	1 (0.7%)
4	1 (0.7%)	2 (1.4%)
5	4 (2.6%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Participants by number of SPTs, n(%)		
6	1 (0.7%)	0
7	0	2 (1.4%)
11	1 (0.7%)	0
16	0	1 (0.7%)
43	0	1 (0.7%)
Location of SPT		
Head and Neck	20 (13.1%)	29 (20.6%)
Non Head and Neck	17 (11.1%)	12 (8.5%)
Total number of SPTs	77	115
Total patient-years followed	368.7	277.5
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 1: >=65

	Cemiplimab (N=153)	Placebo (N=141)
Adjusted annualized SPT rate [2] (95% CI)	0.619 (0.355,1.078)	0.958 (0.464,1.978)
SPT rate ratio [2] (95% CI)	1.547 (0.818,2.927)	
P-value [2]	0.1794	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Number of participants with at least one SPT, n(%)	7 (12.5%)	9 (13.8%)
Odds ratio (95% CI)	0.885 (0.299, 2.616)	
P-value for Odds Ratio	0.8249	
Relative Risk (95% CI)	0.92 (0.37, 2.27)	
P-value for Relative Risk	0.8577	
Heterogeneity p-value of RR	0.3892	
Risk difference (95% CI)	-1.25 (-19.22, 16.73)	
P-value for Risk Difference	0.8919	
Participants by number of SPTs, n(%)		
1	7 (12.5%)	6 (9.2%)
2	0	1 (1.5%)
3	0	1 (1.5%)
6	0	1 (1.5%)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: <65

	Cemiplimab (N=56)	Placebo (N=65)
Location of SPT		
Head and Neck	6 (10.7%)	9 (13.8%)
Non Head and Neck	1 (1.8%)	1 (1.5%)
Total number of SPTs	7	17
Total patient-years followed	135.2	121.5
Unadjusted SPT rate [1]	0.1	0.1
Adjusted annualized SPT rate [2] (95% CI)	0.785 (0.233,2.648)	1.440 (0.434,4.781)
SPT rate ratio [2] (95% CI)	1.834 (0.605,5.563)	
P-value [2]	0.2841	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Number of participants with at least one SPT, n(%)	9 (11.3%)	15 (21.7%)
Odds ratio (95% CI)	0.520 (0.201, 1.341)	
P-value for Odds Ratio	0.1759	
Relative Risk (95% CI)	0.60 (0.29, 1.23)	
P-value for Relative Risk	0.1621	
Heterogeneity p-value of RR	0.3892	
Risk difference (95% CI)	-5.37 (-22.60, 11.85)	
P-value for Risk Difference	0.5409	
Participants by number of SPTs, n(%)		
1	4 (5.0%)	11 (15.9%)
2	1 (1.3%)	2 (2.9%)
3	2 (2.5%)	0
4	1 (1.3%)	1 (1.4%)
5	1 (1.3%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75

	Cemiplimab (N=80)	Placebo (N=69)
Participants by number of SPTs, n(%)		
7	0	1 (1.4%)
Location of SPT		
Head and Neck	4 (5.0%)	12 (17.4%)
Non Head and Neck	7 (8.8%)	7 (10.1%)
Total number of SPTs	21	26
Total patient-years followed	188.2	151.6
Unadjusted SPT rate [1]	0.1	0.2
Adjusted annualized SPT rate [2] (95% CI)	0.619 (0.342,1.121)	0.277 (0.118,0.653)
SPT rate ratio [2] (95% CI)	0.448 (0.219,0.914)	
P-value [2]	0.0274	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Number of participants with at least one SPT, n(%)	21 (28.8%)	18 (25.0%)
Odds ratio (95% CI)	1.064 (0.483, 2.344)	
P-value for Odds Ratio	0.8777	
Relative Risk (95% CI)	1.05 (0.63, 1.77)	
P-value for Relative Risk	0.8462	
Heterogeneity p-value of RR	0.3892	
Risk difference (95% CI)	1.47 (-13.93, 16.86)	
P-value for Risk Difference	0.8520	
Participants by number of SPTs, n(%)		
1	10 (13.7%)	10 (13.9%)
2	4 (5.5%)	3 (4.2%)
3	2 (2.7%)	1 (1.4%)
4	0	1 (1.4%)
5	3 (4.1%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Participants by number of SPTs, n(%)		
6	1 (1.4%)	0
7	0	1 (1.4%)
11	1 (1.4%)	0
16	0	1 (1.4%)
43	0	1 (1.4%)
Location of SPT		
Head and Neck	16 (21.9%)	17 (23.6%)
Non Head and Neck	10 (13.7%)	5 (6.9%)
Total number of SPTs	56	89
Total patient-years followed	180.5	125.9
Unadjusted SPT rate [1]	0.3	0.7

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Age group 2: >=75

	Cemiplimab (N=73)	Placebo (N=72)
Adjusted annualized SPT rate [2] (95% CI)	0.559 (0.262,1.193)	1.601 (0.601,4.264)
SPT rate ratio [2] (95% CI)	2.864 (1.290,6.358)	
P-value [2]	0.0097	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Number of participants with at least one SPT, n(%)	33 (19.0%)	40 (23.0%)
Odds ratio (95% CI)	0.782 (0.459, 1.333)	
P-value for Odds Ratio	0.3665	
Relative Risk (95% CI)	0.85 (0.57, 1.26)	
P-value for Relative Risk	0.4090	
Heterogeneity p-value of RR	0.3148	
Risk difference (95% CI)	-4.36 (-12.89, 4.17)	
P-value for Risk Difference	0.3168	
Participants by number of SPTs, n(%)		
1	17 (9.8%)	25 (14.4%)
2	5 (2.9%)	6 (3.4%)
3	4 (2.3%)	2 (1.1%)
4	1 (0.6%)	2 (1.1%)
5	4 (2.3%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Participants by number of SPTs, n(%)		
6	1 (0.6%)	1 (0.6%)
7	0	2 (1.1%)
11	1 (0.6%)	0
16	0	1 (0.6%)
43	0	1 (0.6%)
Location of SPT		
Head and Neck	24 (13.8%)	37 (21.3%)
Non Head and Neck	16 (9.2%)	12 (6.9%)
Total number of SPTs	80	130
Total patient-years followed	432.8	343.1
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Male

	Cemiplimab (N=174)	Placebo (N=174)
Adjusted annualized SPT rate [2] (95% CI)	0.584 (0.331,1.031)	0.935 (0.468,1.867)
SPT rate ratio [2] (95% CI)	1.599 (0.900,2.842)	
P-value [2]	0.1094	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Number of participants with at least one SPT, n(%)	4 (11.4%)	2 (6.3%)
Odds ratio (95% CI)	2.052 (0.323, 13.032)	
P-value for Odds Ratio	0.4462	
Relative Risk (95% CI)	2.01 (0.41, 9.88)	
P-value for Relative Risk	0.3888	
Heterogeneity p-value of RR	0.3148	
Risk difference (95% CI)	0.28 (-30.36, 30.91)	
P-value for Risk Difference	0.9860	
Participants by number of SPTs, n(%)		
1	4 (11.4%)	2 (6.3%)
Location of SPT		
Head and Neck	2 (5.7%)	1 (3.1%)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Gender group: Female

	Cemiplimab (N=35)	Placebo (N=32)
Location of SPT		
Non Head and Neck	2 (5.7%)	1 (3.1%)
Total number of SPTs	4	2
Total patient-years followed	71.1	55.9
Unadjusted SPT rate [1]	0.1	0.0
Adjusted annualized SPT rate [2] (95% CI)	0.806 (0.206,3.161)	0.596 (0.101,3.515)
SPT rate ratio [2] (95% CI)	0.740 (0.067,8.157)	
P-value [2]	0.8055	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Number of participants with at least one SPT, n(%)	6 (16.2%)	6 (19.4%)
Odds ratio (95% CI)	0.819 (0.233, 2.877)	
P-value for Odds Ratio	0.7557	
Relative Risk (95% CI)	0.85 (0.30, 2.37)	
P-value for Relative Risk	0.7494	
Heterogeneity p-value of RR	0.2082	
Risk difference (95% CI)	-2.72 (-21.77, 16.33)	
P-value for Risk Difference	0.7793	
Participants by number of SPTs, n(%)		
1	3 (8.1%)	5 (16.1%)
2	1 (2.7%)	1 (3.2%)
3	1 (2.7%)	0
5	1 (2.7%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America

	Cemiplimab (N=37)	Placebo (N=31)
Location of SPT		
Head and Neck	2 (5.4%)	5 (16.1%)
Non Head and Neck	4 (10.8%)	1 (3.2%)
Total number of SPTs	13	7
Total patient-years followed	97.8	62.4
Unadjusted SPT rate [1]	0.1	0.1
Adjusted annualized SPT rate [2] (95% CI)	0.385 (0.139,1.067)	0.313 (0.089,1.103)
SPT rate ratio [2] (95% CI)	0.813 (0.320,2.064)	
P-value [2]	0.6626	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Number of participants with at least one SPT, n(%)	27 (30.0%)	25 (27.8%)
Odds ratio (95% CI)	1.119 (0.586, 2.137)	
P-value for Odds Ratio	0.7326	
Relative Risk (95% CI)	1.08 (0.68, 1.71)	
P-value for Relative Risk	0.7478	
Heterogeneity p-value of RR	0.2082	
Risk difference (95% CI)	2.69 (-11.04, 16.43)	
P-value for Risk Difference	0.7006	
Participants by number of SPTs, n(%)		
1	16 (17.8%)	15 (16.7%)
2	4 (4.4%)	4 (4.4%)
3	3 (3.3%)	1 (1.1%)
4	1 (1.1%)	1 (1.1%)
5	2 (2.2%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
Participants by number of SPTs, n(%)		
7	0	2 (2.2%)
11	1 (1.1%)	0
16	0	1 (1.1%)
43	0	1 (1.1%)
Location of SPT		
Head and Neck	20 (22.2%)	22 (24.4%)
Non Head and Neck	12 (13.3%)	10 (11.1%)
Total number of SPTs	58	103
Total patient-years followed	225.3	178.8
Unadjusted SPT rate [1]	0.3	0.6
Adjusted annualized SPT rate [2] (95% CI)	0.734 (0.389,1.385)	1.703 (0.770,3.766)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand

	Cemiplimab (N=90)	Placebo (N=90)
SPT rate ratio [2] (95% CI)	2.319 (1.122,4.791)	
P-value [2]	0.0231	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Number of participants with at least one SPT, n(%)	4 (4.9%)	11 (12.9%)
Odds ratio (95% CI)	0.375 (0.113, 1.241)	
P-value for Odds Ratio	0.1082	
Relative Risk (95% CI)	0.41 (0.14, 1.22)	
P-value for Relative Risk	0.1079	
Heterogeneity p-value of RR	0.2082	
Risk difference (95% CI)	-5.42 (-16.08, 5.24)	
P-value for Risk Difference	0.3188	
Participants by number of SPTs, n(%)		
1	2 (2.4%)	7 (8.2%)
2	0	1 (1.2%)
3	0	1 (1.2%)
4	0	1 (1.2%)
5	1 (1.2%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World

	Cemiplimab (N=82)	Placebo (N=85)
Participants by number of SPTs, n(%)		
6	1 (1.2%)	1 (1.2%)
Location of SPT		
Head and Neck	4 (4.9%)	11 (12.9%)
Non Head and Neck	2 (2.4%)	2 (2.4%)
Total number of SPTs	13	22
Total patient-years followed	180.9	157.9
Unadjusted SPT rate [1]	0.1	0.1
Adjusted annualized SPT rate [2] (95% CI)	1.199 (0.626,2.294)	0.708 (0.312,1.604)
SPT rate ratio [2] (95% CI)	0.590 (0.231,1.507)	
P-value [2]	0.2702	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Number of participants with at least one SPT, n(%)	37 (19.6%)	42 (22.2%)
Odds ratio (95% CI)	0.874 (0.524, 1.456)	
P-value for Odds Ratio	0.6043	
Relative Risk (95% CI)	0.91 (0.62, 1.34)	
P-value for Relative Risk	0.6475	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-2.80 (-11.34, 5.75)	
P-value for Risk Difference	0.5214	
Participants by number of SPTs, n(%)		
1	21 (11.1%)	27 (14.3%)
2	5 (2.6%)	6 (3.2%)
3	4 (2.1%)	2 (1.1%)
4	1 (0.5%)	2 (1.1%)
5	4 (2.1%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Participants by number of SPTs, n(%)		
6	1 (0.5%)	1 (0.5%)
7	0	2 (1.1%)
11	1 (0.5%)	0
16	0	1 (0.5%)
43	0	1 (0.5%)
Location of SPT		
Head and Neck	26 (13.8%)	38 (20.1%)
Non Head and Neck	18 (9.5%)	13 (6.9%)
Total number of SPTs	84	132
Total patient-years followed	466.4	369.1
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: White

	Cemiplimab (N=189)	Placebo (N=189)
Adjusted annualized SPT rate [2] (95% CI)	0.594 (0.354,0.997)	0.987 (0.522,1.867)
SPT rate ratio [2] (95% CI)	1.661 (0.950,2.904)	
P-value [2]	0.0748	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Race: Non-white

	Cemiplimab (N=20)	Placebo (N=17)
Number of participants with at least one SPT, n(%)	0	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Number of participants with at least one SPT, n(%)	29 (17.5%)	42 (23.7%)
Odds ratio (95% CI)	0.656 (0.382, 1.127)	
P-value for Odds Ratio	0.1270	
Relative Risk (95% CI)	0.75 (0.49, 1.13)	
P-value for Relative Risk	0.1634	
Heterogeneity p-value of RR	0.0008	
Risk difference (95% CI)	-7.84 (-15.64, -0.04)	
P-value for Risk Difference	0.0488	
Participants by number of SPTs, n(%)		
1	16 (9.6%)	27 (15.3%)
2	4 (2.4%)	6 (3.4%)
3	3 (1.8%)	2 (1.1%)
4	1 (0.6%)	2 (1.1%)
5	3 (1.8%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Participants by number of SPTs, n(%)		
6	1 (0.6%)	1 (0.6%)
7	0	2 (1.1%)
11	1 (0.6%)	0
16	0	1 (0.6%)
43	0	1 (0.6%)
Location of SPT		
Head and Neck	22 (13.3%)	38 (21.5%)
Non Head and Neck	12 (7.2%)	13 (7.3%)
Total number of SPTs	69	132
Total patient-years followed	404.9	344.1
Unadjusted SPT rate [1]	0.2	0.4

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

	Cemiplimab (N=166)	Placebo (N=177)
Adjusted annualized SPT rate [2] (95% CI)	0.747 (0.459,1.213)	1.253 (0.821,1.914)
SPT rate ratio [2] (95% CI)	1.679 (0.945,2.980)	
P-value [2]	0.0770	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Number of participants with at least one SPT, n(%)	8 (18.6%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	NE (NE, NE)	
P-value for Relative Risk	NE	
Heterogeneity p-value of RR	0.0008	
Risk difference (95% CI)	11.73 (-24.53, 47.99)	
P-value for Risk Difference	0.5260	
Participants by number of SPTs, n(%)		
1	5 (11.6%)	0
2	1 (2.3%)	0
3	1 (2.3%)	0
5	1 (2.3%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)
Location of SPT		
Head and Neck	4 (9.3%)	0
Non Head and Neck	6 (14.0%)	0
Total number of SPTs	15	0
Total patient-years followed	99.0	55.0
Unadjusted SPT rate [1]	0.2	0
Adjusted annualized SPT rate [2] (95% CI)	0.472 (0.223,0.997)	
SPT rate ratio [2] (95% CI)	NE (NE,NE)	
P-value [2]	NE	

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

	Cemiplimab (N=43)	Placebo (N=29)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Number of participants with at least one SPT, n(%)	23 (17.3%)	25 (19.1%)
Odds ratio (95% CI)	0.915 (0.480, 1.745)	
P-value for Odds Ratio	0.7874	

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Relative Risk (95% CI)	0.93 (0.56, 1.52)	
P-value for Relative Risk	0.7592	
Heterogeneity p-value of RR	0.8266	
Risk difference (95% CI)	0.57 (-9.59, 10.72)	
P-value for Risk Difference	0.9130	
Participants by number of SPTs, n(%)		
1	11 (8.3%)	13 (9.9%)
2	4 (3.0%)	6 (4.6%)
3	3 (2.3%)	2 (1.5%)
4	0	2 (1.5%)
5	4 (3.0%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
Participants by number of SPTs, n(%)		
6	1 (0.8%)	0
7	0	1 (0.8%)
16	0	1 (0.8%)
Location of SPT		
Head and Neck	16 (12.0%)	22 (16.8%)
Non Head and Neck	11 (8.3%)	9 (6.9%)
Total number of SPTs	54	62
Total patient-years followed	311.6	263.2
Unadjusted SPT rate [1]	0.2	0.2
Adjusted annualized SPT rate [2] (95% CI)	0.758 (0.443,1.299)	0.807 (0.399,1.633)
SPT rate ratio [2] (95% CI)	1.064 (0.577,1.962)	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 0

	Cemiplimab (N=133)	Placebo (N=131)
P-value [2]	0.8434	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Number of participants with at least one SPT, n(%)	14 (18.4%)	17 (22.7%)
Odds ratio (95% CI)	0.744 (0.326, 1.698)	
P-value for Odds Ratio	0.4825	
Relative Risk (95% CI)	0.86 (0.47, 1.59)	
P-value for Relative Risk	0.6349	
Heterogeneity p-value of RR	0.8266	
Risk difference (95% CI)	-9.77 (-26.05, 6.51)	
P-value for Risk Difference	0.2394	
Participants by number of SPTs, n(%)		
1	10 (13.2%)	14 (18.7%)
2	1 (1.3%)	0
3	1 (1.3%)	0
4	1 (1.3%)	0
6	0	1 (1.3%)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
Participants by number of SPTs, n(%)		
7	0	1 (1.3%)
11	1 (1.3%)	0
43	0	1 (1.3%)
Location of SPT		
Head and Neck	10 (13.2%)	16 (21.3%)
Non Head and Neck	7 (9.2%)	4 (5.3%)
Total number of SPTs	30	70
Total patient-years followed	192.3	135.8
Unadjusted SPT rate [1]	0.2	0.5
Adjusted annualized SPT rate [2] (95% CI)	0.308 (0.102,0.925)	1.005 (0.320,3.161)
SPT rate ratio [2] (95% CI)	3.266 (1.172,9.100)	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

ECOG status: 1

	Cemiplimab (N=76)	Placebo (N=75)
P-value [2]	0.0236	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Number of participants with at least one SPT, n(%)	29 (23.2%)	25 (21.4%)
Odds ratio (95% CI)	1.207 (0.640, 2.276)	
P-value for Odds Ratio	0.5615	
Relative Risk (95% CI)	1.15 (0.73, 1.81)	
P-value for Relative Risk	0.5338	
Heterogeneity p-value of RR	0.0499	
Risk difference (95% CI)	3.36 (-8.56, 15.28)	
P-value for Risk Difference	0.5806	
Participants by number of SPTs, n(%)		
1	14 (11.2%)	16 (13.7%)
2	5 (4.0%)	4 (3.4%)
3	3 (2.4%)	1 (0.9%)
4	1 (0.8%)	1 (0.9%)
5	4 (3.2%)	0

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
Participants by number of SPTs, n(%)		
6	1 (0.8%)	1 (0.9%)
7	0	1 (0.9%)
11	1 (0.8%)	0
43	0	1 (0.9%)
Location of SPT		
Head and Neck	19 (15.2%)	22 (18.8%)
Non Head and Neck	16 (12.8%)	9 (7.7%)
Total number of SPTs	74	87
Total patient-years followed	289.0	229.6
Unadjusted SPT rate [1]	0.3	0.4
Adjusted annualized SPT rate [2] (95% CI)	0.607 (0.339,1.088)	0.918 (0.427,1.971)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Nodal

	Cemiplimab (N=125)	Placebo (N=117)
SPT rate ratio [2] (95% CI)	1.512 (0.778,2.939)	
P-value [2]	0.2226	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Number of participants with at least one SPT, n(%)	8 (9.5%)	17 (19.1%)
Odds ratio (95% CI)	0.418 (0.166, 1.050)	
P-value for Odds Ratio	0.0635	
Relative Risk (95% CI)	0.50 (0.23, 1.08)	
P-value for Relative Risk	0.0768	
Heterogeneity p-value of RR	0.0499	
Risk difference (95% CI)	-10.11 (-21.10, 0.87)	
P-value for Risk Difference	0.0711	
Participants by number of SPTs, n(%)		
1	7 (8.3%)	11 (12.4%)
2	0	2 (2.2%)
3	1 (1.2%)	1 (1.1%)
4	0	1 (1.1%)
7	0	1 (1.1%)

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.3.1.1 Annualized SPT Rate During Study Period by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal

	Cemiplimab (N=84)	Placebo (N=89)
Participants by number of SPTs, n(%)		
16	0	1 (1.1%)
Location of SPT		
Head and Neck	7 (8.3%)	16 (18.0%)
Non Head and Neck	2 (2.4%)	4 (4.5%)
Total number of SPTs	10	45
Total patient-years followed	214.9	169.5
Unadjusted SPT rate [1]	0.0	0.3
Adjusted annualized SPT rate [2] (95% CI)	0.388 (0.120,1.253)	1.473 (0.447,4.856)
SPT rate ratio [2] (95% CI)	3.801 (1.117,12.938)	
P-value [2]	0.0326	

Data cut-off as of April 07, 2025. CI= Confidence Interval.
[1] The total number of SPT that occurred during study period divided by the total number of patient-years followed.
[2] Derived using negative binomial model with the total number of SPTs during study period as the response variable, with the treatment group, anatomical region of resected high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor), and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) as covariate, and log-transformed standardized observation duration as an offset variable.
Odds ratio, relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and (geographical regionNorth America vs Australia/New Zealand vs ROW; except when subgroup was geographical region.
*The estimate is either invalid or at a limit of its range for some observations.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

2.7 EORTC QLQ-C30

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Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	28 (50.0%)	30 (46.2%)
Number of censored cases	n (%)	28 (50.0%)	35 (53.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (39.3%)	32 (49.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.65]	5.52 [2.86, 7.06]
	Median [95% CI]	11.14 [5.62, NC]	9.33 [7.06, NC]
	Q3 [95% CI]	NYR [29.31, NC]	NYR [27.47, NC]
	p-value[b][d]		0.465
	HR [95 % CI][c][d]		1.23 [0.71, 2.14]
	Heterogeneity p-value[e][d]		0.6376

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	20 (35.7%)	21 (32.3%)
Number of censored cases	n (%)	36 (64.3%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	30 (53.6%)	41 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.86, 21.68]	5.72 [2.89, 9.95]
	Median [95% CI]	30.19 [10.64, NC]	NYR [9.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.869
	HR [95 % CI][c][d]		1.06 [0.56, 2.02]
	Heterogeneity p-value[e][d]		0.9512

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	28 (43.1%)
Number of censored cases	n (%)	27 (48.2%)	37 (56.9%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	3 (5.4%)	0
No first deterioration	n (%)	18 (32.1%)	34 (52.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.62]	5.52 [2.86, 8.34]
	Median [95% CI]	8.44 [5.59, 14.06]	14.78 [5.72, NC]
	Q3 [95% CI]	30.19 [13.86, NC]	NYR [36.40, NC]
	p-value[b][d]		0.135
	HR [95 % CI][c][d]		1.52 [0.87, 2.64]
	Heterogeneity p-value[e][d]		0.5261

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	27 (41.5%)
Number of censored cases	n (%)	27 (48.2%)	38 (58.5%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (37.5%)	35 (53.8%)
Time to first deterioration (months)	Q1 [95% CI]	2.99 [2.79, 5.59]	5.59 [3.25, 9.95]
	Median [95% CI]	8.44 [5.59, 26.45]	17.54 [8.38, NC]
	Q3 [95% CI]	NYR [14.46, NC]	NYR [27.47, NC]
	p-value[b][d]		0.262
	HR [95 % CI][c][d]		1.38 [0.79, 2.43]
	Heterogeneity p-value[e][d]		0.1377

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	30 (53.6%)	33 (50.8%)
Number of censored cases	n (%)	26 (46.4%)	32 (49.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	20 (35.7%)	29 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	3.12 [2.79, 5.59]	2.96 [2.83, 6.11]
	Median [95% CI]	8.41 [5.59, 18.23]	9.72 [6.11, 14.52]
	Q3 [95% CI]	NYR [14.46, NC]	34.86 [14.29, NC]
	p-value[b][d]		0.779
	HR [95 % CI][c][d]		1.08 [0.65, 1.80]
	Heterogeneity p-value[e][d]		0.6967

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	24 (42.9%)	36 (55.4%)
Number of censored cases	n (%)	32 (57.1%)	29 (44.6%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (46.4%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.41]	2.89 [2.79, 5.55]
	Median [95% CI]	18.30 [8.34, NC]	8.34 [5.55, 11.30]
	Q3 [95% CI]	NYR [27.63, NC]	NYR [11.30, NC]
	p-value[b][d]		0.229
	HR [95 % CI][c][d]		0.72 [0.42, 1.22]
	Heterogeneity p-value[e][d]		0.0189

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	36 (64.3%)	37 (56.9%)
Number of censored cases	n (%)	20 (35.7%)	28 (43.1%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	13 (23.2%)	25 (38.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 3.02]	2.86 [2.79, 4.27]
	Median [95% CI]	5.59 [2.99, 8.44]	8.31 [5.55, 8.41]
	Q3 [95% CI]	21.68 [8.34, NC]	13.54 [8.41, NC]
	p-value[b][d]		0.990
	HR [95 % CI][c][d]		0.99 [0.61, 1.63]
	Heterogeneity p-value[e][d]		0.6434

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	30 (53.6%)	35 (53.8%)
Number of censored cases	n (%)	26 (46.4%)	30 (46.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	1 (1.5%)
No first deterioration	n (%)	19 (33.9%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 5.59]	3.09 [2.86, 5.55]
	Median [95% CI]	8.34 [5.59, 21.68]	8.31 [5.55, 20.90]
	Q3 [95% CI]	30.19 [11.30, NC]	NYR [9.72, NC]
	p-value[b][d]		0.737
	HR [95 % CI][c][d]		1.10 [0.66, 1.84]
	Heterogeneity p-value[e][d]		0.4175

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	12 (21.4%)	14 (21.5%)
Number of censored cases	n (%)	44 (78.6%)	51 (78.5%)
No baseline score	n (%)	4 (7.1%)	2 (3.1%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	3 (5.4%)	1 (1.5%)
No first deterioration	n (%)	35 (62.5%)	46 (70.8%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [5.59, NC]	9.95 [2.96, NC]
	Median [95% CI]	NYR [29.73, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.710
	HR [95 % CI][c][d]		1.17 [0.51, 2.68]
	Heterogeneity p-value[e][d]		0.3348

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	13 (23.2%)	18 (27.7%)
Number of censored cases	n (%)	43 (76.8%)	47 (72.3%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (66.1%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [2.86, NC]	8.31 [3.02, 14.75]
	Median [95% CI]	NYR [30.59, NC]	NYR [10.78, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.379
	HR [95 % CI][c][d]		0.71 [0.33, 1.50]
	Heterogeneity p-value[e][d]		0.2712

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	28 (50.0%)	21 (32.3%)
Number of censored cases	n (%)	28 (50.0%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	21 (37.5%)	41 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 9.79]	8.54 [2.89, 15.93]
	Median [95% CI]	14.49 [8.34, 29.73]	40.71 [13.83, NC]
	Q3 [95% CI]	30.98 [22.14, NC]	43.56 [40.71, NC]
	p-value[b][d]		0.028
	HR [95 % CI][c][d]		1.96 [1.07, 3.61]
	Heterogeneity p-value[e][d]		0.0523

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	25 (44.6%)	29 (44.6%)
Number of censored cases	n (%)	31 (55.4%)	36 (55.4%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	4 (7.1%)	1 (1.5%)
No first deterioration	n (%)	21 (37.5%)	32 (49.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.25]	2.89 [2.79, 8.31]
	Median [95% CI]	14.46 [5.65, NC]	14.59 [8.31, NC]
	Q3 [95% CI]	NYR [14.98, NC]	NYR [21.72, NC]
	p-value[b][d]		0.446
	HR [95 % CI][c][d]		1.24 [0.70, 2.18]
	Heterogeneity p-value[e][d]		0.5501

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	17 (30.4%)	15 (23.1%)
Number of censored cases	n (%)	39 (69.6%)	50 (76.9%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	3 (4.6%)
No first deterioration	n (%)	32 (57.1%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [2.89, 17.77]	9.95 [5.55, NC]
	Median [95% CI]	NYR [14.49, NC]	NYR [18.00, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.516
	HR [95 % CI][c][d]		1.27 [0.61, 2.63]
	Heterogeneity p-value[e][d]		0.7759

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	11 (19.6%)	17 (26.2%)
Number of censored cases	n (%)	45 (80.4%)	48 (73.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	1 (1.5%)
No first deterioration	n (%)	39 (69.6%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	18.00 [5.65, NC]	8.61 [5.59, 30.69]
	Median [95% CI]	NYR [NC, NC]	NYR [21.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.574
	HR [95 % CI][c][d]		0.80 [0.36, 1.77]
	Heterogeneity p-value[e][d]		0.3832

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	15 (26.8%)	22 (33.8%)
Number of censored cases	n (%)	41 (73.2%)	43 (66.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	35 (62.5%)	40 (61.5%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [5.59, 25.59]	5.65 [2.89, 8.57]
	Median [95% CI]	NYR [21.45, NC]	NYR [8.57, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.336
	HR [95 % CI][c][d]		0.71 [0.36, 1.42]
	Heterogeneity p-value[e][d]		0.2310

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	69 (45.1%)	50 (35.5%)
Number of censored cases	n (%)	84 (54.9%)	91 (64.5%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	63 (41.2%)	67 (47.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.78, 6.97]	5.55 [2.89, 6.28]
	Median [95% CI]	14.23 [8.48, 34.66]	22.21 [8.38, NC]
	Q3 [95% CI]	41.46 [35.98, NC]	50.92 [45.83, NC]
	p-value[b][d]		0.258
	HR [95 % CI][c][d]		1.23 [0.85, 1.79]
	Heterogeneity p-value[e][d]		0.6376

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	59 (38.6%)	48 (34.0%)
Number of censored cases	n (%)	94 (61.4%)	93 (66.0%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	1 (0.7%)	0
No first deterioration	n (%)	72 (47.1%)	70 (49.6%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [3.29, 10.97]	5.75 [4.27, 8.38]
	Median [95% CI]	18.00 [14.23, 33.74]	18.04 [9.69, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [34.83, NC]
	p-value[b][d]		0.854
	HR [95 % CI][c][d]		0.96 [0.65, 1.43]
	Heterogeneity p-value[e][d]		0.9512

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	76 (49.7%)	55 (39.0%)
Number of censored cases	n (%)	77 (50.3%)	86 (61.0%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	2 (1.3%)	0
No first deterioration	n (%)	54 (35.3%)	63 (44.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.65]	3.84 [2.89, 5.78]
	Median [95% CI]	10.84 [8.38, 17.54]	10.97 [8.38, 25.69]
	Q3 [95% CI]	34.66 [22.18, NC]	NYR [NC, NC]
	p-value[b][d]		0.648
	HR [95 % CI][c][d]		1.09 [0.76, 1.56]
	Heterogeneity p-value[e][d]		0.5261

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	48 (31.4%)	44 (31.2%)
Number of censored cases	n (%)	105 (68.6%)	97 (68.8%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	1 (0.7%)	1 (0.7%)
No first deterioration	n (%)	83 (54.2%)	73 (51.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.61 [5.62, 13.57]	6.34 [5.59, 8.34]
	Median [95% CI]	40.31 [18.00, NC]	22.47 [10.61, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.271
	HR [95 % CI][c][d]		0.79 [0.51, 1.21]
	Heterogeneity p-value[e][d]		0.1377

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	65 (42.5%)	51 (36.2%)
Number of censored cases	n (%)	88 (57.5%)	90 (63.8%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	67 (43.8%)	66 (46.8%)
Time to first deterioration (months)	Q1 [95% CI]	6.47 [3.61, 8.44]	5.62 [2.92, 8.34]
	Median [95% CI]	17.77 [11.10, 25.63]	18.50 [10.18, 25.69]
	Q3 [95% CI]	46.03 [31.77, NC]	51.12 [25.69, NC]
	p-value[b][d]		0.497
	HR [95 % CI][c][d]		0.87 [0.59, 1.29]
	Heterogeneity p-value[e][d]		0.6967

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	69 (45.1%)	43 (30.5%)
Number of censored cases	n (%)	84 (54.9%)	98 (69.5%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	2 (1.4%)
No first deterioration	n (%)	63 (41.2%)	73 (51.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.29, 8.28]	5.59 [2.92, 8.41]
	Median [95% CI]	14.23 [9.03, 25.13]	25.86 [12.12, NC]
	Q3 [95% CI]	46.95 [26.38, NC]	NYR [45.83, NC]
	p-value[b][d]		0.174
	HR [95 % CI][c][d]		1.31 [0.88, 1.94]
	Heterogeneity p-value[e][d]		0.0189

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	90 (58.8%)	65 (46.1%)
Number of censored cases	n (%)	63 (41.2%)	76 (53.9%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	42 (27.5%)	52 (36.9%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.92]
	Median [95% CI]	5.68 [5.29, 8.48]	7.85 [5.55, 10.61]
	Q3 [95% CI]	26.81 [13.83, 40.31]	NYR [13.86, NC]
	p-value[b][d]		0.300
	HR [95 % CI][c][d]		1.19 [0.85, 1.65]
	Heterogeneity p-value[e][d]		0.6434

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	78 (51.0%)	57 (40.4%)
Number of censored cases	n (%)	75 (49.0%)	84 (59.6%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	1 (0.7%)	1 (0.7%)
No first deterioration	n (%)	53 (34.6%)	60 (42.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.25, 5.78]	3.88 [2.89, 8.38]
	Median [95% CI]	10.91 [8.34, 15.08]	14.98 [10.84, 34.07]
	Q3 [95% CI]	33.61 [20.50, NC]	46.16 [34.07, NC]
	p-value[b][d]		0.074
	HR [95 % CI][c][d]		1.37 [0.97, 1.95]
	Heterogeneity p-value[e][d]		0.4175

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	36 (23.5%)	19 (13.5%)
Number of censored cases	n (%)	117 (76.5%)	122 (86.5%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	2 (1.3%)	1 (0.7%)
No first deterioration	n (%)	94 (61.4%)	98 (69.5%)
Time to first deterioration (months)	Q1 [95% CI]	14.09 [8.31, 25.63]	30.65 [10.64, NC]
	Median [95% CI]	NYR [34.37, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.111
	HR [95 % CI][c][d]		1.59 [0.90, 2.80]
	Heterogeneity p-value[e][d]		0.3348

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	40 (26.1%)	30 (21.3%)
Number of censored cases	n (%)	113 (73.9%)	111 (78.7%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	92 (60.1%)	88 (62.4%)
Time to first deterioration (months)	Q1 [95% CI]	13.83 [8.44, 21.22]	17.87 [5.55, 26.48]
	Median [95% CI]	45.70 [27.07, NC]	45.83 [26.48, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.998
	HR [95 % CI][c][d]		1.00 [0.61, 1.62]
	Heterogeneity p-value[e][d]		0.2712

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	50 (32.7%)	40 (28.4%)
Number of censored cases	n (%)	103 (67.3%)	101 (71.6%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	2 (1.3%)	0
No first deterioration	n (%)	80 (52.3%)	78 (55.3%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [5.68, 14.46]	8.31 [5.55, 9.82]
	Median [95% CI]	26.48 [21.42, 34.27]	28.55 [11.37, NC]
	Q3 [95% CI]	44.65 [34.27, NC]	NYR [NC, NC]
	p-value[b][d]		0.472
	HR [95 % CI][c][d]		0.85 [0.55, 1.32]
	Heterogeneity p-value[e][d]		0.0523

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	62 (40.5%)	39 (27.7%)
Number of censored cases	n (%)	91 (59.5%)	102 (72.3%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	1 (0.7%)	5 (3.5%)
No first deterioration	n (%)	69 (45.1%)	74 (52.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.35, 7.89]	7.85 [5.55, 8.51]
	Median [95% CI]	14.23 [8.48, 39.82]	34.53 [16.89, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.208
	HR [95 % CI][c][d]		1.31 [0.86, 1.98]
	Heterogeneity p-value[e][d]		0.5501

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	45 (29.4%)	31 (22.0%)
Number of censored cases	n (%)	108 (70.6%)	110 (78.0%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	3 (2.0%)	2 (1.4%)
No first deterioration	n (%)	84 (54.9%)	85 (60.3%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [5.62, 14.52]	8.38 [2.92, 28.85]
	Median [95% CI]	37.06 [21.59, NC]	NYR [28.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.530
	HR [95 % CI][c][d]		1.16 [0.73, 1.86]
	Heterogeneity p-value[e][d]		0.7759

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	53 (34.6%)	43 (30.5%)
Number of censored cases	n (%)	100 (65.4%)	98 (69.5%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	1 (0.7%)	2 (1.4%)
No first deterioration	n (%)	78 (51.0%)	73 (51.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [5.62, 14.23]	8.41 [5.55, 11.07]
	Median [95% CI]	25.13 [23.03, 45.70]	27.56 [15.15, NC]
	Q3 [95% CI]	NYR [43.96, NC]	NYR [34.53, NC]
	p-value[b][d]		0.845
	HR [95 % CI][c][d]		0.96 [0.63, 1.45]
	Heterogeneity p-value[e][d]		0.3832

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	39 (25.5%)	26 (18.4%)
Number of censored cases	n (%)	114 (74.5%)	115 (81.6%)
No baseline score	n (%)	13 (8.5%)	15 (10.6%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	1 (0.7%)	0
No first deterioration	n (%)	92 (60.1%)	92 (65.2%)
Time to first deterioration (months)	Q1 [95% CI]	10.61 [8.34, 21.88]	18.79 [8.34, 28.81]
	Median [95% CI]	NYR [25.79, NC]	NYR [28.81, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.646
	HR [95 % CI][c][d]		1.12 [0.67, 1.87]
	Heterogeneity p-value[e][d]		0.2310

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	28 (50.0%)	30 (46.2%)
Number of censored cases	n (%)	28 (50.0%)	35 (53.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (39.3%)	32 (49.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.65]	5.52 [2.86, 7.06]
	Median [95% CI]	11.14 [5.62, NC]	9.33 [7.06, NC]
	Q3 [95% CI]	NYR [29.31, NC]	NYR [27.47, NC]
	p-value[b][d]		0.465
	HR [95 % CI][c][d]		1.23 [0.71, 2.14]
	Heterogeneity p-value[e][d]		0.2698

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	20 (35.7%)	21 (32.3%)
Number of censored cases	n (%)	36 (64.3%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	30 (53.6%)	41 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.86, 21.68]	5.72 [2.89, 9.95]
	Median [95% CI]	30.19 [10.64, NC]	NYR [9.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.869
	HR [95 % CI][c][d]		1.06 [0.56, 2.02]
	Heterogeneity p-value[e][d]		0.7390

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	28 (43.1%)
Number of censored cases	n (%)	27 (48.2%)	37 (56.9%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	3 (5.4%)	0
No first deterioration	n (%)	18 (32.1%)	34 (52.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.62]	5.52 [2.86, 8.34]
	Median [95% CI]	8.44 [5.59, 14.06]	14.78 [5.72, NC]
	Q3 [95% CI]	30.19 [13.86, NC]	NYR [36.40, NC]
	p-value[b][d]		0.135
	HR [95 % CI][c][d]		1.52 [0.87, 2.64]
	Heterogeneity p-value[e][d]		0.8126

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	27 (41.5%)
Number of censored cases	n (%)	27 (48.2%)	38 (58.5%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (37.5%)	35 (53.8%)
Time to first deterioration (months)	Q1 [95% CI]	2.99 [2.79, 5.59]	5.59 [3.25, 9.95]
	Median [95% CI]	8.44 [5.59, 26.45]	17.54 [8.38, NC]
	Q3 [95% CI]	NYR [14.46, NC]	NYR [27.47, NC]
	p-value[b][d]		0.262
	HR [95 % CI][c][d]		1.38 [0.79, 2.43]
	Heterogeneity p-value[e][d]		0.1263

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	30 (53.6%)	33 (50.8%)
Number of censored cases	n (%)	26 (46.4%)	32 (49.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	20 (35.7%)	29 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	3.12 [2.79, 5.59]	2.96 [2.83, 6.11]
	Median [95% CI]	8.41 [5.59, 18.23]	9.72 [6.11, 14.52]
	Q3 [95% CI]	NYR [14.46, NC]	34.86 [14.29, NC]
	p-value[b][d]		0.779
	HR [95 % CI][c][d]		1.08 [0.65, 1.80]
	Heterogeneity p-value[e][d]		0.2554

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	24 (42.9%)	36 (55.4%)
Number of censored cases	n (%)	32 (57.1%)	29 (44.6%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (46.4%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.41]	2.89 [2.79, 5.55]
	Median [95% CI]	18.30 [8.34, NC]	8.34 [5.55, 11.30]
	Q3 [95% CI]	NYR [27.63, NC]	NYR [11.30, NC]
	p-value[b][d]		0.229
	HR [95 % CI][c][d]		0.72 [0.42, 1.22]
	Heterogeneity p-value[e][d]		0.0126

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	36 (64.3%)	37 (56.9%)
Number of censored cases	n (%)	20 (35.7%)	28 (43.1%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	13 (23.2%)	25 (38.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 3.02]	2.86 [2.79, 4.27]
	Median [95% CI]	5.59 [2.99, 8.44]	8.31 [5.55, 8.41]
	Q3 [95% CI]	21.68 [8.34, NC]	13.54 [8.41, NC]
	p-value[b][d]		0.990
	HR [95 % CI][c][d]		0.99 [0.61, 1.63]
	Heterogeneity p-value[e][d]		0.5254

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	30 (53.6%)	35 (53.8%)
Number of censored cases	n (%)	26 (46.4%)	30 (46.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	1 (1.5%)
No first deterioration	n (%)	19 (33.9%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 5.59]	3.09 [2.86, 5.55]
	Median [95% CI]	8.34 [5.59, 21.68]	8.31 [5.55, 20.90]
	Q3 [95% CI]	30.19 [11.30, NC]	NYR [9.72, NC]
	p-value[b][d]		0.737
	HR [95 % CI][c][d]		1.10 [0.66, 1.84]
	Heterogeneity p-value[e][d]		0.2912

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	12 (21.4%)	14 (21.5%)
Number of censored cases	n (%)	44 (78.6%)	51 (78.5%)
No baseline score	n (%)	4 (7.1%)	2 (3.1%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	3 (5.4%)	1 (1.5%)
No first deterioration	n (%)	35 (62.5%)	46 (70.8%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [5.59, NC]	9.95 [2.96, NC]
	Median [95% CI]	NYR [29.73, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.710
	HR [95 % CI][c][d]		1.17 [0.51, 2.68]
	Heterogeneity p-value[e][d]		0.5971

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	13 (23.2%)	18 (27.7%)
Number of censored cases	n (%)	43 (76.8%)	47 (72.3%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (66.1%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [2.86, NC]	8.31 [3.02, 14.75]
	Median [95% CI]	NYR [30.59, NC]	NYR [10.78, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.379
	HR [95 % CI][c][d]		0.71 [0.33, 1.50]
	Heterogeneity p-value[e][d]		0.5187

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	28 (50.0%)	21 (32.3%)
Number of censored cases	n (%)	28 (50.0%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	21 (37.5%)	41 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 9.79]	8.54 [2.89, 15.93]
	Median [95% CI]	14.49 [8.34, 29.73]	40.71 [13.83, NC]
	Q3 [95% CI]	30.98 [22.14, NC]	43.56 [40.71, NC]
	p-value[b][d]		0.028
	HR [95 % CI][c][d]		1.96 [1.07, 3.61]
	Heterogeneity p-value[e][d]		0.1499

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	25 (44.6%)	29 (44.6%)
Number of censored cases	n (%)	31 (55.4%)	36 (55.4%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	4 (7.1%)	1 (1.5%)
No first deterioration	n (%)	21 (37.5%)	32 (49.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.25]	2.89 [2.79, 8.31]
	Median [95% CI]	14.46 [5.65, NC]	14.59 [8.31, NC]
	Q3 [95% CI]	NYR [14.98, NC]	NYR [21.72, NC]
	p-value[b][d]		0.446
	HR [95 % CI][c][d]		1.24 [0.70, 2.18]
	Heterogeneity p-value[e][d]		0.4277

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	17 (30.4%)	15 (23.1%)
Number of censored cases	n (%)	39 (69.6%)	50 (76.9%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	1 (1.8%)	3 (4.6%)
No first deterioration	n (%)	32 (57.1%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [2.89, 17.77]	9.95 [5.55, NC]
	Median [95% CI]	NYR [14.49, NC]	NYR [18.00, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.516
	HR [95 % CI][c][d]		1.27 [0.61, 2.63]
	Heterogeneity p-value[e][d]		0.7154

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	11 (19.6%)	17 (26.2%)
Number of censored cases	n (%)	45 (80.4%)	48 (73.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	1 (1.5%)
No first deterioration	n (%)	39 (69.6%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	18.00 [5.65, NC]	8.61 [5.59, 30.69]
	Median [95% CI]	NYR [NC, NC]	NYR [21.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.574
	HR [95 % CI][c][d]		0.80 [0.36, 1.77]
	Heterogeneity p-value[e][d]		0.6307

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	15 (26.8%)	22 (33.8%)
Number of censored cases	n (%)	41 (73.2%)	43 (66.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	2 (3.6%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	35 (62.5%)	40 (61.5%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [5.59, 25.59]	5.65 [2.89, 8.57]
	Median [95% CI]	NYR [21.45, NC]	NYR [8.57, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.336
	HR [95 % CI][c][d]		0.71 [0.36, 1.42]
	Heterogeneity p-value[e][d]		0.4277

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	31 (38.8%)	26 (37.7%)
Number of censored cases	n (%)	49 (61.3%)	43 (62.3%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	40 (50.0%)	33 (47.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [5.59, 11.30]	3.84 [2.86, 8.38]
	Median [95% CI]	19.81 [11.30, 40.31]	18.60 [8.38, NC]
	Q3 [95% CI]	NYR [34.66, NC]	NYR [45.83, NC]
	p-value[b][d]		0.686
	HR [95 % CI][c][d]		0.89 [0.51, 1.53]
	Heterogeneity p-value[e][d]		0.2698

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	29 (36.3%)	22 (31.9%)
Number of censored cases	n (%)	51 (63.8%)	47 (68.1%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	41 (51.3%)	37 (53.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.92, 13.83]	8.34 [3.84, 14.72]
	Median [95% CI]	17.58 [13.83, NC]	18.46 [10.78, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.475
	HR [95 % CI][c][d]		1.24 [0.69, 2.24]
	Heterogeneity p-value[e][d]		0.7390

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	37 (46.3%)	27 (39.1%)
Number of censored cases	n (%)	43 (53.8%)	42 (60.9%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	2 (2.5%)	0
No first deterioration	n (%)	32 (40.0%)	32 (46.4%)
Time to first deterioration (months)	Q1 [95% CI]	3.02 [2.83, 5.62]	5.55 [2.83, 8.34]
	Median [95% CI]	10.84 [6.37, 34.37]	10.97 [5.78, NC]
	Q3 [95% CI]	34.66 [34.37, NC]	NYR [NC, NC]
	p-value[b][d]		0.651
	HR [95 % CI][c][d]		1.14 [0.67, 1.93]
	Heterogeneity p-value[e][d]		0.8126

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	24 (30.0%)	26 (37.7%)
Number of censored cases	n (%)	56 (70.0%)	43 (62.3%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	47 (58.8%)	32 (46.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.61 [5.55, 14.23]	5.59 [2.92, 8.34]
	Median [95% CI]	NYR [14.23, NC]	20.73 [8.34, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [25.36, NC]
	p-value[b][d]		0.078
	HR [95 % CI][c][d]		0.59 [0.32, 1.07]
	Heterogeneity p-value[e][d]		0.1263

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	29 (36.3%)	28 (40.6%)
Number of censored cases	n (%)	51 (63.8%)	41 (59.4%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	42 (52.5%)	30 (43.5%)
Time to first deterioration (months)	Q1 [95% CI]	8.38 [2.99, 13.90]	5.55 [2.83, 8.31]
	Median [95% CI]	35.84 [13.90, 46.03]	10.84 [8.31, 51.12]
	Q3 [95% CI]	46.03 [35.84, NC]	51.12 [22.34, NC]
	p-value[b][d]		0.049
	HR [95 % CI][c][d]		0.57 [0.32, 1.01]
	Heterogeneity p-value[e][d]		0.2554

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	34 (42.5%)	26 (37.7%)
Number of censored cases	n (%)	46 (57.5%)	43 (62.3%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	37 (46.3%)	32 (46.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.28 [5.55, 11.24]	2.92 [2.86, 8.34]
	Median [95% CI]	15.38 [11.24, 26.38]	25.40 [5.78, NC]
	Q3 [95% CI]	40.31 [25.13, NC]	NYR [25.86, NC]
	p-value[b][d]		0.628
	HR [95 % CI][c][d]		0.87 [0.50, 1.52]
	Heterogeneity p-value[e][d]		0.0126

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	45 (56.3%)	33 (47.8%)
Number of censored cases	n (%)	35 (43.8%)	36 (52.2%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	26 (32.5%)	25 (36.2%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.83, 2.92]	2.86 [2.83, 2.89]
	Median [95% CI]	8.38 [2.92, 11.40]	5.65 [2.89, 10.61]
	Q3 [95% CI]	24.08 [11.40, NC]	NYR [8.38, NC]
	p-value[b][d]		0.947
	HR [95 % CI][c][d]		0.99 [0.61, 1.58]
	Heterogeneity p-value[e][d]		0.5254

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	37 (46.3%)	32 (46.4%)
Number of censored cases	n (%)	43 (53.8%)	37 (53.6%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	33 (41.3%)	27 (39.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [3.61, 8.34]	3.84 [2.89, 10.78]
	Median [95% CI]	17.58 [8.34, 24.08]	13.90 [10.61, 34.07]
	Q3 [95% CI]	37.06 [23.72, NC]	39.16 [22.34, NC]
	p-value[b][d]		0.979
	HR [95 % CI][c][d]		1.01 [0.61, 1.67]
	Heterogeneity p-value[e][d]		0.2912

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	21 (26.3%)	12 (17.4%)
Number of censored cases	n (%)	59 (73.8%)	57 (82.6%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	2 (2.5%)	1 (1.4%)
No first deterioration	n (%)	48 (60.0%)	46 (66.7%)
Time to first deterioration (months)	Q1 [95% CI]	11.47 [5.62, 30.65]	23.95 [8.38, NC]
	Median [95% CI]	34.37 [25.13, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.167
	HR [95 % CI][c][d]		1.66 [0.80, 3.44]
	Heterogeneity p-value[e][d]		0.5971

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	19 (23.8%)	16 (23.2%)
Number of censored cases	n (%)	61 (76.3%)	53 (76.8%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	52 (65.0%)	43 (62.3%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [8.44, 40.31]	23.26 [2.92, 45.83]
	Median [95% CI]	NYR [26.41, NC]	45.83 [25.56, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.924
	HR [95 % CI][c][d]		1.03 [0.52, 2.05]
	Heterogeneity p-value[e][d]		0.5187

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	21 (26.3%)	19 (27.5%)
Number of censored cases	n (%)	59 (73.8%)	50 (72.5%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	49 (61.3%)	40 (58.0%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [5.68, 26.48]	8.34 [2.89, 17.97]
	Median [95% CI]	33.91 [25.86, NC]	NYR [11.33, NC]
	Q3 [95% CI]	NYR [33.91, NC]	NYR [NC, NC]
	p-value[b][d]		0.590
	HR [95 % CI][c][d]		0.83 [0.43, 1.61]
	Heterogeneity p-value[e][d]		0.1499

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	32 (40.0%)	24 (34.8%)
Number of censored cases	n (%)	48 (60.0%)	45 (65.2%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	1 (1.3%)	1 (1.4%)
No first deterioration	n (%)	38 (47.5%)	34 (49.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 8.34]	5.78 [2.92, 8.38]
	Median [95% CI]	11.33 [8.34, NC]	23.26 [8.34, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [38.70, NC]
	p-value[b][d]		0.855
	HR [95 % CI][c][d]		1.05 [0.60, 1.83]
	Heterogeneity p-value[e][d]		0.4277

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	19 (23.8%)	15 (21.7%)
Number of censored cases	n (%)	61 (76.3%)	54 (78.3%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	1 (1.3%)	2 (2.9%)
No first deterioration	n (%)	51 (63.8%)	42 (60.9%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [5.55, 37.06]	13.60 [2.89, NC]
	Median [95% CI]	NYR [24.08, NC]	NYR [25.66, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.859
	HR [95 % CI][c][d]		0.93 [0.46, 1.91]
	Heterogeneity p-value[e][d]		0.7154

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	23 (28.8%)	20 (29.0%)
Number of censored cases	n (%)	57 (71.3%)	49 (71.0%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	47 (58.8%)	39 (56.5%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [5.68, 24.74]	8.51 [5.59, 14.69]
	Median [95% CI]	39.46 [23.23, NC]	28.81 [11.40, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.665
	HR [95 % CI][c][d]		0.88 [0.47, 1.62]
	Heterogeneity p-value[e][d]		0.6307

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	18 (22.5%)	14 (20.3%)
Number of censored cases	n (%)	62 (77.5%)	55 (79.7%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	3 (3.8%)	2 (2.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	53 (66.3%)	45 (65.2%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [8.31, NC]	11.40 [8.34, NC]
	Median [95% CI]	NYR [24.74, NC]	NYR [18.79, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.974
	HR [95 % CI][c][d]		1.00 [0.48, 2.07]
	Heterogeneity p-value[e][d]		0.4277

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	38 (52.1%)	24 (33.3%)
Number of censored cases	n (%)	35 (47.9%)	48 (66.7%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	23 (31.5%)	34 (47.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.86, 5.62]	5.55 [2.86, 8.31]
	Median [95% CI]	8.38 [5.62, 17.77]	22.21 [7.85, NC]
	Q3 [95% CI]	41.46 [17.77, NC]	50.92 [NC, NC]
	p-value[b][d]		0.085
	HR [95 % CI][c][d]		1.60 [0.93, 2.73]
	Heterogeneity p-value[e][d]		0.2698

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	30 (41.1%)	26 (36.1%)
Number of censored cases	n (%)	43 (58.9%)	46 (63.9%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	31 (42.5%)	33 (45.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.86, 10.97]	5.62 [2.83, 7.85]
	Median [95% CI]	18.00 [10.97, 33.74]	13.93 [6.34, NC]
	Q3 [95% CI]	NYR [24.18, NC]	34.83 [25.79, NC]
	p-value[b][d]		0.546
	HR [95 % CI][c][d]		0.84 [0.48, 1.47]
	Heterogeneity p-value[e][d]		0.7390

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	39 (53.4%)	28 (38.9%)
Number of censored cases	n (%)	34 (46.6%)	44 (61.1%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (30.1%)	31 (43.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 8.34]	3.65 [2.83, 7.85]
	Median [95% CI]	10.87 [8.34, 18.00]	11.40 [6.51, NC]
	Q3 [95% CI]	23.03 [17.54, NC]	NYR [16.89, NC]
	p-value[b][d]		0.878
	HR [95 % CI][c][d]		1.04 [0.62, 1.75]
	Heterogeneity p-value[e][d]		0.8126

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	24 (32.9%)	18 (25.0%)
Number of censored cases	n (%)	49 (67.1%)	54 (75.0%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	1 (1.4%)	0
No first deterioration	n (%)	36 (49.3%)	41 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [5.29, 14.98]	6.70 [5.65, 16.89]
	Median [95% CI]	24.94 [14.46, NC]	NYR [10.61, NC]
	Q3 [95% CI]	NYR [27.93, NC]	NYR [NC, NC]
	p-value[b][d]		0.948
	HR [95 % CI][c][d]		1.02 [0.53, 1.96]
	Heterogeneity p-value[e][d]		0.1263

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	36 (49.3%)	23 (31.9%)
Number of censored cases	n (%)	37 (50.7%)	49 (68.1%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	25 (34.2%)	36 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.86, 8.34]	5.65 [4.27, 13.47]
	Median [95% CI]	10.87 [8.31, 18.99]	18.50 [10.91, 25.69]
	Q3 [95% CI]	25.63 [17.77, NC]	NYR [22.21, NC]
	p-value[b][d]		0.168
	HR [95 % CI][c][d]		1.49 [0.84, 2.65]
	Heterogeneity p-value[e][d]		0.2554

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	35 (47.9%)	17 (23.6%)
Number of censored cases	n (%)	38 (52.1%)	55 (76.4%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	26 (35.6%)	41 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.83, 5.62]	8.41 [5.59, 13.73]
	Median [95% CI]	8.48 [5.62, 25.63]	NYR [10.81, NC]
	Q3 [95% CI]	NYR [25.63, NC]	NYR [NC, NC]
	p-value[b][d]		0.017
	HR [95 % CI][c][d]		2.03 [1.12, 3.67]
	Heterogeneity p-value[e][d]		0.0126

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	45 (61.6%)	32 (44.4%)
Number of censored cases	n (%)	28 (38.4%)	40 (55.6%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (21.9%)	27 (37.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.84 [2.79, 2.99]	2.89 [2.83, 5.65]
	Median [95% CI]	5.60 [2.99, 8.31]	8.38 [5.65, 13.86]
	Q3 [95% CI]	26.81 [8.31, NC]	34.83 [11.40, NC]
	p-value[b][d]		0.181
	HR [95 % CI][c][d]		1.39 [0.85, 2.25]
	Heterogeneity p-value[e][d]		0.5254

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	41 (56.2%)	25 (34.7%)
Number of censored cases	n (%)	32 (43.8%)	47 (65.3%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	20 (27.4%)	33 (45.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.83, 6.24]	3.88 [2.83, 8.44]
	Median [95% CI]	8.48 [6.24, 13.67]	23.49 [8.38, NC]
	Q3 [95% CI]	20.50 [13.67, NC]	NYR [44.75, NC]
	p-value[b][d]		0.007
	HR [95 % CI][c][d]		2.01 [1.19, 3.38]
	Heterogeneity p-value[e][d]		0.2912

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	15 (20.5%)	7 (9.7%)
Number of censored cases	n (%)	58 (79.5%)	65 (90.3%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	46 (63.0%)	52 (72.2%)
Time to first deterioration (months)	Q1 [95% CI]	16.33 [5.62, NC]	30.65 [7.85, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [30.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.214
	HR [95 % CI][c][d]		1.82 [0.71, 4.66]
	Heterogeneity p-value[e][d]		0.5971

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	21 (28.8%)	14 (19.4%)
Number of censored cases	n (%)	52 (71.2%)	58 (80.6%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	40 (54.8%)	45 (62.5%)
Time to first deterioration (months)	Q1 [95% CI]	13.67 [5.65, 21.22]	10.81 [5.55, 26.48]
	Median [95% CI]	45.70 [17.18, NC]	NYR [21.65, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [NC, NC]
	p-value[b][d]		0.792
	HR [95 % CI][c][d]		1.10 [0.54, 2.21]
	Heterogeneity p-value[e][d]		0.5187

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	29 (39.7%)	21 (29.2%)
Number of censored cases	n (%)	44 (60.3%)	51 (70.8%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	1 (1.4%)	0
No first deterioration	n (%)	31 (42.5%)	38 (52.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.29, 14.46]	8.31 [3.88, 8.44]
	Median [95% CI]	21.59 [14.09, 29.14]	18.20 [8.41, NC]
	Q3 [95% CI]	34.27 [23.52, NC]	NYR [28.55, NC]
	p-value[b][d]		0.721
	HR [95 % CI][c][d]		0.90 [0.50, 1.63]
	Heterogeneity p-value[e][d]		0.1499

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	30 (41.1%)	15 (20.8%)
Number of censored cases	n (%)	43 (58.9%)	57 (79.2%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	4 (5.6%)
No first deterioration	n (%)	31 (42.5%)	40 (55.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.06, 8.41]	7.85 [2.92, 34.53]
	Median [95% CI]	16.33 [8.31, NC]	NYR [15.70, NC]
	Q3 [95% CI]	NYR [31.38, NC]	NYR [34.53, NC]
	p-value[b][d]		0.199
	HR [95 % CI][c][d]		1.53 [0.80, 2.95]
	Heterogeneity p-value[e][d]		0.4277

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	26 (35.6%)	16 (22.2%)
Number of censored cases	n (%)	47 (64.4%)	56 (77.8%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	2 (2.7%)	0
No first deterioration	n (%)	33 (45.2%)	43 (59.7%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [5.29, 13.86]	6.93 [2.86, NC]
	Median [95% CI]	21.59 [13.63, NC]	NYR [15.70, NC]
	Q3 [95% CI]	NYR [33.74, NC]	NYR [NC, NC]
	p-value[b][d]		0.387
	HR [95 % CI][c][d]		1.33 [0.69, 2.56]
	Heterogeneity p-value[e][d]		0.7154

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	30 (41.1%)	23 (31.9%)
Number of censored cases	n (%)	43 (58.9%)	49 (68.1%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	0	2 (2.8%)
No first deterioration	n (%)	31 (42.5%)	34 (47.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.78 [3.22, 10.84]	8.41 [2.86, 18.53]
	Median [95% CI]	23.33 [10.64, 45.70]	22.34 [10.81, 34.53]
	Q3 [95% CI]	45.70 [31.77, NC]	34.53 [27.56, NC]
	p-value[b][d]		0.868
	HR [95 % CI][c][d]		1.05 [0.59, 1.88]
	Heterogeneity p-value[e][d]		0.6307

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	21 (28.8%)	12 (16.7%)
Number of censored cases	n (%)	52 (71.2%)	60 (83.3%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	5 (6.8%)	6 (8.3%)
No deterioration possible	n (%)	1 (1.4%)	0
No first deterioration	n (%)	39 (53.4%)	47 (65.3%)
Time to first deterioration (months)	Q1 [95% CI]	9.26 [5.59, 21.88]	22.21 [5.59, 32.89]
	Median [95% CI]	41.46 [21.39, NC]	32.89 [25.66, NC]
	Q3 [95% CI]	NYR [41.46, NC]	NYR [32.89, NC]
	p-value[b][d]		0.344
	HR [95 % CI][c][d]		1.42 [0.68, 2.95]
	Heterogeneity p-value[e][d]		0.4277

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	82 (47.1%)	65 (37.4%)
Number of censored cases	n (%)	92 (52.9%)	109 (62.6%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	73 (42.0%)	87 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.12, 6.24]	4.27 [2.89, 5.65]
	Median [95% CI]	15.51 [8.48, 29.31]	22.21 [8.44, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [45.83, NC]
	p-value[b][d]		0.497
	HR [95 % CI][c][d]		1.12 [0.80, 1.56]
	Heterogeneity p-value[e][d]		0.6865

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	69 (39.7%)	58 (33.3%)
Number of censored cases	n (%)	105 (60.3%)	116 (66.7%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	85 (48.9%)	94 (54.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.78, 8.54]	5.65 [2.96, 8.41]
	Median [95% CI]	21.22 [15.51, 33.74]	25.79 [13.44, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.896
	HR [95 % CI][c][d]		1.02 [0.72, 1.46]
	Heterogeneity p-value[e][d]		0.5237

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	89 (51.1%)	70 (40.2%)
Number of censored cases	n (%)	85 (48.9%)	104 (59.8%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	4 (2.3%)	0
No first deterioration	n (%)	62 (35.6%)	82 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.65]	4.27 [2.89, 5.62]
	Median [95% CI]	11.20 [8.41, 16.89]	10.97 [8.38, NC]
	Q3 [95% CI]	34.66 [22.74, NC]	NYR [NC, NC]
	p-value[b][d]		0.609
	HR [95 % CI][c][d]		1.08 [0.79, 1.49]
	Heterogeneity p-value[e][d]		0.4490

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	65 (37.4%)	58 (33.3%)
Number of censored cases	n (%)	109 (62.6%)	116 (66.7%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	89 (51.1%)	93 (53.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.25, 10.61]	5.65 [5.55, 8.34]
	Median [95% CI]	25.63 [14.46, NC]	22.21 [11.43, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.867
	HR [95 % CI][c][d]		0.97 [0.68, 1.39]
	Heterogeneity p-value[e][d]		0.6115

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	81 (46.6%)	71 (40.8%)
Number of censored cases	n (%)	93 (53.4%)	103 (59.2%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	74 (42.5%)	80 (46.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.02, 8.31]	5.55 [2.89, 6.11]
	Median [95% CI]	14.46 [8.54, 24.08]	13.50 [8.51, 22.21]
	Q3 [95% CI]	46.03 [31.77, NC]	51.12 [34.86, NC]
	p-value[b][d]		0.573
	HR [95 % CI][c][d]		0.91 [0.65, 1.26]
	Heterogeneity p-value[e][d]		0.9569

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	79 (45.4%)	67 (38.5%)
Number of censored cases	n (%)	95 (54.6%)	107 (61.5%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	76 (43.7%)	84 (48.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.55, 8.28]	4.27 [2.89, 5.62]
	Median [95% CI]	14.36 [10.48, 25.63]	12.12 [8.41, 45.83]
	Q3 [95% CI]	46.95 [31.77, NC]	NYR [45.83, NC]
	p-value[b][d]		0.914
	HR [95 % CI][c][d]		0.98 [0.70, 1.36]
	Heterogeneity p-value[e][d]		0.6120

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	108 (62.1%)	83 (47.7%)
Number of censored cases	n (%)	66 (37.9%)	91 (52.3%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	46 (26.4%)	68 (39.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.89]
	Median [95% CI]	5.68 [5.55, 8.34]	8.31 [5.65, 10.45]
	Q3 [95% CI]	24.08 [14.23, 41.26]	NYR [13.54, NC]
	p-value[b][d]		0.383
	HR [95 % CI][c][d]		1.14 [0.85, 1.52]
	Heterogeneity p-value[e][d]		0.7582

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	92 (52.9%)	74 (42.5%)
Number of censored cases	n (%)	82 (47.1%)	100 (57.5%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	62 (35.6%)	77 (44.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.68]	5.55 [2.92, 5.65]
	Median [95% CI]	10.64 [8.34, 14.09]	13.90 [9.33, 29.57]
	Q3 [95% CI]	33.61 [21.22, NC]	49.74 [39.16, NC]
	p-value[b][d]		0.099
	HR [95 % CI][c][d]		1.30 [0.95, 1.78]
	Heterogeneity p-value[e][d]		0.4775

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	40 (23.0%)	28 (16.1%)
Number of censored cases	n (%)	134 (77.0%)	146 (83.9%)
No baseline score	n (%)	13 (7.5%)	13 (7.5%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	4 (2.3%)	1 (0.6%)
No first deterioration	n (%)	111 (63.8%)	122 (70.1%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [8.34, 30.65]	23.95 [8.51, NC]
	Median [95% CI]	NYR [34.37, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.386
	HR [95 % CI][c][d]		1.24 [0.76, 2.03]
	Heterogeneity p-value[e][d]		0.6999

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	47 (27.0%)	35 (20.1%)
Number of censored cases	n (%)	127 (73.0%)	139 (79.9%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	108 (62.1%)	117 (67.2%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [8.48, 21.22]	14.75 [8.31, 45.83]
	Median [95% CI]	NYR [30.59, NC]	45.83 [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.668
	HR [95 % CI][c][d]		1.10 [0.71, 1.71]
	Heterogeneity p-value[e][d]		0.0238

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	67 (38.5%)	52 (29.9%)
Number of censored cases	n (%)	107 (61.5%)	122 (70.1%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	3 (1.7%)	0
No first deterioration	n (%)	85 (48.9%)	100 (57.5%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 11.30]	8.31 [5.65, 10.64]
	Median [95% CI]	23.52 [14.49, 30.98]	28.55 [17.97, NC]
	Q3 [95% CI]	44.65 [34.27, NC]	NYR [43.56, NC]
	p-value[b][d]		0.678
	HR [95 % CI][c][d]		1.08 [0.74, 1.56]
	Heterogeneity p-value[e][d]		0.8106

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	71 (40.8%)	55 (31.6%)
Number of censored cases	n (%)	103 (59.2%)	119 (68.4%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	4 (2.3%)	4 (2.3%)
No first deterioration	n (%)	80 (46.0%)	93 (53.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.25, 8.25]	5.65 [2.92, 8.51]
	Median [95% CI]	14.98 [10.64, 39.82]	34.53 [15.70, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [38.70, NC]
	p-value[b][d]		0.420
	HR [95 % CI][c][d]		1.16 [0.81, 1.67]
	Heterogeneity p-value[e][d]		0.8374

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[(a)]	n	174	174
Number of patients with events	n (%)	54 (31.0%)	35 (20.1%)
Number of censored cases	n (%)	120 (69.0%)	139 (79.9%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	3 (1.7%)	2 (1.1%)
No first deterioration	n (%)	98 (56.3%)	115 (66.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [5.62, 14.23]	15.70 [5.62, 45.83]
	Median [95% CI]	37.06 [21.59, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[(b)(d)]		0.140
	HR [95 % CI][(c)(d)]		1.38 [0.90, 2.12]
	Heterogeneity p-value[(e)(d)]		0.1382

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	55 (31.6%)	48 (27.6%)
Number of censored cases	n (%)	119 (68.4%)	126 (72.4%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	100 (57.5%)	103 (59.2%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.78, 17.87]	9.95 [5.72, 15.15]
	Median [95% CI]	45.70 [23.33, NC]	30.65 [22.34, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.848
	HR [95 % CI][c][d]		0.96 [0.65, 1.43]
	Heterogeneity p-value[e][d]		0.3653

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	43 (24.7%)	40 (23.0%)
Number of censored cases	n (%)	131 (75.3%)	134 (77.0%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	111 (63.8%)	112 (64.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [8.34, 24.74]	8.57 [5.65, 25.66]
	Median [95% CI]	NYR [41.46, NC]	NYR [28.81, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.518
	HR [95 % CI][c][d]		0.86 [0.55, 1.34]
	Heterogeneity p-value[e][d]		0.3150

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	15 (42.9%)	15 (46.9%)
Number of censored cases	n (%)	20 (57.1%)	17 (53.1%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	1 (3.1%)
No first deterioration	n (%)	12 (34.3%)	12 (37.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.79, 5.85]	6.11 [2.79, 8.38]
	Median [95% CI]	10.97 [5.55, NC]	8.41 [6.11, 27.47]
	Q3 [95% CI]	NYR [13.80, NC]	27.47 [8.41, NC]
	p-value[b][d]		0.209
	HR [95 % CI][c][d]		1.71 [0.74, 3.98]
	Heterogeneity p-value[e][d]		0.6865

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	10 (28.6%)	11 (34.4%)
Number of censored cases	n (%)	25 (71.4%)	21 (65.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (48.6%)	17 (53.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.83, 24.18]	5.72 [2.79, 8.38]
	Median [95% CI]	24.18 [8.31, NC]	8.38 [6.74, NC]
	Q3 [95% CI]	NYR [24.18, NC]	NYR [8.38, NC]
	p-value[b][d]		0.495
	HR [95 % CI][c][d]		0.71 [0.27, 1.83]
	Heterogeneity p-value[e][d]		0.5237

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	16 (45.7%)	13 (40.6%)
Number of censored cases	n (%)	19 (54.3%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	1 (2.9%)	0
No first deterioration	n (%)	10 (28.6%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.10, 5.59]	5.52 [2.79, 15.21]
	Median [95% CI]	5.59 [3.29, 8.51]	17.58 [5.72, NC]
	Q3 [95% CI]	NYR [6.37, NC]	25.69 [17.58, NC]
	p-value[b][d]		0.271
	HR [95 % CI][c][d]		1.60 [0.68, 3.76]
	Heterogeneity p-value[e][d]		0.4490

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	12 (34.3%)	13 (40.6%)
Number of censored cases	n (%)	23 (65.7%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	15 (42.9%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.10, 10.81]	5.65 [2.79, 8.31]
	Median [95% CI]	11.37 [8.34, NC]	13.54 [5.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [13.54, NC]
	p-value[b][d]		0.770
	HR [95 % CI][c][d]		0.88 [0.37, 2.07]
	Heterogeneity p-value[e][d]		0.6115

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	14 (40.0%)	13 (40.6%)
Number of censored cases	n (%)	21 (60.0%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	13 (37.1%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	3.12 [2.10, 13.57]	5.62 [2.79, 11.37]
	Median [95% CI]	13.90 [3.61, NC]	11.37 [5.62, 26.48]
	Q3 [95% CI]	NYR [13.90, NC]	26.48 [11.37, NC]
	p-value[b][d]		0.967
	HR [95 % CI][c][d]		1.02 [0.43, 2.42]
	Heterogeneity p-value[e][d]		0.9569

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	14 (40.0%)	12 (37.5%)
Number of censored cases	n (%)	21 (60.0%)	20 (62.5%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	1 (3.1%)
No first deterioration	n (%)	13 (37.1%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	2.96 [2.73, 8.34]	5.59 [2.79, 13.73]
	Median [95% CI]	13.90 [3.12, NC]	15.21 [5.59, NC]
	Q3 [95% CI]	NYR [13.90, NC]	NYR [15.21, NC]
	p-value[b][d]		0.520
	HR [95 % CI][c][d]		1.37 [0.55, 3.42]
	Heterogeneity p-value[e][d]		0.6120

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	18 (51.4%)	19 (59.4%)
Number of censored cases	n (%)	17 (48.6%)	13 (40.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	9 (25.7%)	9 (28.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.83 [2.10, 3.12]	2.86 [2.79, 5.09]
	Median [95% CI]	5.55 [2.83, 11.10]	5.78 [2.92, 8.34]
	Q3 [95% CI]	21.68 [8.31, NC]	8.38 [8.31, NC]
	p-value[b][d]		0.836
	HR [95 % CI][c][d]		0.93 [0.45, 1.94]
	Heterogeneity p-value[e][d]		0.7582

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	16 (45.7%)	18 (56.3%)
Number of censored cases	n (%)	19 (54.3%)	14 (43.8%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	1 (2.9%)	1 (3.1%)
No first deterioration	n (%)	10 (28.6%)	9 (28.1%)
Time to first deterioration (months)	Q1 [95% CI]	3.61 [2.79, 5.68]	2.86 [2.79, 3.09]
	Median [95% CI]	5.75 [3.61, 23.72]	5.65 [2.89, 34.07]
	Q3 [95% CI]	23.72 [8.34, NC]	34.07 [8.31, NC]
	p-value[b][d]		0.949
	HR [95 % CI][c][d]		1.04 [0.48, 2.26]
	Heterogeneity p-value[e][d]		0.4775

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	8 (22.9%)	5 (15.6%)
Number of censored cases	n (%)	27 (77.1%)	27 (84.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	1 (2.9%)	1 (3.1%)
No first deterioration	n (%)	18 (51.4%)	22 (68.8%)
Time to first deterioration (months)	Q1 [95% CI]	13.14 [2.73, NC]	40.05 [2.83, NC]
	Median [95% CI]	NYR [13.14, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [40.05, NC]
	p-value[b][d]		0.205
	HR [95 % CI][c][d]		2.35 [0.61, 9.12]
	Heterogeneity p-value[e][d]		0.6999

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	6 (17.1%)	13 (40.6%)
Number of censored cases	n (%)	29 (82.9%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (60.0%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.83, NC]	5.55 [2.83, 10.78]
	Median [95% CI]	NYR [NC, NC]	17.87 [5.55, NC]
	Q3 [95% CI]	NYR [NC, NC]	23.26 [17.87, NC]
	p-value[b][d]		0.070
	HR [95 % CI][c][d]		0.38 [0.13, 1.13]
	Heterogeneity p-value[e][d]		0.0238

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	11 (31.4%)	9 (28.1%)
Number of censored cases	n (%)	24 (68.6%)	23 (71.9%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (45.7%)	19 (59.4%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [2.79, 25.59]	8.31 [2.79, 40.71]
	Median [95% CI]	25.59 [17.77, NC]	40.71 [8.41, NC]
	Q3 [95% CI]	33.91 [25.59, NC]	NYR [40.71, NC]
	p-value[b][d]		0.714
	HR [95 % CI][c][d]		1.24 [0.39, 3.94]
	Heterogeneity p-value[e][d]		0.8106

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	16 (45.7%)	13 (40.6%)
Number of censored cases	n (%)	19 (54.3%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	1 (2.9%)	2 (6.3%)
No first deterioration	n (%)	10 (28.6%)	13 (40.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.79, 7.89]	5.68 [2.79, 8.31]
	Median [95% CI]	8.31 [5.55, NC]	8.31 [5.68, 23.26]
	Q3 [95% CI]	NYR [8.34, NC]	23.26 [8.38, NC]
	p-value[b][d]		0.516
	HR [95 % CI][c][d]		1.31 [0.56, 3.02]
	Heterogeneity p-value[e][d]		0.8374

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	8 (22.9%)	11 (34.4%)
Number of censored cases	n (%)	27 (77.1%)	21 (65.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	1 (2.9%)	3 (9.4%)
No first deterioration	n (%)	18 (51.4%)	14 (43.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [2.79, NC]	2.86 [2.79, 10.45]
	Median [95% CI]	NYR [10.97, NC]	28.85 [3.02, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [28.85, NC]
	p-value[b][d]		0.761
	HR [95 % CI][c][d]		0.85 [0.31, 2.33]
	Heterogeneity p-value[e][d]		0.1382

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	9 (25.7%)	12 (37.5%)
Number of censored cases	n (%)	26 (74.3%)	20 (62.5%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	1 (2.9%)	2 (6.3%)
No first deterioration	n (%)	17 (48.6%)	14 (43.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.87 [2.73, NC]	5.55 [2.79, 8.41]
	Median [95% CI]	43.96 [10.87, NC]	10.45 [5.55, NC]
	Q3 [95% CI]	43.96 [23.46, NC]	NYR [10.45, NC]
	p-value[b][d]		0.278
	HR [95 % CI][c][d]		0.58 [0.21, 1.60]
	Heterogeneity p-value[e][d]		0.3653

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	11 (31.4%)	8 (25.0%)
Number of censored cases	n (%)	24 (68.6%)	24 (75.0%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	4 (11.4%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (45.7%)	20 (62.5%)
Time to first deterioration (months)	Q1 [95% CI]	9.03 [3.25, 20.50]	13.54 [2.89, 21.65]
	Median [95% CI]	20.50 [9.03, NC]	21.65 [13.54, NC]
	Q3 [95% CI]	NYR [20.50, NC]	NYR [21.65, NC]
	p-value[b][d]		0.432
	HR [95 % CI][c][d]		1.64 [0.47, 5.66]
	Heterogeneity p-value[e][d]		0.3150

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	10 (27.0%)	10 (32.3%)
Number of censored cases	n (%)	27 (73.0%)	21 (67.7%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (56.8%)	16 (51.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, NC]	5.78 [1.97, 8.31]
	Median [95% CI]	37.06 [11.30, NC]	8.44 [5.78, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [8.44, NC]
	p-value[b][d]		0.470
	HR [95 % CI][c][d]		0.73 [0.30, 1.75]
	Heterogeneity p-value[e][d]		0.2601

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	9 (24.3%)	6 (19.4%)
Number of censored cases	n (%)	28 (75.7%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (59.5%)	20 (64.5%)
Time to first deterioration (months)	Q1 [95% CI]	17.58 [3.78, NC]	7.85 [1.18, NC]
	Median [95% CI]	NYR [17.58, NC]	NYR [7.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.596
	HR [95 % CI][c][d]		0.75 [0.26, 2.19]
	Heterogeneity p-value[e][d]		0.6578

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	15 (40.5%)	11 (35.5%)
Number of censored cases	n (%)	22 (59.5%)	20 (64.5%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	15 (40.5%)	15 (48.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [3.02, 8.41]	2.89 [2.20, 8.38]
	Median [95% CI]	22.74 [6.37, NC]	10.97 [5.78, NC]
	Q3 [95% CI]	NYR [22.74, NC]	NYR [10.97, NC]
	p-value[b][d]		0.572
	HR [95 % CI][c][d]		0.79 [0.35, 1.76]
	Heterogeneity p-value[e][d]		0.3906

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	13 (35.1%)	9 (29.0%)
Number of censored cases	n (%)	24 (64.9%)	22 (71.0%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	18 (48.6%)	17 (54.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.18 [2.92, 14.46]	5.55 [2.20, 8.38]
	Median [95% CI]	NYR [8.31, NC]	NYR [5.55, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.484
	HR [95 % CI][c][d]		0.73 [0.30, 1.78]
	Heterogeneity p-value[e][d]		0.8353

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	18 (48.6%)	9 (29.0%)
Number of censored cases	n (%)	19 (51.4%)	22 (71.0%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	13 (35.1%)	17 (54.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.83, 8.38]	2.89 [2.20, 8.38]
	Median [95% CI]	14.46 [5.68, NC]	NYR [2.89, NC]
	Q3 [95% CI]	46.03 [18.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.764
	HR [95 % CI][c][d]		1.12 [0.49, 2.55]
	Heterogeneity p-value[e][d]		0.8413

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	15 (40.5%)	12 (38.7%)
Number of censored cases	n (%)	22 (59.5%)	19 (61.3%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (43.2%)	14 (45.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.92, 15.38]	2.79 [2.20, 2.92]
	Median [95% CI]	27.63 [8.44, NC]	7.85 [2.79, NC]
	Q3 [95% CI]	46.95 [27.63, NC]	NYR [7.85, NC]
	p-value[b][d]		0.214
	HR [95 % CI][c][d]		0.60 [0.27, 1.32]
	Heterogeneity p-value[e][d]		0.2083

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	19 (51.4%)	12 (38.7%)
Number of censored cases	n (%)	18 (48.6%)	19 (61.3%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	12 (32.4%)	14 (45.2%)
Time to first deterioration (months)	Q1 [95% CI]	3.61 [2.79, 8.31]	2.89 [2.20, 8.31]
	Median [95% CI]	11.10 [5.29, 26.81]	8.31 [2.89, NC]
	Q3 [95% CI]	26.81 [18.33, NC]	NYR [8.31, NC]
	p-value[b][d]		0.646
	HR [95 % CI][c][d]		0.83 [0.39, 1.76]
	Heterogeneity p-value[e][d]		0.5206

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	14 (37.8%)	9 (29.0%)
Number of censored cases	n (%)	23 (62.2%)	22 (71.0%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (45.9%)	17 (54.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [3.25, 18.33]	5.55 [1.97, 10.97]
	Median [95% CI]	27.63 [8.54, NC]	NYR [5.65, NC]
	Q3 [95% CI]	37.06 [27.63, NC]	NYR [10.97, NC]
	p-value[b][d]		0.868
	HR [95 % CI][c][d]		0.93 [0.40, 2.19]
	Heterogeneity p-value[e][d]		0.6308

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	4 (10.8%)	6 (19.4%)
Number of censored cases	n (%)	33 (89.2%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	2 (5.4%)	1 (3.2%)
No first deterioration	n (%)	25 (67.6%)	19 (61.3%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [5.55, NC]	7.85 [2.76, NC]
	Median [95% CI]	NYR [NC, NC]	30.65 [7.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [30.65, NC]
	p-value[b][d]		0.060
	HR [95 % CI][c][d]		0.28 [0.07, 1.15]
	Heterogeneity p-value[e][d]		0.0640

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	5 (13.5%)	4 (12.9%)
Number of censored cases	n (%)	32 (86.5%)	27 (87.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (70.3%)	22 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [5.65, NC]	NYR [2.89, NC]
	Median [95% CI]	NYR [27.07, NC]	NYR [8.31, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.461
	HR [95 % CI][c][d]		0.61 [0.16, 2.32]
	Heterogeneity p-value[e][d]		0.8849

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	10 (27.0%)	8 (25.8%)
Number of censored cases	n (%)	27 (73.0%)	23 (74.2%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	20 (54.1%)	18 (58.1%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [5.29, 27.07]	6.24 [1.18, NC]
	Median [95% CI]	NYR [14.98, NC]	NYR [6.24, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.434
	HR [95 % CI][c][d]		0.68 [0.26, 1.78]
	Heterogeneity p-value[e][d]		0.2040

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	14 (37.8%)	8 (25.8%)
Number of censored cases	n (%)	23 (62.2%)	23 (74.2%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	16 (43.2%)	18 (58.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.92, 8.41]	7.85 [2.20, 34.53]
	Median [95% CI]	14.98 [8.31, NC]	34.53 [7.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.871
	HR [95 % CI][c][d]		0.92 [0.37, 2.29]
	Heterogeneity p-value[e][d]		0.1228

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	7 (18.9%)	4 (12.9%)
Number of censored cases	n (%)	30 (81.1%)	27 (87.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	23 (62.2%)	22 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	37.06 [5.62, NC]	NYR [2.20, NC]
	Median [95% CI]	37.06 [37.06, NC]	NYR [8.38, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.914
	HR [95 % CI][c][d]		1.07 [0.30, 3.80]
	Heterogeneity p-value[e][d]		0.6625

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	12 (32.4%)	5 (16.1%)
Number of censored cases	n (%)	25 (67.6%)	26 (83.9%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	1 (3.2%)
No first deterioration	n (%)	19 (51.4%)	20 (64.5%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [3.25, 23.03]	30.65 [2.20, NC]
	Median [95% CI]	23.46 [14.23, NC]	NYR [30.65, NC]
	Q3 [95% CI]	NYR [23.46, NC]	NYR [30.65, NC]
	p-value[b][d]		0.350
	HR [95 % CI][c][d]		1.65 [0.57, 4.82]
	Heterogeneity p-value[e][d]		0.5123

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	10 (27.0%)	4 (12.9%)
Number of censored cases	n (%)	27 (73.0%)	27 (87.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (56.8%)	22 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.61 [3.25, NC]	NYR [2.79, NC]
	Median [95% CI]	NYR [21.88, NC]	NYR [8.57, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.898
	HR [95 % CI][c][d]		1.08 [0.32, 3.65]
	Heterogeneity p-value[e][d]		0.1394

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	45 (50.0%)	35 (38.9%)
Number of censored cases	n (%)	45 (50.0%)	55 (61.1%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (41.1%)	48 (53.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.98 [3.02, 8.44]	2.92 [2.86, 7.06]
	Median [95% CI]	16.33 [8.44, 34.66]	45.83 [13.63, NC]
	Q3 [95% CI]	40.31 [34.66, NC]	NYR [45.83, NC]
	p-value[b][d]		0.568
	HR [95 % CI][c][d]		1.13 [0.72, 1.78]
	Heterogeneity p-value[e][d]		0.2601

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	37 (41.1%)	32 (35.6%)
Number of censored cases	n (%)	53 (58.9%)	58 (64.4%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	1 (1.1%)	0
No first deterioration	n (%)	44 (48.9%)	51 (56.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.86, 10.64]	5.72 [2.92, 9.69]
	Median [95% CI]	21.68 [10.71, NC]	34.83 [10.78, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.578
	HR [95 % CI][c][d]		1.15 [0.71, 1.84]
	Heterogeneity p-value[e][d]		0.6578

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	52 (57.8%)	37 (41.1%)
Number of censored cases	n (%)	38 (42.2%)	53 (58.9%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	2 (2.2%)	0
No first deterioration	n (%)	28 (31.1%)	46 (51.1%)
Time to first deterioration (months)	Q1 [95% CI]	3.94 [2.83, 5.59]	5.55 [2.89, 8.34]
	Median [95% CI]	9.72 [5.65, 13.83]	11.40 [8.34, NC]
	Q3 [95% CI]	34.37 [14.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.194
	HR [95 % CI][c][d]		1.33 [0.87, 2.03]
	Heterogeneity p-value[e][d]		0.3906

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	36 (40.0%)	35 (38.9%)
Number of censored cases	n (%)	54 (60.0%)	55 (61.1%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	46 (51.1%)	47 (52.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.99, 10.68]	5.62 [4.27, 8.41]
	Median [95% CI]	24.94 [12.65, NC]	22.21 [11.43, NC]
	Q3 [95% CI]	NYR [40.31, NC]	NYR [34.30, NC]
	p-value[b][d]		0.751
	HR [95 % CI][c][d]		0.93 [0.58, 1.48]
	Heterogeneity p-value[e][d]		0.8353

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	46 (51.1%)	44 (48.9%)
Number of censored cases	n (%)	44 (48.9%)	46 (51.1%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	36 (40.0%)	38 (42.2%)
Time to first deterioration (months)	Q1 [95% CI]	3.02 [2.86, 5.62]	5.55 [2.86, 5.78]
	Median [95% CI]	10.87 [6.47, 24.94]	10.91 [8.31, 22.21]
	Q3 [95% CI]	NYR [24.94, NC]	51.12 [22.21, NC]
	p-value[b][d]		0.774
	HR [95 % CI][c][d]		0.94 [0.62, 1.44]
	Heterogeneity p-value[e][d]		0.8413

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	47 (52.2%)	37 (41.1%)
Number of censored cases	n (%)	43 (47.8%)	53 (58.9%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	35 (38.9%)	45 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.99, 5.68]	4.27 [2.86, 5.62]
	Median [95% CI]	11.24 [8.28, 18.40]	25.86 [8.31, NC]
	Q3 [95% CI]	NYR [18.40, NC]	NYR [45.83, NC]
	p-value[b][d]		0.490
	HR [95 % CI][c][d]		1.16 [0.75, 1.79]
	Heterogeneity p-value[e][d]		0.2083

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	62 (68.9%)	49 (54.4%)
Number of censored cases	n (%)	28 (31.1%)	41 (45.6%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	20 (22.2%)	33 (36.7%)
Time to first deterioration (months)	Q1 [95% CI]	2.83 [2.79, 2.86]	2.86 [2.83, 2.89]
	Median [95% CI]	5.55 [2.92, 5.68]	5.65 [4.27, 10.61]
	Q3 [95% CI]	21.68 [8.44, 41.26]	34.83 [11.40, NC]
	p-value[b][d]		0.270
	HR [95 % CI][c][d]		1.23 [0.84, 1.80]
	Heterogeneity p-value[e][d]		0.5206

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	55 (61.1%)	48 (53.3%)
Number of censored cases	n (%)	35 (38.9%)	42 (46.7%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	27 (30.0%)	35 (38.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.62]	3.09 [2.89, 5.62]
	Median [95% CI]	8.38 [5.68, 11.33]	13.60 [8.38, 29.57]
	Q3 [95% CI]	21.68 [13.67, NC]	46.16 [29.57, NC]
	p-value[b][d]		0.204
	HR [95 % CI][c][d]		1.29 [0.87, 1.91]
	Heterogeneity p-value[e][d]		0.6308

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	25 (27.8%)	14 (15.6%)
Number of censored cases	n (%)	65 (72.2%)	76 (84.4%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	1 (1.1%)	1 (1.1%)
No first deterioration	n (%)	56 (62.2%)	68 (75.6%)
Time to first deterioration (months)	Q1 [95% CI]	13.86 [8.34, 29.73]	40.05 [9.95, NC]
	Median [95% CI]	NYR [29.73, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.187
	HR [95 % CI][c][d]		1.56 [0.80, 3.01]
	Heterogeneity p-value[e][d]		0.0640

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	28 (31.1%)	26 (28.9%)
Number of censored cases	n (%)	62 (68.9%)	64 (71.1%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	54 (60.0%)	57 (63.3%)
Time to first deterioration (months)	Q1 [95% CI]	10.74 [8.34, 18.30]	8.44 [2.92, 25.56]
	Median [95% CI]	NYR [26.41, NC]	45.83 [25.56, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.653
	HR [95 % CI][c][d]		0.88 [0.52, 1.51]
	Heterogeneity p-value[e][d]		0.8849

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	37 (41.1%)	24 (26.7%)
Number of censored cases	n (%)	53 (58.9%)	66 (73.3%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	1 (1.1%)	0
No first deterioration	n (%)	44 (48.9%)	59 (65.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [3.94, 12.52]	10.64 [5.72, 17.97]
	Median [95% CI]	26.48 [14.06, 34.27]	NYR [17.97, NC]
	Q3 [95% CI]	41.26 [30.98, NC]	NYR [NC, NC]
	p-value[b][d]		0.168
	HR [95 % CI][c][d]		1.44 [0.85, 2.42]
	Heterogeneity p-value[e][d]		0.2040

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	34 (37.8%)	33 (36.7%)
Number of censored cases	n (%)	56 (62.2%)	57 (63.3%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	2 (2.2%)	2 (2.2%)
No first deterioration	n (%)	46 (51.1%)	48 (53.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.92, 10.64]	5.59 [2.89, 8.51]
	Median [95% CI]	39.82 [11.30, NC]	23.26 [8.61, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.461
	HR [95 % CI][c][d]		0.83 [0.51, 1.36]
	Heterogeneity p-value[e][d]		0.1228

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	28 (31.1%)	23 (25.6%)
Number of censored cases	n (%)	62 (68.9%)	67 (74.4%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	2 (2.2%)
No first deterioration	n (%)	54 (60.0%)	58 (64.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [5.55, 14.52]	9.95 [2.89, 45.83]
	Median [95% CI]	NYR [17.77, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.898
	HR [95 % CI][c][d]		1.04 [0.60, 1.80]
	Heterogeneity p-value[e][d]		0.6625

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	31 (34.4%)	31 (34.4%)
Number of censored cases	n (%)	59 (65.6%)	59 (65.6%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	51 (56.7%)	52 (57.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.59, 21.62]	8.34 [5.55, 11.07]
	Median [95% CI]	39.46 [23.23, NC]	28.81 [11.40, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.493
	HR [95 % CI][c][d]		0.84 [0.51, 1.39]
	Heterogeneity p-value[e][d]		0.5123

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	23 (25.6%)	29 (32.2%)
Number of censored cases	n (%)	67 (74.4%)	61 (67.8%)
No baseline score	n (%)	4 (4.4%)	3 (3.3%)
No post-baseline score	n (%)	4 (4.4%)	4 (4.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	59 (65.6%)	54 (60.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [8.34, 25.79]	8.34 [3.09, 11.40]
	Median [95% CI]	NYR [24.74, NC]	28.81 [13.54, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.079
	HR [95 % CI][c][d]		0.61 [0.35, 1.06]
	Heterogeneity p-value[e][d]		0.1394

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	42 (51.2%)	35 (41.2%)
Number of censored cases	n (%)	40 (48.8%)	50 (58.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	27 (32.9%)	35 (41.2%)
Time to first deterioration (months)	Q1 [95% CI]	3.71 [2.89, 5.59]	5.55 [2.89, 5.65]
	Median [95% CI]	8.28 [5.59, 13.80]	8.44 [6.70, 38.90]
	Q3 [95% CI]	35.98 [13.80, NC]	50.92 [27.47, NC]
	p-value[b][d]		0.361
	HR [95 % CI][c][d]		1.24 [0.78, 1.95]
	Heterogeneity p-value[e][d]		0.2601

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	33 (40.2%)	31 (36.5%)
Number of censored cases	n (%)	49 (59.8%)	54 (63.5%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	36 (43.9%)	40 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [2.92, 10.97]	5.65 [2.89, 8.38]
	Median [95% CI]	17.68 [10.97, 30.19]	13.93 [8.38, 25.79]
	Q3 [95% CI]	NYR [29.70, NC]	NYR [18.00, NC]
	p-value[b][d]		0.576
	HR [95 % CI][c][d]		0.87 [0.53, 1.42]
	Heterogeneity p-value[e][d]		0.6578

Data cut-off as of October 4, 2024.

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.

[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.

The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.

Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	38 (46.3%)	35 (41.2%)
Number of censored cases	n (%)	44 (53.7%)	50 (58.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	2 (2.4%)	0
No first deterioration	n (%)	29 (35.4%)	36 (42.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 6.47]	3.25 [2.83, 5.59]
	Median [95% CI]	9.79 [6.47, 17.54]	11.33 [5.62, 25.69]
	Q3 [95% CI]	35.98 [15.44, NC]	NYR [17.58, NC]
	p-value[b][d]		0.841
	HR [95 % CI][c][d]		1.05 [0.66, 1.66]
	Heterogeneity p-value[e][d]		0.3906

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	28 (34.1%)	27 (31.8%)
Number of censored cases	n (%)	54 (65.9%)	58 (68.2%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	40 (48.8%)	44 (51.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.83, 11.27]	6.51 [5.55, 8.34]
	Median [95% CI]	25.63 [11.27, NC]	27.47 [8.34, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.838
	HR [95 % CI][c][d]		1.06 [0.62, 1.80]
	Heterogeneity p-value[e][d]		0.8353

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	31 (37.8%)	31 (36.5%)
Number of censored cases	n (%)	51 (62.2%)	54 (63.5%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	38 (46.3%)	40 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [3.12, 12.55]	5.78 [2.83, 8.61]
	Median [95% CI]	18.23 [10.32, 31.77]	13.93 [8.61, 25.69]
	Q3 [95% CI]	35.84 [25.63, NC]	34.86 [21.45, NC]
	p-value[b][d]		0.391
	HR [95 % CI][c][d]		0.80 [0.48, 1.33]
	Heterogeneity p-value[e][d]		0.8413

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	31 (37.8%)	30 (35.3%)
Number of censored cases	n (%)	51 (62.2%)	55 (64.7%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	38 (46.3%)	40 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 8.41]	5.62 [3.25, 9.82]
	Median [95% CI]	14.23 [8.41, NC]	15.21 [9.82, 25.40]
	Q3 [95% CI]	NYR [31.77, NC]	NYR [19.22, NC]
	p-value[b][d]		0.984
	HR [95 % CI][c][d]		1.01 [0.61, 1.67]
	Heterogeneity p-value[e][d]		0.2083

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	45 (54.9%)	41 (48.2%)
Number of censored cases	n (%)	37 (45.1%)	44 (51.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	23 (28.0%)	30 (35.3%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.79, 5.55]	2.92 [2.83, 5.55]
	Median [95% CI]	5.78 [5.55, 8.57]	8.31 [5.65, 10.45]
	Q3 [95% CI]	15.51 [8.57, NC]	NYR [10.45, NC]
	p-value[b][d]		0.689
	HR [95 % CI][c][d]		1.08 [0.70, 1.67]
	Heterogeneity p-value[e][d]		0.5206

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	39 (47.6%)	35 (41.2%)
Number of censored cases	n (%)	43 (52.4%)	50 (58.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	2 (2.4%)	2 (2.4%)
No first deterioration	n (%)	28 (34.1%)	34 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	4.73 [2.83, 6.47]	3.48 [2.89, 5.65]
	Median [95% CI]	8.34 [6.47, 21.22]	10.84 [6.70, 44.75]
	Q3 [95% CI]	28.68 [14.23, NC]	44.75 [29.80, NC]
	p-value[b][d]		0.319
	HR [95 % CI][c][d]		1.27 [0.80, 2.00]
	Heterogeneity p-value[e][d]		0.6308

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	19 (23.2%)	13 (15.3%)
Number of censored cases	n (%)	63 (76.8%)	72 (84.7%)
No baseline score	n (%)	9 (11.0%)	10 (11.8%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	2 (2.4%)	0
No first deterioration	n (%)	48 (58.5%)	57 (67.1%)
Time to first deterioration (months)	Q1 [95% CI]	7.89 [2.89, 25.63]	NYR [6.24, NC]
	Median [95% CI]	NYR [25.63, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.194
	HR [95 % CI][c][d]		1.59 [0.79, 3.23]
	Heterogeneity p-value[e][d]		0.0640

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	20 (24.4%)	18 (21.2%)
Number of censored cases	n (%)	62 (75.6%)	67 (78.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	49 (59.8%)	53 (62.4%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [5.55, 21.59]	14.75 [3.65, 26.48]
	Median [95% CI]	45.70 [21.22, NC]	NYR [21.65, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [NC, NC]
	p-value[b][d]		0.885
	HR [95 % CI][c][d]		0.95 [0.50, 1.82]
	Heterogeneity p-value[e][d]		0.8849

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	31 (37.8%)	29 (34.1%)
Number of censored cases	n (%)	51 (62.2%)	56 (65.9%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	37 (45.1%)	42 (49.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.29, 14.23]	8.31 [3.65, 8.54]
	Median [95% CI]	21.59 [13.63, 29.14]	21.72 [8.54, NC]
	Q3 [95% CI]	44.65 [25.59, NC]	43.56 [22.14, NC]
	p-value[b][d]		0.803
	HR [95 % CI][c][d]		0.94 [0.56, 1.56]
	Heterogeneity p-value[e][d]		0.2040

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	39 (47.6%)	27 (31.8%)
Number of censored cases	n (%)	43 (52.4%)	58 (68.2%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	2 (2.4%)	4 (4.7%)
No first deterioration	n (%)	28 (34.1%)	40 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.89, 5.65]	5.68 [2.92, 8.51]
	Median [95% CI]	8.34 [5.65, 12.55]	16.89 [8.38, NC]
	Q3 [95% CI]	31.38 [12.55, NC]	NYR [38.70, NC]
	p-value[b][d]		0.042
	HR [95 % CI][c][d]		1.66 [1.01, 2.71]
	Heterogeneity p-value[e][d]		0.1228

Data cut-off as of October 4, 2024.

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.

[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.

The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.

Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	27 (32.9%)	19 (22.4%)
Number of censored cases	n (%)	55 (67.1%)	66 (77.6%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	3 (3.7%)	3 (3.5%)
No first deterioration	n (%)	39 (47.6%)	49 (57.6%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [2.96, 13.63]	8.38 [3.02, 31.18]
	Median [95% CI]	21.59 [11.20, NC]	NYR [28.85, NC]
	Q3 [95% CI]	NYR [26.71, NC]	NYR [NC, NC]
	p-value[b][d]		0.181
	HR [95 % CI][c][d]		1.50 [0.83, 2.71]
	Heterogeneity p-value[e][d]		0.6625

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	21 (25.6%)	24 (28.2%)
Number of censored cases	n (%)	61 (74.4%)	61 (71.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	1 (1.2%)	2 (2.4%)
No first deterioration	n (%)	47 (57.3%)	45 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	10.58 [5.62, 23.33]	8.41 [5.59, 21.75]
	Median [95% CI]	45.70 [23.33, NC]	27.56 [21.75, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [30.69, NC]
	p-value[b][d]		0.382
	HR [95 % CI][c][d]		0.77 [0.43, 1.39]
	Heterogeneity p-value[e][d]		0.5123

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	21 (25.6%)	15 (17.6%)
Number of censored cases	n (%)	61 (74.4%)	70 (82.4%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	4 (4.9%)	5 (5.9%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	47 (57.3%)	56 (65.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [2.99, 21.39]	21.65 [5.65, NC]
	Median [95% CI]	41.46 [14.92, NC]	NYR [25.66, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.266
	HR [95 % CI][c][d]		1.45 [0.75, 2.83]
	Heterogeneity p-value[e][d]		0.1394

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	92 (48.7%)	71 (37.6%)
Number of censored cases	n (%)	97 (51.3%)	118 (62.4%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	76 (40.2%)	91 (48.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.29, 5.75]	4.27 [2.89, 5.65]
	Median [95% CI]	13.80 [8.44, 21.03]	22.21 [8.44, 45.83]
	Q3 [95% CI]	41.46 [35.98, NC]	50.92 [45.83, NC]
	p-value[b][d]		0.425
	HR [95 % CI][c][d]		1.13 [0.83, 1.56]
	Heterogeneity p-value[e][d]		0.5161

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	73 (38.6%)	60 (31.7%)
Number of censored cases	n (%)	116 (61.4%)	129 (68.3%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	1 (0.5%)	0
No first deterioration	n (%)	94 (49.7%)	103 (54.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.29, 8.44]	5.78 [5.55, 8.38]
	Median [95% CI]	21.22 [16.39, 39.82]	25.79 [13.93, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.772
	HR [95 % CI][c][d]		1.05 [0.74, 1.49]
	Heterogeneity p-value[e][d]		0.2922

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	97 (51.3%)	75 (39.7%)
Number of censored cases	n (%)	92 (48.7%)	114 (60.3%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	5 (2.6%)	0
No first deterioration	n (%)	66 (34.9%)	88 (46.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.96, 5.59]	5.52 [2.89, 5.75]
	Median [95% CI]	9.79 [8.34, 13.86]	11.40 [8.51, 25.69]
	Q3 [95% CI]	34.66 [22.18, NC]	NYR [36.40, NC]
	p-value[b][d]		0.321
	HR [95 % CI][c][d]		1.17 [0.86, 1.59]
	Heterogeneity p-value[e][d]		0.6012

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	74 (39.2%)	64 (33.9%)
Number of censored cases	n (%)	115 (60.8%)	125 (66.1%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	1 (0.5%)	1 (0.5%)
No first deterioration	n (%)	93 (49.2%)	98 (51.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.55, 8.41]	5.65 [5.55, 8.31]
	Median [95% CI]	24.94 [13.57, NC]	22.21 [11.43, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.932
	HR [95 % CI][c][d]		0.98 [0.70, 1.39]
	Heterogeneity p-value[e][d]		0.2103

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	89 (47.1%)	75 (39.7%)
Number of censored cases	n (%)	100 (52.9%)	114 (60.3%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	79 (41.8%)	87 (46.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.12, 8.31]	5.55 [2.89, 6.34]
	Median [95% CI]	13.86 [8.57, 18.99]	13.93 [8.61, 22.21]
	Q3 [95% CI]	46.03 [31.77, NC]	51.12 [25.69, NC]
	p-value[b][d]		0.685
	HR [95 % CI][c][d]		0.93 [0.68, 1.28]
	Heterogeneity p-value[e][d]		0.7590

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	87 (46.0%)	71 (37.6%)
Number of censored cases	n (%)	102 (54.0%)	118 (62.4%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	0	2 (1.1%)
No first deterioration	n (%)	81 (42.9%)	90 (47.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [5.29, 6.24]	4.27 [2.89, 5.59]
	Median [95% CI]	14.36 [8.48, 25.13]	15.21 [8.41, 45.83]
	Q3 [95% CI]	46.95 [31.77, NC]	NYR [45.83, NC]
	p-value[b][d]		0.910
	HR [95 % CI][c][d]		1.02 [0.74, 1.40]
	Heterogeneity p-value[e][d]		0.8807

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	118 (62.4%)	91 (48.1%)
Number of censored cases	n (%)	71 (37.6%)	98 (51.9%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	1 (0.5%)	1 (0.5%)
No first deterioration	n (%)	49 (25.9%)	71 (37.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.89]
	Median [95% CI]	5.62 [5.55, 8.31]	8.31 [5.65, 8.44]
	Q3 [95% CI]	21.68 [11.40, 40.31]	NYR [13.54, NC]
	p-value[b][d]		0.294
	HR [95 % CI][c][d]		1.16 [0.87, 1.54]
	Heterogeneity p-value[e][d]		0.3821

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	100 (52.9%)	84 (44.4%)
Number of censored cases	n (%)	89 (47.1%)	105 (55.6%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	2 (1.1%)	1 (0.5%)
No first deterioration	n (%)	66 (34.9%)	78 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.65]	3.88 [2.92, 5.65]
	Median [95% CI]	10.64 [8.34, 13.93]	13.60 [8.44, 23.49]
	Q3 [95% CI]	33.61 [21.22, NC]	46.16 [34.07, NC]
	p-value[b][d]		0.112
	HR [95 % CI][c][d]		1.27 [0.95, 1.71]
	Heterogeneity p-value[e][d]		0.5845

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	46 (24.3%)	32 (16.9%)
Number of censored cases	n (%)	143 (75.7%)	157 (83.1%)
No baseline score	n (%)	13 (6.9%)	17 (9.0%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	5 (2.6%)	1 (0.5%)
No first deterioration	n (%)	117 (61.9%)	129 (68.3%)
Time to first deterioration (months)	Q1 [95% CI]	13.86 [8.31, 25.63]	23.95 [8.41, NC]
	Median [95% CI]	NYR [34.37, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.353
	HR [95 % CI][c][d]		1.25 [0.79, 1.97]
	Heterogeneity p-value[e][d]		0.6834

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	51 (27.0%)	45 (23.8%)
Number of censored cases	n (%)	138 (73.0%)	144 (76.2%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	117 (61.9%)	118 (62.4%)
Time to first deterioration (months)	Q1 [95% CI]	13.83 [8.44, 21.22]	8.44 [5.55, 23.26]
	Median [95% CI]	NYR [40.31, NC]	45.83 [26.48, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.578
	HR [95 % CI][c][d]		0.89 [0.59, 1.34]
	Heterogeneity p-value[e][d]		0.6665

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	71 (37.6%)	56 (29.6%)
Number of censored cases	n (%)	118 (62.4%)	133 (70.4%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	3 (1.6%)	0
No first deterioration	n (%)	94 (49.7%)	107 (56.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [5.59, 12.52]	8.31 [5.65, 9.82]
	Median [95% CI]	25.59 [19.81, 30.98]	40.71 [15.93, NC]
	Q3 [95% CI]	44.65 [33.91, NC]	NYR [43.56, NC]
	p-value[b][d]		0.831
	HR [95 % CI][c][d]		1.04 [0.72, 1.49]
	Heterogeneity p-value[e][d]		0.3043

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	80 (42.3%)	61 (32.3%)
Number of censored cases	n (%)	109 (57.7%)	128 (67.7%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	5 (2.6%)	4 (2.1%)
No first deterioration	n (%)	83 (43.9%)	98 (51.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.25, 7.89]	5.65 [2.92, 8.34]
	Median [95% CI]	14.46 [8.61, 31.38]	34.53 [15.70, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [38.70, NC]
	p-value[b][d]		0.501
	HR [95 % CI][c][d]		1.13 [0.80, 1.58]
	Heterogeneity p-value[e][d]		0.5502

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	58 (30.7%)	40 (21.2%)
Number of censored cases	n (%)	131 (69.3%)	149 (78.8%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	3 (1.6%)	5 (2.6%)
No first deterioration	n (%)	107 (56.6%)	118 (62.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.38 [5.59, 14.23]	8.38 [5.59, 28.85]
	Median [95% CI]	NYR [22.51, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.263
	HR [95 % CI][c][d]		1.26 [0.84, 1.91]
	Heterogeneity p-value[e][d]		0.4797

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	60 (31.7%)	54 (28.6%)
Number of censored cases	n (%)	129 (68.3%)	135 (71.4%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	1 (0.5%)	3 (1.6%)
No first deterioration	n (%)	107 (56.6%)	106 (56.1%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [5.78, 17.87]	8.51 [5.59, 11.40]
	Median [95% CI]	39.46 [23.46, NC]	30.65 [21.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.631
	HR [95 % CI][c][d]		0.91 [0.63, 1.32]
	Heterogeneity p-value[e][d]		0.5898

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	51 (27.0%)	44 (23.3%)
Number of censored cases	n (%)	138 (73.0%)	145 (76.7%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	8 (4.2%)	10 (5.3%)
No deterioration possible	n (%)	1 (0.5%)	0
No first deterioration	n (%)	116 (61.4%)	119 (63.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [8.31, 21.39]	8.57 [5.68, 21.65]
	Median [95% CI]	NYR [25.79, NC]	NYR [25.66, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.535
	HR [95 % CI][c][d]		0.87 [0.58, 1.32]
	Heterogeneity p-value[e][d]		0.8386

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	5 (25.0%)	9 (52.9%)
Number of censored cases	n (%)	15 (75.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	9 (45.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.79, NC]	5.78 [2.79, 8.31]
	Median [95% CI]	NYR [2.92, NC]	8.41 [5.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [8.41, NC]
	p-value[b][d]		0.918
	HR [95 % CI][c][d]		0.94 [0.30, 2.98]
	Heterogeneity p-value[e][d]		0.5161

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	6 (30.0%)	9 (52.9%)
Number of censored cases	n (%)	14 (70.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	12.86 [2.92, NC]	2.86 [2.79, 8.41]
	Median [95% CI]	30.19 [8.54, NC]	8.41 [2.83, NC]
	Q3 [95% CI]	30.19 [17.61, NC]	18.00 [8.41, NC]
	p-value[b][d]		0.342
	HR [95 % CI][c][d]		0.53 [0.14, 1.99]
	Heterogeneity p-value[e][d]		0.2922

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	8 (40.0%)	8 (47.1%)
Number of censored cases	n (%)	12 (60.0%)	9 (52.9%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	6 (30.0%)	9 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	6.37 [2.76, 17.54]	2.86 [2.79, 5.78]
	Median [95% CI]	21.52 [2.92, NC]	5.78 [2.83, NC]
	Q3 [95% CI]	30.19 [17.54, NC]	NYR [5.78, NC]
	p-value[b][d]		0.678
	HR [95 % CI][c][d]		0.75 [0.20, 2.83]
	Heterogeneity p-value[e][d]		0.6012

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	3 (15.0%)	7 (41.2%)
Number of censored cases	n (%)	17 (85.0%)	10 (58.8%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	11 (55.0%)	10 (58.8%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.76, NC]	5.65 [2.79, 11.63]
	Median [95% CI]	NYR [2.92, NC]	11.63 [5.59, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [11.63, NC]
	p-value[b][d]		0.284
	HR [95 % CI][c][d]		0.42 [0.08, 2.14]
	Heterogeneity p-value[e][d]		0.2103

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	6 (30.0%)	9 (52.9%)
Number of censored cases	n (%)	14 (70.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	3.61 [2.76, NC]	5.62 [2.79, 10.18]
	Median [95% CI]	24.08 [2.92, NC]	13.50 [2.83, NC]
	Q3 [95% CI]	24.08 [18.23, NC]	34.86 [10.18, NC]
	p-value[b][d]		0.759
	HR [95 % CI][c][d]		0.79 [0.19, 3.22]
	Heterogeneity p-value[e][d]		0.7590

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	6 (30.0%)	8 (47.1%)
Number of censored cases	n (%)	14 (70.0%)	9 (52.9%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	9 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.76, 14.32]	5.78 [2.79, 13.73]
	Median [95% CI]	14.32 [2.92, NC]	13.73 [5.78, NC]
	Q3 [95% CI]	NYR [14.32, NC]	19.22 [8.41, NC]
	p-value[b][d]		0.856
	HR [95 % CI][c][d]		0.89 [0.24, 3.23]
	Heterogeneity p-value[e][d]		0.8807

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	8 (40.0%)	11 (64.7%)
Number of censored cases	n (%)	12 (60.0%)	6 (35.3%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	6 (30.0%)	6 (35.3%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.76, 3.61]	2.92 [2.79, 8.31]
	Median [95% CI]	14.32 [2.92, NC]	8.31 [2.83, 10.81]
	Q3 [95% CI]	24.08 [3.61, NC]	10.81 [8.31, NC]
	p-value[b][d]		0.393
	HR [95 % CI][c][d]		0.61 [0.19, 2.00]
	Heterogeneity p-value[e][d]		0.3821

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	8 (40.0%)	8 (47.1%)
Number of censored cases	n (%)	12 (60.0%)	9 (52.9%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	1 (5.9%)
No first deterioration	n (%)	6 (30.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	6.87 [2.76, 8.54]	2.89 [2.79, 5.65]
	Median [95% CI]	8.54 [2.92, NC]	8.31 [2.89, NC]
	Q3 [95% CI]	24.08 [8.54, NC]	NYR [8.31, NC]
	p-value[b][d]		0.387
	HR [95 % CI][c][d]		0.57 [0.15, 2.08]
	Heterogeneity p-value[e][d]		0.5845

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	2 (10.0%)	1 (5.9%)
Number of censored cases	n (%)	18 (90.0%)	16 (94.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	1 (5.9%)
No first deterioration	n (%)	12 (60.0%)	15 (88.2%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.92, NC]	NYR [2.79, NC]
	Median [95% CI]	NYR [10.97, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.733
	HR [95 % CI][c][d]		1.52 [0.13, 17.56]
	Heterogeneity p-value[e][d]		0.6834

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	2 (10.0%)	3 (17.6%)
Number of censored cases	n (%)	18 (90.0%)	14 (82.4%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	12 (60.0%)	14 (82.4%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.76, NC]	17.87 [2.79, NC]
	Median [95% CI]	NYR [6.87, NC]	NYR [17.87, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [17.87, NC]
	p-value[b][d]		0.399
	HR [95 % CI][c][d]		0.38 [0.04, 3.89]
	Heterogeneity p-value[e][d]		0.6665

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	7 (35.0%)	5 (29.4%)
Number of censored cases	n (%)	13 (65.0%)	12 (70.6%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	7 (35.0%)	12 (70.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.59, 13.63]	11.63 [2.79, 22.14]
	Median [95% CI]	13.63 [5.59, NC]	22.14 [8.31, NC]
	Q3 [95% CI]	NYR [13.63, NC]	NYR [22.14, NC]
	p-value[b][d]		0.076
	HR [95 % CI][c][d]		4.81 [0.78, 29.59]
	Heterogeneity p-value[e][d]		0.3043

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	7 (35.0%)	7 (41.2%)
Number of censored cases	n (%)	13 (65.0%)	10 (58.8%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	2 (11.8%)
No first deterioration	n (%)	7 (35.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.76, 6.37]	5.78 [2.83, 15.08]
	Median [95% CI]	8.44 [2.83, NC]	15.08 [5.55, NC]
	Q3 [95% CI]	NYR [6.37, NC]	NYR [8.31, NC]
	p-value[b][d]		0.170
	HR [95 % CI][c][d]		3.11 [0.62, 15.70]
	Heterogeneity p-value[e][d]		0.5502

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	4 (20.0%)	6 (35.3%)
Number of censored cases	n (%)	16 (80.0%)	11 (64.7%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	1 (5.0%)	0
No first deterioration	n (%)	9 (45.0%)	11 (64.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.49 [10.97, 24.08]	10.45 [2.79, 31.18]
	Median [95% CI]	24.08 [10.97, NC]	18.00 [10.45, NC]
	Q3 [95% CI]	NYR [14.49, NC]	31.18 [18.00, NC]
	p-value[b][d]		0.389
	HR [95 % CI][c][d]		0.47 [0.09, 2.58]
	Heterogeneity p-value[e][d]		0.4797

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	4 (20.0%)	6 (35.3%)
Number of censored cases	n (%)	16 (80.0%)	11 (64.7%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	10 (50.0%)	11 (64.7%)
Time to first deterioration (months)	Q1 [95% CI]	6.87 [0.72, NC]	6.24 [2.79, NC]
	Median [95% CI]	NYR [5.68, NC]	NYR [6.24, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [10.81, NC]
	p-value[b][d]		0.952
	HR [95 % CI][c][d]		1.04 [0.27, 4.00]
	Heterogeneity p-value[e][d]		0.5898

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	3 (15.0%)	4 (23.5%)
Number of censored cases	n (%)	17 (85.0%)	13 (76.5%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	11 (55.0%)	13 (76.5%)
Time to first deterioration (months)	Q1 [95% CI]	9.03 [2.92, NC]	5.72 [2.79, NC]
	Median [95% CI]	NYR [8.34, NC]	NYR [5.72, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.993
	HR [95 % CI][c][d]		1.01 [0.16, 6.43]
	Heterogeneity p-value[e][d]		0.8386

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	77 (46.4%)	65 (36.7%)
Number of censored cases	n (%)	89 (53.6%)	112 (63.3%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	71 (42.8%)	88 (49.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.02, 5.68]	5.55 [2.89, 6.28]
	Median [95% CI]	15.51 [8.44, 35.98]	23.26 [9.33, 50.92]
	Q3 [95% CI]	41.46 [37.06, NC]	50.92 [45.83, NC]
	p-value[b][d]		0.277
	HR [95 % CI][c][d]		1.20 [0.86, 1.68]
	Heterogeneity p-value[e][d]		0.3483

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	63 (38.0%)	54 (30.5%)
Number of censored cases	n (%)	103 (62.0%)	123 (69.5%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	84 (50.6%)	99 (55.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.29, 10.64]	7.85 [5.55, 9.33]
	Median [95% CI]	21.68 [17.58, 39.82]	34.83 [13.93, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.666
	HR [95 % CI][c][d]		1.08 [0.75, 1.56]
	Heterogeneity p-value[e][d]		0.1570

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	80 (48.2%)	67 (37.9%)
Number of censored cases	n (%)	86 (51.8%)	110 (62.1%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	4 (2.4%)	0
No first deterioration	n (%)	64 (38.6%)	86 (48.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.62]	5.55 [2.89, 8.34]
	Median [95% CI]	11.20 [8.44, 18.00]	13.86 [9.82, 36.40]
	Q3 [95% CI]	NYR [23.03, NC]	NYR [NC, NC]
	p-value[b][d]		0.344
	HR [95 % CI][c][d]		1.17 [0.84, 1.62]
	Heterogeneity p-value[e][d]		0.7792

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	59 (35.5%)	62 (35.0%)
Number of censored cases	n (%)	107 (64.5%)	115 (65.0%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	88 (53.0%)	90 (50.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.99, 8.44]	5.65 [5.55, 6.74]
	Median [95% CI]	27.93 [14.98, NC]	22.21 [10.61, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.498
	HR [95 % CI][c][d]		0.88 [0.62, 1.26]
	Heterogeneity p-value[e][d]		0.2932

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	77 (46.4%)	68 (38.4%)
Number of censored cases	n (%)	89 (53.6%)	109 (61.6%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	71 (42.8%)	84 (47.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.68]	5.62 [2.89, 8.31]
	Median [95% CI]	14.46 [10.32, 24.08]	14.09 [10.18, 22.41]
	Q3 [95% CI]	46.03 [31.77, NC]	51.12 [25.69, NC]
	p-value[b][d]		0.863
	HR [95 % CI][c][d]		1.03 [0.74, 1.43]
	Heterogeneity p-value[e][d]		0.1203

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	76 (45.8%)	66 (37.3%)
Number of censored cases	n (%)	90 (54.2%)	111 (62.7%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	72 (43.4%)	86 (48.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.78, 5.98]	5.55 [2.89, 5.62]
	Median [95% CI]	15.38 [8.44, 25.13]	17.77 [8.41, 45.83]
	Q3 [95% CI]	46.95 [31.77, NC]	NYR [45.83, NC]
	p-value[b][d]		0.869
	HR [95 % CI][c][d]		1.03 [0.74, 1.43]
	Heterogeneity p-value[e][d]		0.5308

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	100 (60.2%)	83 (46.9%)
Number of censored cases	n (%)	66 (39.8%)	94 (53.1%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	47 (28.3%)	69 (39.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.92]
	Median [95% CI]	5.62 [5.55, 8.38]	8.38 [5.78, 10.61]
	Q3 [95% CI]	24.08 [18.33, 41.26]	NYR [13.86, NC]
	p-value[b][d]		0.204
	HR [95 % CI][c][d]		1.20 [0.90, 1.61]
	Heterogeneity p-value[e][d]		0.3093

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	88 (53.0%)	77 (43.5%)
Number of censored cases	n (%)	78 (47.0%)	100 (56.5%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	59 (35.5%)	75 (42.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.68]	5.55 [2.92, 5.78]
	Median [95% CI]	10.87 [8.34, 15.08]	13.93 [9.33, 29.57]
	Q3 [95% CI]	33.61 [21.68, NC]	46.16 [34.07, NC]
	p-value[b][d]		0.091
	HR [95 % CI][c][d]		1.31 [0.96, 1.78]
	Heterogeneity p-value[e][d]		0.2630

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	41 (24.7%)	25 (14.1%)
Number of censored cases	n (%)	125 (75.3%)	152 (85.9%)
No baseline score	n (%)	13 (7.8%)	17 (9.6%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	3 (1.8%)	2 (1.1%)
No first deterioration	n (%)	104 (62.7%)	125 (70.6%)
Time to first deterioration (months)	Q1 [95% CI]	13.86 [8.34, 25.63]	40.05 [9.95, NC]
	Median [95% CI]	NYR [30.65, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.069
	HR [95 % CI][c][d]		1.59 [0.96, 2.62]
	Heterogeneity p-value[e][d]		0.1036

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	43 (25.9%)	42 (23.7%)
Number of censored cases	n (%)	123 (74.1%)	135 (76.3%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	105 (63.3%)	111 (62.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [8.48, 21.59]	8.44 [5.55, 25.56]
	Median [95% CI]	NYR [30.59, NC]	45.83 [30.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.496
	HR [95 % CI][c][d]		0.86 [0.56, 1.32]
	Heterogeneity p-value[e][d]		0.6369

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	63 (38.0%)	47 (26.6%)
Number of censored cases	n (%)	103 (62.0%)	130 (73.4%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	2 (1.2%)	0
No first deterioration	n (%)	83 (50.0%)	106 (59.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.62, 12.52]	8.41 [5.65, 11.37]
	Median [95% CI]	25.59 [17.77, 30.98]	43.56 [21.72, NC]
	Q3 [95% CI]	44.65 [34.27, NC]	NYR [NC, NC]
	p-value[b][d]		0.291
	HR [95 % CI][c][d]		1.23 [0.84, 1.80]
	Heterogeneity p-value[e][d]		0.2211

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	64 (38.6%)	53 (29.9%)
Number of censored cases	n (%)	102 (61.4%)	124 (70.1%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	4 (2.4%)	5 (2.8%)
No first deterioration	n (%)	80 (48.2%)	95 (53.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.06, 6.41]	6.11 [2.96, 8.51]
	Median [95% CI]	21.22 [11.24, NC]	34.53 [16.89, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.364
	HR [95 % CI][c][d]		1.18 [0.82, 1.71]
	Heterogeneity p-value[e][d]		0.8876

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	47 (28.3%)	36 (20.3%)
Number of censored cases	n (%)	119 (71.7%)	141 (79.7%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	3 (1.8%)	5 (2.8%)
No first deterioration	n (%)	98 (59.0%)	112 (63.3%)
Time to first deterioration (months)	Q1 [95% CI]	12.52 [6.97, 17.58]	9.95 [5.55, 45.83]
	Median [95% CI]	NYR [22.51, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.276
	HR [95 % CI][c][d]		1.27 [0.82, 1.97]
	Heterogeneity p-value[e][d]		0.6920

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	55 (33.1%)	52 (29.4%)
Number of censored cases	n (%)	111 (66.9%)	125 (70.6%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	2 (1.1%)
No first deterioration	n (%)	93 (56.0%)	99 (55.9%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.68, 15.54]	8.51 [5.59, 11.07]
	Median [95% CI]	31.77 [23.03, NC]	28.81 [21.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.697
	HR [95 % CI][c][d]		0.93 [0.63, 1.36]
	Heterogeneity p-value[e][d]		0.6032

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	42 (25.3%)	37 (20.9%)
Number of censored cases	n (%)	124 (74.7%)	140 (79.1%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	105 (63.3%)	116 (65.5%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [8.34, 21.88]	9.95 [5.68, 28.81]
	Median [95% CI]	NYR [27.07, NC]	NYR [28.81, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.875
	HR [95 % CI][c][d]		0.96 [0.61, 1.50]
	Heterogeneity p-value[e][d]		0.5287

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	20 (46.5%)	15 (51.7%)
Number of censored cases	n (%)	23 (53.5%)	14 (48.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	1 (3.4%)
No first deterioration	n (%)	14 (32.6%)	11 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.75 [2.83, 8.48]	3.84 [2.33, 5.65]
	Median [95% CI]	13.80 [5.85, 34.66]	8.31 [4.27, 11.43]
	Q3 [95% CI]	NYR [13.83, NC]	NYR [8.41, NC]
	p-value[b][d]		0.581
	HR [95 % CI][c][d]		0.82 [0.41, 1.63]
	Heterogeneity p-value[e][d]		0.3483

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	16 (37.2%)	15 (51.7%)
Number of censored cases	n (%)	27 (62.8%)	14 (48.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	18 (41.9%)	12 (41.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.83, 11.40]	2.89 [2.79, 5.55]
	Median [95% CI]	13.90 [8.34, NC]	5.72 [2.96, 18.00]
	Q3 [95% CI]	NYR [17.58, NC]	18.00 [8.31, NC]
	p-value[b][d]		0.230
	HR [95 % CI][c][d]		0.64 [0.31, 1.33]
	Heterogeneity p-value[e][d]		0.1570

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	25 (58.1%)	16 (55.2%)
Number of censored cases	n (%)	18 (41.9%)	13 (44.8%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	1 (2.3%)	0
No first deterioration	n (%)	8 (18.6%)	11 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.79, 5.65]	2.89 [2.79, 5.52]
	Median [95% CI]	6.74 [5.55, 8.51]	5.55 [3.48, 15.21]
	Q3 [95% CI]	13.83 [8.34, 34.66]	NYR [5.59, NC]
	p-value[b][d]		0.956
	HR [95 % CI][c][d]		0.98 [0.51, 1.89]
	Heterogeneity p-value[e][d]		0.7792

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	18 (41.9%)	9 (31.0%)
Number of censored cases	n (%)	25 (58.1%)	20 (69.0%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (37.2%)	18 (62.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.12, 10.68]	8.31 [2.83, 13.54]
	Median [95% CI]	11.37 [8.61, NC]	20.73 [8.31, NC]
	Q3 [95% CI]	NYR [12.65, NC]	NYR [13.54, NC]
	p-value[b][d]		0.499
	HR [95 % CI][c][d]		1.33 [0.58, 3.07]
	Heterogeneity p-value[e][d]		0.2932

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	18 (41.9%)	16 (55.2%)
Number of censored cases	n (%)	25 (58.1%)	13 (44.8%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (37.2%)	11 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.92, 8.51]	2.96 [2.79, 5.62]
	Median [95% CI]	13.90 [8.44, 24.94]	8.31 [2.96, 14.52]
	Q3 [95% CI]	NYR [18.23, NC]	14.52 [8.31, NC]
	p-value[b][d]		0.050
	HR [95 % CI][c][d]		0.48 [0.23, 1.01]
	Heterogeneity p-value[e][d]		0.1203

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	17 (39.5%)	13 (44.8%)
Number of censored cases	n (%)	26 (60.5%)	16 (55.2%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	1 (3.4%)
No first deterioration	n (%)	17 (39.5%)	13 (44.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.83, 13.60]	3.48 [2.33, 8.34]
	Median [95% CI]	13.90 [6.74, NC]	13.73 [3.48, NC]
	Q3 [95% CI]	NYR [14.32, NC]	NYR [13.73, NC]
	p-value[b][d]		0.786
	HR [95 % CI][c][d]		0.90 [0.43, 1.89]
	Heterogeneity p-value[e][d]		0.5308

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	26 (60.5%)	19 (65.5%)
Number of censored cases	n (%)	17 (39.5%)	10 (34.5%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (18.6%)	8 (27.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.79, 3.12]	2.89 [2.79, 3.48]
	Median [95% CI]	6.74 [2.92, 8.57]	4.27 [2.89, 8.31]
	Q3 [95% CI]	11.40 [8.34, NC]	8.31 [5.55, NC]
	p-value[b][d]		0.488
	HR [95 % CI][c][d]		0.80 [0.42, 1.50]
	Heterogeneity p-value[e][d]		0.3093

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	20 (46.5%)	15 (51.7%)
Number of censored cases	n (%)	23 (53.5%)	14 (48.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	1 (2.3%)	1 (3.4%)
No first deterioration	n (%)	13 (30.2%)	11 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	3.61 [2.76, 6.74]	2.96 [2.33, 3.84]
	Median [95% CI]	8.38 [5.59, 14.09]	5.59 [2.96, NC]
	Q3 [95% CI]	NYR [8.48, NC]	NYR [5.65, NC]
	p-value[b][d]		0.867
	HR [95 % CI][c][d]		0.95 [0.48, 1.87]
	Heterogeneity p-value[e][d]		0.2630

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	7 (16.3%)	8 (27.6%)
Number of censored cases	n (%)	36 (83.7%)	21 (72.4%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	2 (4.7%)	0
No first deterioration	n (%)	25 (58.1%)	19 (65.5%)
Time to first deterioration (months)	Q1 [95% CI]	14.09 [3.25, NC]	21.32 [2.79, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [21.32, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.197
	HR [95 % CI][c][d]		0.49 [0.17, 1.47]
	Heterogeneity p-value[e][d]		0.1036

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	10 (23.3%)	6 (20.7%)
Number of censored cases	n (%)	33 (76.7%)	23 (79.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	24 (55.8%)	21 (72.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [2.89, NC]	17.87 [2.86, NC]
	Median [95% CI]	45.70 [18.30, NC]	NYR [17.87, NC]
	Q3 [95% CI]	45.70 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		1.000
	HR [95 % CI][c][d]		1.00 [0.35, 2.85]
	Heterogeneity p-value[e][d]		0.6369

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	15 (34.9%)	14 (48.3%)
Number of censored cases	n (%)	28 (65.1%)	15 (51.7%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	1 (2.3%)	0
No first deterioration	n (%)	18 (41.9%)	13 (44.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [2.86, 14.46]	5.72 [2.79, 10.64]
	Median [95% CI]	21.42 [10.64, 33.91]	11.63 [8.31, NC]
	Q3 [95% CI]	33.91 [22.14, NC]	22.14 [11.63, NC]
	p-value[b][d]		0.283
	HR [95 % CI][c][d]		0.66 [0.31, 1.42]
	Heterogeneity p-value[e][d]		0.2211

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	23 (53.5%)	15 (51.7%)
Number of censored cases	n (%)	20 (46.5%)	14 (48.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	1 (2.3%)	1 (3.4%)
No first deterioration	n (%)	10 (23.3%)	11 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.83, 8.31]	2.96 [2.33, 8.31]
	Median [95% CI]	8.41 [6.37, 11.30]	8.31 [3.02, NC]
	Q3 [95% CI]	14.09 [8.61, NC]	38.70 [8.31, NC]
	p-value[b][d]		0.992
	HR [95 % CI][c][d]		1.00 [0.49, 2.04]
	Heterogeneity p-value[e][d]		0.8876

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	15 (34.9%)	10 (34.5%)
Number of censored cases	n (%)	28 (65.1%)	19 (65.5%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	1 (2.3%)	0
No first deterioration	n (%)	18 (41.9%)	17 (58.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 10.68]	8.31 [2.79, 18.00]
	Median [95% CI]	26.71 [5.59, NC]	18.00 [8.31, NC]
	Q3 [95% CI]	NYR [NC, NC]	31.18 [18.00, NC]
	p-value[b][d]		0.941
	HR [95 % CI][c][d]		1.04 [0.46, 2.35]
	Heterogeneity p-value[e][d]		0.6920

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	9 (20.9%)	8 (27.6%)
Number of censored cases	n (%)	34 (79.1%)	21 (72.4%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	1 (2.3%)	1 (3.4%)
No first deterioration	n (%)	24 (55.8%)	18 (62.1%)
Time to first deterioration (months)	Q1 [95% CI]	13.60 [3.25, NC]	8.31 [2.79, NC]
	Median [95% CI]	NYR [23.46, NC]	NYR [8.31, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [NC, NC]
	p-value[b][d]		0.364
	HR [95 % CI][c][d]		0.63 [0.23, 1.72]
	Heterogeneity p-value[e][d]		0.6032

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	12 (27.9%)	11 (37.9%)
Number of censored cases	n (%)	31 (72.1%)	18 (62.1%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	5 (11.6%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (51.2%)	16 (55.2%)
Time to first deterioration (months)	Q1 [95% CI]	8.48 [2.99, 25.79]	5.72 [2.89, 13.54]
	Median [95% CI]	NYR [9.03, NC]	13.83 [5.72, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [13.83, NC]
	p-value[b][d]		0.377
	HR [95 % CI][c][d]		0.68 [0.28, 1.62]
	Heterogeneity p-value[e][d]		0.5287

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	56 (42.1%)	54 (41.2%)
Number of censored cases	n (%)	77 (57.9%)	77 (58.8%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	60 (45.1%)	62 (47.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.75 [5.55, 8.38]	5.52 [2.86, 6.70]
	Median [95% CI]	16.39 [8.48, 35.98]	13.90 [8.41, 50.92]
	Q3 [95% CI]	NYR [35.98, NC]	50.92 [45.83, NC]
	p-value[b][d]		0.494
	HR [95 % CI][c][d]		0.87 [0.59, 1.28]
	Heterogeneity p-value[e][d]		0.0856

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	38 (28.6%)	40 (30.5%)
Number of censored cases	n (%)	95 (71.4%)	91 (69.5%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	1 (0.8%)	0
No first deterioration	n (%)	77 (57.9%)	76 (58.0%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.55, 14.23]	5.72 [3.48, 10.78]
	Median [95% CI]	NYR [17.68, NC]	NYR [14.98, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.419
	HR [95 % CI][c][d]		0.83 [0.53, 1.30]
	Heterogeneity p-value[e][d]		0.5175

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	63 (47.4%)	56 (42.7%)
Number of censored cases	n (%)	70 (52.6%)	75 (57.3%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	2 (1.5%)	0
No first deterioration	n (%)	51 (38.3%)	60 (45.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.02, 6.74]	4.27 [2.83, 5.72]
	Median [95% CI]	12.62 [8.48, 21.22]	10.94 [8.34, 36.40]
	Q3 [95% CI]	35.98 [23.03, NC]	NYR [36.40, NC]
	p-value[b][d]		0.917
	HR [95 % CI][c][d]		0.98 [0.68, 1.42]
	Heterogeneity p-value[e][d]		0.1729

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	43 (32.3%)	44 (33.6%)
Number of censored cases	n (%)	90 (67.7%)	87 (66.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	1 (0.8%)	0
No first deterioration	n (%)	72 (54.1%)	72 (55.0%)
Time to first deterioration (months)	Q1 [95% CI]	8.41 [5.59, 11.30]	6.70 [5.59, 8.38]
	Median [95% CI]	26.45 [14.46, NC]	25.36 [11.43, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.583
	HR [95 % CI][c][d]		0.88 [0.58, 1.36]
	Heterogeneity p-value[e][d]		0.8676

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	54 (40.6%)	52 (39.7%)
Number of censored cases	n (%)	79 (59.4%)	79 (60.3%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	62 (46.6%)	64 (48.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.12, 8.44]	5.55 [2.86, 8.51]
	Median [95% CI]	22.47 [11.30, 35.84]	14.52 [10.84, 34.86]
	Q3 [95% CI]	46.03 [35.84, NC]	51.12 [26.48, NC]
	p-value[b][d]		0.354
	HR [95 % CI][c][d]		0.83 [0.56, 1.23]
	Heterogeneity p-value[e][d]		0.7481

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	53 (39.8%)	48 (36.6%)
Number of censored cases	n (%)	80 (60.2%)	83 (63.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	63 (47.4%)	68 (51.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.55, 8.34]	5.55 [2.89, 7.85]
	Median [95% CI]	18.40 [10.48, 31.77]	25.86 [9.82, NC]
	Q3 [95% CI]	46.95 [31.77, NC]	NYR [NC, NC]
	p-value[b][d]		0.973
	HR [95 % CI][c][d]		1.00 [0.67, 1.50]
	Heterogeneity p-value[e][d]		0.8411

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	76 (57.1%)	70 (53.4%)
Number of censored cases	n (%)	57 (42.9%)	61 (46.6%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	1 (0.8%)	0
No first deterioration	n (%)	39 (29.3%)	46 (35.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.83 [2.83, 3.02]
	Median [95% CI]	5.62 [3.94, 8.57]	8.31 [5.55, 8.41]
	Q3 [95% CI]	24.08 [11.40, NC]	NYR [10.45, NC]
	p-value[b][d]		0.661
	HR [95 % CI][c][d]		0.92 [0.66, 1.30]
	Heterogeneity p-value[e][d]		0.1522

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	64 (48.1%)	60 (45.8%)
Number of censored cases	n (%)	69 (51.9%)	71 (54.2%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	2 (1.5%)	1 (0.8%)
No first deterioration	n (%)	50 (37.6%)	55 (42.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.68]	3.88 [2.89, 5.65]
	Median [95% CI]	10.87 [8.34, 17.58]	13.60 [8.38, 34.07]
	Q3 [95% CI]	30.19 [18.33, NC]	44.75 [39.16, NC]
	p-value[b][d]		0.291
	HR [95 % CI][c][d]		1.22 [0.85, 1.76]
	Heterogeneity p-value[e][d]		0.9597

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	21 (15.8%)	21 (16.0%)
Number of censored cases	n (%)	112 (84.2%)	110 (84.0%)
No baseline score	n (%)	11 (8.3%)	9 (6.9%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	2 (1.5%)	1 (0.8%)
No first deterioration	n (%)	93 (69.9%)	93 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	25.63 [11.24, NC]	23.95 [8.51, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.920
	HR [95 % CI][c][d]		0.97 [0.53, 1.80]
	Heterogeneity p-value[e][d]		0.1424

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	34 (25.6%)	28 (21.4%)
Number of censored cases	n (%)	99 (74.4%)	103 (78.6%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	82 (61.7%)	88 (67.2%)
Time to first deterioration (months)	Q1 [95% CI]	13.67 [8.44, 21.59]	14.75 [5.65, 45.83]
	Median [95% CI]	45.70 [30.59, NC]	45.83 [26.48, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.660
	HR [95 % CI][c][d]		1.12 [0.67, 1.86]
	Heterogeneity p-value[e][d]		0.1433

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	45 (33.8%)	39 (29.8%)
Number of censored cases	n (%)	88 (66.2%)	92 (70.2%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	2 (1.5%)	0
No first deterioration	n (%)	69 (51.9%)	77 (58.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.65, 13.63]	8.44 [8.31, 11.63]
	Median [95% CI]	22.18 [14.49, 30.98]	28.55 [15.93, NC]
	Q3 [95% CI]	NYR [30.98, NC]	NYR [43.56, NC]
	p-value[b][d]		0.659
	HR [95 % CI][c][d]		1.10 [0.71, 1.71]
	Heterogeneity p-value[e][d]		0.5942

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	57 (42.9%)	43 (32.8%)
Number of censored cases	n (%)	76 (57.1%)	88 (67.2%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	4 (3.0%)	5 (3.8%)
No first deterioration	n (%)	55 (41.4%)	68 (51.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.12, 6.41]	5.62 [2.89, 8.31]
	Median [95% CI]	11.30 [8.38, 21.22]	34.53 [16.89, NC]
	Q3 [95% CI]	NYR [31.38, NC]	NYR [NC, NC]
	p-value[b][d]		0.221
	HR [95 % CI][c][d]		1.28 [0.86, 1.92]
	Heterogeneity p-value[e][d]		0.3960

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[(a)]	n	133	131
Number of patients with events	n (%)	38 (28.6%)	27 (20.6%)
Number of censored cases	n (%)	95 (71.4%)	104 (79.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	1 (0.8%)	2 (1.5%)
No first deterioration	n (%)	77 (57.9%)	87 (66.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [5.59, 14.52]	18.00 [8.31, 45.83]
	Median [95% CI]	37.06 [21.22, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[(b)(d)]		0.234
	HR [95 % CI][(c)(d)]		1.35 [0.82, 2.23]
	Heterogeneity p-value[(e)(d)]		0.4410

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	38 (28.6%)	38 (29.0%)
Number of censored cases	n (%)	95 (71.4%)	93 (71.0%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	0	1 (0.8%)
No first deterioration	n (%)	78 (58.6%)	77 (58.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [8.28, 22.74]	8.34 [5.59, 11.07]
	Median [95% CI]	45.70 [23.33, NC]	34.53 [21.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.643
	HR [95 % CI][c][d]		0.90 [0.57, 1.42]
	Heterogeneity p-value[e][d]		0.9011

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	31 (23.3%)	32 (24.4%)
Number of censored cases	n (%)	102 (76.7%)	99 (75.6%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	6 (4.5%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	85 (63.9%)	84 (64.1%)
Time to first deterioration (months)	Q1 [95% CI]	14.72 [8.48, 25.59]	8.34 [5.68, 13.83]
	Median [95% CI]	NYR [27.07, NC]	NYR [28.81, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.270
	HR [95 % CI][c][d]		0.74 [0.45, 1.24]
	Heterogeneity p-value[e][d]		0.4194

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	41 (53.9%)	26 (34.7%)
Number of censored cases	n (%)	35 (46.1%)	49 (65.3%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	25 (32.9%)	37 (49.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.02 [2.83, 5.59]	5.55 [2.89, 6.28]
	Median [95% CI]	10.74 [5.59, 18.20]	22.21 [5.78, NC]
	Q3 [95% CI]	40.31 [18.20, NC]	NYR [27.47, NC]
	p-value[b][d]		0.039
	HR [95 % CI][c][d]		1.69 [1.02, 2.80]
	Heterogeneity p-value[e][d]		0.0856

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	41 (53.9%)	29 (38.7%)
Number of censored cases	n (%)	35 (46.1%)	46 (61.3%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	25 (32.9%)	35 (46.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.44]	5.65 [2.89, 8.38]
	Median [95% CI]	15.51 [8.44, 21.68]	12.12 [8.38, 18.46]
	Q3 [95% CI]	39.82 [20.60, NC]	34.83 [17.77, NC]
	p-value[b][d]		0.940
	HR [95 % CI][c][d]		1.02 [0.62, 1.68]
	Heterogeneity p-value[e][d]		0.5175

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	42 (55.3%)	27 (36.0%)
Number of censored cases	n (%)	34 (44.7%)	48 (64.0%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	3 (3.9%)	0
No first deterioration	n (%)	21 (27.6%)	37 (49.3%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.79, 5.59]	3.84 [2.89, 8.41]
	Median [95% CI]	8.34 [5.59, 14.06]	11.33 [5.78, NC]
	Q3 [95% CI]	34.37 [14.06, NC]	NYR [17.58, NC]
	p-value[b][d]		0.100
	HR [95 % CI][c][d]		1.53 [0.92, 2.54]
	Heterogeneity p-value[e][d]		0.1729

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	34 (44.7%)	27 (36.0%)
Number of censored cases	n (%)	42 (55.3%)	48 (64.0%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	32 (42.1%)	36 (48.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.68]	5.55 [2.89, 6.74]
	Median [95% CI]	14.06 [8.31, NC]	22.21 [6.74, 34.30]
	Q3 [95% CI]	NYR [40.31, NC]	NYR [22.47, NC]
	p-value[b][d]		0.893
	HR [95 % CI][c][d]		0.96 [0.56, 1.63]
	Heterogeneity p-value[e][d]		0.8676

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	41 (53.9%)	32 (42.7%)
Number of censored cases	n (%)	35 (46.1%)	43 (57.3%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	25 (32.9%)	31 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.68]	5.62 [2.86, 6.11]
	Median [95% CI]	10.32 [5.78, 15.38]	8.41 [5.78, 14.29]
	Q3 [95% CI]	40.31 [15.38, NC]	22.34 [11.37, NC]
	p-value[b][d]		0.829
	HR [95 % CI][c][d]		0.95 [0.59, 1.53]
	Heterogeneity p-value[e][d]		0.7481

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	40 (52.6%)	31 (41.3%)
Number of censored cases	n (%)	36 (47.4%)	44 (58.7%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	2 (2.7%)
No first deterioration	n (%)	26 (34.2%)	31 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.78 [2.83, 5.62]	2.96 [2.86, 5.75]
	Median [95% CI]	10.81 [5.62, 16.33]	8.61 [5.75, 13.73]
	Q3 [95% CI]	40.31 [16.33, NC]	17.77 [12.12, NC]
	p-value[b][d]		0.785
	HR [95 % CI][c][d]		0.93 [0.57, 1.52]
	Heterogeneity p-value[e][d]		0.8411

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	50 (65.8%)	32 (42.7%)
Number of censored cases	n (%)	26 (34.2%)	43 (57.3%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	16 (21.1%)	31 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 2.92]	2.89 [2.79, 5.55]
	Median [95% CI]	5.68 [3.78, 8.34]	8.31 [5.55, 34.83]
	Q3 [95% CI]	21.68 [8.44, 40.31]	NYR [11.40, NC]
	p-value[b][d]		0.155
	HR [95 % CI][c][d]		1.37 [0.87, 2.16]
	Heterogeneity p-value[e][d]		0.1522

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	44 (57.9%)	32 (42.7%)
Number of censored cases	n (%)	32 (42.1%)	43 (57.3%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	22 (28.9%)	31 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.68]	3.09 [2.86, 5.62]
	Median [95% CI]	8.38 [5.72, 18.00]	10.97 [5.62, 29.57]
	Q3 [95% CI]	33.61 [18.00, NC]	46.16 [23.49, NC]
	p-value[b][d]		0.502
	HR [95 % CI][c][d]		1.18 [0.74, 1.88]
	Heterogeneity p-value[e][d]		0.9597

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	27 (35.5%)	12 (16.0%)
Number of censored cases	n (%)	49 (64.5%)	63 (84.0%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	3 (3.9%)	1 (1.3%)
No first deterioration	n (%)	36 (47.4%)	51 (68.0%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.55, 13.14]	30.65 [2.92, NC]
	Median [95% CI]	30.65 [13.14, NC]	NYR [30.65, NC]
	Q3 [95% CI]	NYR [34.37, NC]	NYR [NC, NC]
	p-value[b][d]		0.068
	HR [95 % CI][c][d]		1.95 [0.94, 4.01]
	Heterogeneity p-value[e][d]		0.1424

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	19 (25.0%)	20 (26.7%)
Number of censored cases	n (%)	57 (75.0%)	55 (73.3%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	47 (61.8%)	44 (58.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [5.68, 40.31]	5.65 [2.92, 17.87]
	Median [95% CI]	NYR [40.31, NC]	30.75 [10.81, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.106
	HR [95 % CI][c][d]		0.58 [0.30, 1.13]
	Heterogeneity p-value[e][d]		0.1433

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	33 (43.4%)	22 (29.3%)
Number of censored cases	n (%)	43 (56.6%)	53 (70.7%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	32 (42.1%)	42 (56.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 14.06]	5.55 [2.86, 9.69]
	Median [95% CI]	26.48 [14.09, 34.27]	NYR [9.69, NC]
	Q3 [95% CI]	41.26 [33.91, NC]	NYR [NC, NC]
	p-value[b][d]		0.739
	HR [95 % CI][c][d]		1.10 [0.63, 1.92]
	Heterogeneity p-value[e][d]		0.5942

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	30 (39.5%)	25 (33.3%)
Number of censored cases	n (%)	46 (60.5%)	50 (66.7%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	1 (1.3%)	1 (1.3%)
No first deterioration	n (%)	35 (46.1%)	38 (50.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.31]	5.78 [2.89, 8.51]
	Median [95% CI]	39.82 [8.31, NC]	14.59 [8.38, NC]
	Q3 [95% CI]	NYR [39.82, NC]	38.70 [22.28, NC]
	p-value[b][d]		0.590
	HR [95 % CI][c][d]		0.86 [0.49, 1.52]
	Heterogeneity p-value[e][d]		0.3960

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	24 (31.6%)	19 (25.3%)
Number of censored cases	n (%)	52 (68.4%)	56 (74.7%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	3 (3.9%)	3 (4.0%)
No first deterioration	n (%)	39 (51.3%)	42 (56.0%)
Time to first deterioration (months)	Q1 [95% CI]	8.38 [2.99, 17.77]	5.59 [2.86, 15.70]
	Median [95% CI]	NYR [17.77, NC]	NYR [15.70, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.945
	HR [95 % CI][c][d]		0.98 [0.52, 1.85]
	Heterogeneity p-value[e][d]		0.4410

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	26 (34.2%)	22 (29.3%)
Number of censored cases	n (%)	50 (65.8%)	53 (70.7%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	1 (1.3%)	2 (2.7%)
No first deterioration	n (%)	39 (51.3%)	40 (53.3%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [5.55, 17.87]	8.61 [2.89, 18.53]
	Median [95% CI]	39.46 [17.87, NC]	27.56 [14.69, NC]
	Q3 [95% CI]	NYR [43.96, NC]	NYR [30.65, NC]
	p-value[b][d]		0.675
	HR [95 % CI][c][d]		0.88 [0.49, 1.59]
	Heterogeneity p-value[e][d]		0.9011

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	23 (30.3%)	16 (21.3%)
Number of censored cases	n (%)	53 (69.7%)	59 (78.7%)
No baseline score	n (%)	6 (7.9%)	8 (10.7%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	42 (55.3%)	48 (64.0%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.62, 20.50]	18.79 [3.09, 25.66]
	Median [95% CI]	NYR [20.50, NC]	NYR [21.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.654
	HR [95 % CI][c][d]		1.17 [0.60, 2.28]
	Heterogeneity p-value[e][d]		0.4194

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	56 (44.8%)	45 (38.5%)
Number of censored cases	n (%)	69 (55.2%)	72 (61.5%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	53 (42.4%)	59 (50.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.62]	4.27 [2.89, 6.11]
	Median [95% CI]	11.30 [6.67, 21.03]	22.21 [8.41, NC]
	Q3 [95% CI]	NYR [35.98, NC]	NYR [45.83, NC]
	p-value[b][d]		0.415
	HR [95 % CI][c][d]		1.18 [0.79, 1.76]
	Heterogeneity p-value[e][d]		0.6622

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	43 (34.4%)	38 (32.5%)
Number of censored cases	n (%)	82 (65.6%)	79 (67.5%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	66 (52.8%)	66 (56.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [3.02, 17.58]	5.65 [2.96, 8.41]
	Median [95% CI]	29.70 [17.68, NC]	34.83 [9.69, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.816
	HR [95 % CI][c][d]		0.95 [0.61, 1.49]
	Heterogeneity p-value[e][d]		0.7241

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	64 (51.2%)	42 (35.9%)
Number of censored cases	n (%)	61 (48.8%)	75 (64.1%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	45 (36.0%)	62 (53.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.92, 5.59]	5.55 [2.89, 6.51]
	Median [95% CI]	10.84 [8.28, 15.44]	13.86 [8.34, NC]
	Q3 [95% CI]	35.98 [18.00, NC]	NYR [NC, NC]
	p-value[b][d]		0.212
	HR [95 % CI][c][d]		1.29 [0.86, 1.92]
	Heterogeneity p-value[e][d]		0.3154

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	45 (36.0%)	38 (32.5%)
Number of censored cases	n (%)	80 (64.0%)	79 (67.5%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	64 (51.2%)	65 (55.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.29, 10.68]	5.65 [5.55, 8.34]
	Median [95% CI]	24.94 [12.65, NC]	22.47 [11.43, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.856
	HR [95 % CI][c][d]		1.04 [0.67, 1.62]
	Heterogeneity p-value[e][d]		0.5374

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	59 (47.2%)	48 (41.0%)
Number of censored cases	n (%)	66 (52.8%)	69 (59.0%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	50 (40.0%)	55 (47.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.96, 6.47]	5.55 [2.86, 5.78]
	Median [95% CI]	13.40 [8.34, 18.23]	10.84 [8.34, 22.41]
	Q3 [95% CI]	31.77 [18.99, NC]	51.12 [22.41, NC]
	p-value[b][d]		0.968
	HR [95 % CI][c][d]		1.00 [0.67, 1.50]
	Heterogeneity p-value[e][d]		0.3816

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	52 (41.6%)	42 (35.9%)
Number of censored cases	n (%)	73 (58.4%)	75 (64.1%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	57 (45.6%)	61 (52.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.99, 5.68]	5.55 [2.89, 8.34]
	Median [95% CI]	14.36 [8.48, 46.95]	11.30 [8.38, NC]
	Q3 [95% CI]	NYR [46.95, NC]	NYR [45.83, NC]
	p-value[b][d]		0.745
	HR [95 % CI][c][d]		1.07 [0.70, 1.63]
	Heterogeneity p-value[e][d]		0.6673

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	72 (57.6%)	55 (47.0%)
Number of censored cases	n (%)	53 (42.4%)	62 (53.0%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	37 (29.6%)	48 (41.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 2.92]	2.89 [2.83, 3.48]
	Median [95% CI]	5.59 [3.12, 8.44]	6.51 [5.55, 11.40]
	Q3 [95% CI]	26.81 [14.32, NC]	NYR [13.54, NC]
	p-value[b][d]		0.296
	HR [95 % CI][c][d]		1.21 [0.84, 1.74]
	Heterogeneity p-value[e][d]		0.7992

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	62 (49.6%)	51 (43.6%)
Number of censored cases	n (%)	63 (50.4%)	66 (56.4%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	1 (0.8%)	1 (0.9%)
No first deterioration	n (%)	46 (36.8%)	52 (44.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.68]	3.48 [2.89, 5.65]
	Median [95% CI]	10.91 [8.34, 18.00]	14.98 [8.38, 29.80]
	Q3 [95% CI]	33.61 [20.50, NC]	46.16 [29.80, NC]
	p-value[b][d]		0.219
	HR [95 % CI][c][d]		1.27 [0.87, 1.86]
	Heterogeneity p-value[e][d]		0.9466

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	27 (21.6%)	17 (14.5%)
Number of censored cases	n (%)	98 (78.4%)	100 (85.5%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	1 (0.8%)	2 (1.7%)
No first deterioration	n (%)	81 (64.8%)	85 (72.6%)
Time to first deterioration (months)	Q1 [95% CI]	14.09 [7.89, NC]	30.65 [10.64, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.564
	HR [95 % CI][c][d]		1.20 [0.64, 2.25]
	Heterogeneity p-value[e][d]		0.9702

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	30 (24.0%)	24 (20.5%)
Number of censored cases	n (%)	95 (76.0%)	93 (79.5%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	79 (63.2%)	80 (68.4%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [8.31, 27.07]	10.81 [5.65, 45.83]
	Median [95% CI]	NYR [45.70, NC]	45.83 [30.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.924
	HR [95 % CI][c][d]		0.97 [0.56, 1.68]
	Heterogeneity p-value[e][d]		0.4715

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	44 (35.2%)	33 (28.2%)
Number of censored cases	n (%)	81 (64.8%)	84 (71.8%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	3 (2.4%)	0
No first deterioration	n (%)	62 (49.6%)	71 (60.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.77 [5.68, 14.49]	8.41 [6.34, 13.83]
	Median [95% CI]	25.86 [17.77, 30.98]	40.71 [17.97, NC]
	Q3 [95% CI]	44.65 [29.73, NC]	NYR [40.71, NC]
	p-value[b][d]		0.491
	HR [95 % CI][c][d]		1.18 [0.74, 1.91]
	Heterogeneity p-value[e][d]		0.8830

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	52 (41.6%)	42 (35.9%)
Number of censored cases	n (%)	73 (58.4%)	75 (64.1%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	2 (1.6%)	2 (1.7%)
No first deterioration	n (%)	55 (44.0%)	60 (51.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [3.06, 5.68]	5.59 [2.89, 8.31]
	Median [95% CI]	14.09 [8.31, NC]	22.28 [8.51, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [38.70, NC]
	p-value[b][d]		0.734
	HR [95 % CI][c][d]		1.07 [0.70, 1.64]
	Heterogeneity p-value[e][d]		0.5463

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	38 (30.4%)	26 (22.2%)
Number of censored cases	n (%)	87 (69.6%)	91 (77.8%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	1 (0.8%)	2 (1.7%)
No first deterioration	n (%)	70 (56.0%)	76 (65.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [5.55, 14.52]	10.45 [5.55, 45.83]
	Median [95% CI]	33.74 [20.60, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.432
	HR [95 % CI][c][d]		1.23 [0.74, 2.03]
	Heterogeneity p-value[e][d]		0.9999

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	38 (30.4%)	34 (29.1%)
Number of censored cases	n (%)	87 (69.6%)	83 (70.9%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	71 (56.8%)	69 (59.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [5.68, 17.87]	10.45 [5.72, 11.40]
	Median [95% CI]	43.96 [21.62, NC]	28.81 [14.69, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.566
	HR [95 % CI][c][d]		0.87 [0.54, 1.40]
	Heterogeneity p-value[e][d]		0.9557

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	33 (26.4%)	33 (28.2%)
Number of censored cases	n (%)	92 (73.6%)	84 (71.8%)
No baseline score	n (%)	8 (6.4%)	9 (7.7%)
No post-baseline score	n (%)	8 (6.4%)	4 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	76 (60.8%)	71 (60.7%)
Time to first deterioration (months)	Q1 [95% CI]	10.61 [5.62, 21.88]	8.34 [3.88, 13.54]
	Median [95% CI]	NYR [25.59, NC]	28.81 [13.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.356
	HR [95 % CI][c][d]		0.79 [0.48, 1.29]
	Heterogeneity p-value[e][d]		0.3293

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	41 (48.8%)	35 (39.3%)
Number of censored cases	n (%)	43 (51.2%)	54 (60.7%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	32 (38.1%)	40 (44.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.85 [5.55, 8.44]	5.55 [2.86, 7.06]
	Median [95% CI]	15.51 [10.64, 34.66]	13.90 [8.31, NC]
	Q3 [95% CI]	40.31 [34.66, NC]	50.92 [27.47, NC]
	p-value[b][d]		0.912
	HR [95 % CI][c][d]		0.97 [0.60, 1.57]
	Heterogeneity p-value[e][d]		0.6622

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	36 (42.9%)	31 (34.8%)
Number of censored cases	n (%)	48 (57.1%)	58 (65.2%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	36 (42.9%)	45 (50.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, 8.44]	5.72 [2.89, 8.38]
	Median [95% CI]	15.51 [10.64, NC]	18.04 [8.38, NC]
	Q3 [95% CI]	NYR [27.63, NC]	NYR [25.79, NC]
	p-value[b][d]		0.809
	HR [95 % CI][c][d]		1.06 [0.65, 1.75]
	Heterogeneity p-value[e][d]		0.7241

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	41 (48.8%)	41 (46.1%)
Number of censored cases	n (%)	43 (51.2%)	48 (53.9%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	5 (6.0%)	0
No first deterioration	n (%)	27 (32.1%)	35 (39.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.89, 6.74]	2.92 [2.83, 5.75]
	Median [95% CI]	11.20 [8.28, 21.22]	10.94 [5.78, 17.58]
	Q3 [95% CI]	34.66 [21.22, NC]	36.40 [17.58, NC]
	p-value[b][d]		0.922
	HR [95 % CI][c][d]		0.98 [0.62, 1.54]
	Heterogeneity p-value[e][d]		0.3154

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	32 (38.1%)	33 (37.1%)
Number of censored cases	n (%)	52 (61.9%)	56 (62.9%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	40 (47.6%)	43 (48.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.86, 10.64]	5.62 [2.92, 8.38]
	Median [95% CI]	25.63 [11.27, NC]	17.54 [8.38, NC]
	Q3 [95% CI]	NYR [40.31, NC]	NYR [27.47, NC]
	p-value[b][d]		0.756
	HR [95 % CI][c][d]		0.93 [0.56, 1.53]
	Heterogeneity p-value[e][d]		0.5374

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	36 (42.9%)	36 (40.4%)
Number of censored cases	n (%)	48 (57.1%)	53 (59.6%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (44.0%)	40 (44.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.89, 8.48]	5.59 [2.86, 8.38]
	Median [95% CI]	18.40 [8.57, 46.03]	13.93 [8.38, 25.69]
	Q3 [95% CI]	46.03 [35.84, NC]	26.48 [21.45, NC]
	p-value[b][d]		0.234
	HR [95 % CI][c][d]		0.75 [0.46, 1.22]
	Heterogeneity p-value[e][d]		0.3816

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	41 (48.8%)	37 (41.6%)
Number of censored cases	n (%)	43 (51.2%)	52 (58.4%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	32 (38.1%)	38 (42.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.78, 8.34]	2.96 [2.86, 5.59]
	Median [95% CI]	14.23 [8.41, 25.63]	13.73 [5.62, 25.40]
	Q3 [95% CI]	40.31 [25.63, NC]	NYR [21.45, NC]
	p-value[b][d]		0.698
	HR [95 % CI][c][d]		0.91 [0.57, 1.46]
	Heterogeneity p-value[e][d]		0.6673

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	54 (64.3%)	47 (52.8%)
Number of censored cases	n (%)	30 (35.7%)	42 (47.2%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	18 (21.4%)	29 (32.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 3.61]	2.86 [2.79, 2.96]
	Median [95% CI]	6.74 [3.94, 8.57]	8.31 [5.55, 8.41]
	Q3 [95% CI]	15.51 [10.64, 41.26]	13.86 [8.41, NC]
	p-value[b][d]		0.956
	HR [95 % CI][c][d]		0.99 [0.65, 1.49]
	Heterogeneity p-value[e][d]		0.7992

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	46 (54.8%)	41 (46.1%)
Number of censored cases	n (%)	38 (45.2%)	48 (53.9%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	1 (1.2%)	1 (1.1%)
No first deterioration	n (%)	26 (31.0%)	34 (38.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 5.68]	3.09 [2.86, 8.25]
	Median [95% CI]	8.34 [5.72, 14.23]	10.97 [8.31, 22.34]
	Q3 [95% CI]	37.06 [14.23, NC]	44.75 [22.34, NC]
	p-value[b][d]		0.274
	HR [95 % CI][c][d]		1.28 [0.82, 2.00]
	Heterogeneity p-value[e][d]		0.9466

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	21 (25.0%)	16 (18.0%)
Number of censored cases	n (%)	63 (75.0%)	73 (82.0%)
No baseline score	n (%)	9 (10.7%)	8 (9.0%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	4 (4.8%)	0
No first deterioration	n (%)	48 (57.1%)	59 (66.3%)
Time to first deterioration (months)	Q1 [95% CI]	17.97 [5.59, 30.65]	23.95 [6.70, NC]
	Median [95% CI]	34.37 [25.63, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.404
	HR [95 % CI][c][d]		1.33 [0.69, 2.60]
	Heterogeneity p-value[e][d]		0.9702

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	23 (27.4%)	24 (27.0%)
Number of censored cases	n (%)	61 (72.6%)	65 (73.0%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	50 (59.5%)	52 (58.4%)
Time to first deterioration (months)	Q1 [95% CI]	13.67 [8.34, 26.41]	8.31 [2.92, 17.87]
	Median [95% CI]	40.31 [26.41, NC]	26.48 [17.87, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.167
	HR [95 % CI][c][d]		0.66 [0.36, 1.19]
	Heterogeneity p-value[e][d]		0.4715

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	34 (40.5%)	28 (31.5%)
Number of censored cases	n (%)	50 (59.5%)	61 (68.5%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	39 (46.4%)	48 (53.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.96, 11.33]	5.59 [2.89, 10.64]
	Median [95% CI]	21.22 [12.52, 41.26]	21.72 [10.64, NC]
	Q3 [95% CI]	NYR [33.91, NC]	NYR [NC, NC]
	p-value[b][d]		0.600
	HR [95 % CI][c][d]		1.15 [0.68, 1.94]
	Heterogeneity p-value[e][d]		0.8830

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	35 (41.7%)	26 (29.2%)
Number of censored cases	n (%)	49 (58.3%)	63 (70.8%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	3 (3.6%)	4 (4.5%)
No first deterioration	n (%)	35 (41.7%)	46 (51.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.92, 8.38]	6.70 [2.89, 14.59]
	Median [95% CI]	14.46 [8.38, NC]	23.26 [14.59, NC]
	Q3 [95% CI]	NYR [31.38, NC]	NYR [34.53, NC]
	p-value[b][d]		0.280
	HR [95 % CI][c][d]		1.33 [0.79, 2.25]
	Heterogeneity p-value[e][d]		0.5463

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	24 (28.6%)	20 (22.5%)
Number of censored cases	n (%)	60 (71.4%)	69 (77.5%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	3 (3.6%)	3 (3.4%)
No first deterioration	n (%)	46 (54.8%)	53 (59.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [5.59, 21.22]	8.38 [2.86, 31.18]
	Median [95% CI]	NYR [21.22, NC]	NYR [28.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.386
	HR [95 % CI][c][d]		1.31 [0.71, 2.44]
	Heterogeneity p-value[e][d]		0.9999

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	26 (31.0%)	26 (29.2%)
Number of censored cases	n (%)	58 (69.0%)	63 (70.8%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	1 (1.2%)	2 (2.2%)
No first deterioration	n (%)	46 (54.8%)	48 (53.9%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.59, 23.33]	5.72 [2.89, 15.15]
	Median [95% CI]	39.46 [23.23, NC]	30.69 [15.15, NC]
	Q3 [95% CI]	NYR [39.46, NC]	NYR [NC, NC]
	p-value[b][d]		0.571
	HR [95 % CI][c][d]		0.85 [0.49, 1.48]
	Heterogeneity p-value[e][d]		0.9557

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	21 (25.0%)	15 (16.9%)
Number of censored cases	n (%)	63 (75.0%)	74 (83.1%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	2 (2.4%)	6 (6.7%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	51 (60.7%)	61 (68.5%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [8.34, 41.46]	21.65 [5.65, NC]
	Median [95% CI]	NYR [24.74, NC]	NYR [32.89, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.873
	HR [95 % CI][c][d]		1.06 [0.53, 2.09]
	Heterogeneity p-value[e][d]		0.3293

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	28 (50.0%)	30 (46.2%)
Number of censored participants, n (%)	28 (50.0%)	35 (53.8%)
Proportionality Test p-value[a][b]	0.8491	
Hazard ratio(interaction)	1.085 (0.470, 2.504)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	20 (35.7%)	21 (32.3%)
Number of censored participants, n (%)	36 (64.3%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.6452	
Hazard ratio(interaction)	0.817 (0.345, 1.934)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	28 (43.1%)
Number of censored participants, n (%)	27 (48.2%)	37 (56.9%)
Proportionality Test p-value[a][b]	0.3359	
Hazard ratio(interaction)	0.680 (0.310, 1.491)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	27 (41.5%)
Number of censored participants, n (%)	27 (48.2%)	38 (58.5%)
Proportionality Test p-value[a][b]	0.1549	
Hazard ratio(interaction)	1.933 (0.779, 4.794)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	30 (53.6%)	33 (50.8%)
Number of censored participants, n (%)	26 (46.4%)	32 (49.2%)
Proportionality Test p-value[a][b]	0.4738	
Hazard ratio(interaction)	1.335 (0.606, 2.940)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	24 (42.9%)	36 (55.4%)
Number of censored participants, n (%)	32 (57.1%)	29 (44.6%)
Proportionality Test p-value[a][b]	0.9520	
Hazard ratio(interaction)	0.979 (0.483, 1.984)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	36 (64.3%)	37 (56.9%)
Number of censored participants, n (%)	20 (35.7%)	28 (43.1%)
Proportionality Test p-value[a][b]	0.3578	
Hazard ratio(interaction)	1.438 (0.663, 3.119)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	13 (23.2%)	18 (27.7%)
Number of censored participants, n (%)	43 (76.8%)	47 (72.3%)
Proportionality Test p-value[a][b]	0.7580	
Hazard ratio(interaction)	1.174 (0.424, 3.250)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Pain (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	30 (53.6%)	35 (53.8%)
Number of censored participants, n (%)	26 (46.4%)	30 (46.2%)
Proportionality Test p-value[a][b]	0.9275	
Hazard ratio(interaction)	1.037 (0.473, 2.275)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	28 (50.0%)	21 (32.3%)
Number of censored participants, n (%)	28 (50.0%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.8834	
Hazard ratio(interaction)	1.054 (0.520, 2.139)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	25 (44.6%)	29 (44.6%)
Number of censored participants, n (%)	31 (55.4%)	36 (55.4%)
Proportionality Test p-value[a][b]	0.3940	
Hazard ratio(interaction)	0.693 (0.298, 1.610)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	17 (30.4%)	15 (23.1%)
Number of censored participants, n (%)	39 (69.6%)	50 (76.9%)
Proportionality Test p-value[a][b]	0.3251	
Hazard ratio(interaction)	1.672 (0.600, 4.657)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	11 (19.6%)	17 (26.2%)
Number of censored participants, n (%)	45 (80.4%)	48 (73.8%)
Proportionality Test p-value[a][b]	0.8894	
Hazard ratio(interaction)	0.936 (0.370, 2.367)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	15 (26.8%)	22 (33.8%)
Number of censored participants, n (%)	41 (73.2%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.3634	
Hazard ratio(interaction)	0.600 (0.200, 1.805)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	12 (21.4%)	14 (21.5%)
Number of censored participants, n (%)	44 (78.6%)	51 (78.5%)
Proportionality Test p-value[a][b]	0.4339	
Hazard ratio(interaction)	0.683 (0.262, 1.776)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	69 (45.1%)	50 (35.5%)
Number of censored participants, n (%)	84 (54.9%)	91 (64.5%)
Proportionality Test p-value[a][b]	0.0357	
Hazard ratio(interaction)	0.570 (0.337, 0.963)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	59 (38.6%)	48 (34.0%)
Number of censored participants, n (%)	94 (61.4%)	93 (66.0%)
Proportionality Test p-value[a][b]	0.5269	
Hazard ratio(interaction)	0.845 (0.503, 1.422)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	76 (49.7%)	55 (39.0%)
Number of censored participants, n (%)	77 (50.3%)	86 (61.0%)
Proportionality Test p-value[a][b]	0.1987	
Hazard ratio(interaction)	0.715 (0.428, 1.193)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	48 (31.4%)	44 (31.2%)
Number of censored participants, n (%)	105 (68.6%)	97 (68.8%)
Proportionality Test p-value[a][b]	0.7892	
Hazard ratio(interaction)	1.082 (0.606, 1.934)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	65 (42.5%)	51 (36.2%)
Number of censored participants, n (%)	88 (57.5%)	90 (63.8%)
Proportionality Test p-value[a][b]	0.9840	
Hazard ratio(interaction)	0.995 (0.591, 1.673)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	69 (45.1%)	43 (30.5%)
Number of censored participants, n (%)	84 (54.9%)	98 (69.5%)
Proportionality Test p-value[a][b]	0.0720	
Hazard ratio(interaction)	0.612 (0.358, 1.045)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	90 (58.8%)	65 (46.1%)
Number of censored participants, n (%)	63 (41.2%)	76 (53.9%)
Proportionality Test p-value[a][b]	0.4011	
Hazard ratio(interaction)	0.812 (0.499, 1.321)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	40 (26.1%)	30 (21.3%)
Number of censored participants, n (%)	113 (73.9%)	111 (78.7%)
Proportionality Test p-value[a][b]	0.1702	
Hazard ratio(interaction)	0.660 (0.364, 1.195)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Pain (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	78 (51.0%)	57 (40.4%)
Number of censored participants, n (%)	75 (49.0%)	84 (59.6%)
Proportionality Test p-value[a][b]	0.1238	
Hazard ratio(interaction)	0.709 (0.458, 1.099)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	50 (32.7%)	40 (28.4%)
Number of censored participants, n (%)	103 (67.3%)	101 (71.6%)
Proportionality Test p-value[a][b]	0.0509	
Hazard ratio(interaction)	0.575 (0.330, 1.002)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	62 (40.5%)	39 (27.7%)
Number of censored participants, n (%)	91 (59.5%)	102 (72.3%)
Proportionality Test p-value[a][b]	0.9508	
Hazard ratio(interaction)	0.981 (0.534, 1.801)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	45 (29.4%)	31 (22.0%)
Number of censored participants, n (%)	108 (70.6%)	110 (78.0%)
Proportionality Test p-value[a][b]	0.0135	
Hazard ratio(interaction)	0.456 (0.245, 0.850)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	53 (34.6%)	43 (30.5%)
Number of censored participants, n (%)	100 (65.4%)	98 (69.5%)
Proportionality Test p-value[a][b]	0.7701	
Hazard ratio(interaction)	0.929 (0.568, 1.520)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	39 (25.5%)	26 (18.4%)
Number of censored participants, n (%)	114 (74.5%)	115 (81.6%)
Proportionality Test p-value[a][b]	0.9405	
Hazard ratio(interaction)	0.976 (0.515, 1.849)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	36 (23.5%)	19 (13.5%)
Number of censored participants, n (%)	117 (76.5%)	122 (86.5%)
Proportionality Test p-value[a][b]	0.8956	
Hazard ratio(interaction)	0.954 (0.469, 1.939)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	28 (50.0%)	30 (46.2%)
Number of censored participants, n (%)	28 (50.0%)	35 (53.8%)
Proportionality Test p-value[a][b]	0.8491	
Hazard ratio(interaction)	1.085 (0.470, 2.504)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	20 (35.7%)	21 (32.3%)
Number of censored participants, n (%)	36 (64.3%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.6452	
Hazard ratio(interaction)	0.817 (0.345, 1.934)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	28 (43.1%)
Number of censored participants, n (%)	27 (48.2%)	37 (56.9%)
Proportionality Test p-value[a][b]	0.3359	
Hazard ratio(interaction)	0.680 (0.310, 1.491)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	27 (41.5%)
Number of censored participants, n (%)	27 (48.2%)	38 (58.5%)
Proportionality Test p-value[a][b]	0.1549	
Hazard ratio(interaction)	1.933 (0.779, 4.794)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	30 (53.6%)	33 (50.8%)
Number of censored participants, n (%)	26 (46.4%)	32 (49.2%)
Proportionality Test p-value[a][b]	0.4738	
Hazard ratio(interaction)	1.335 (0.606, 2.940)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	24 (42.9%)	36 (55.4%)
Number of censored participants, n (%)	32 (57.1%)	29 (44.6%)
Proportionality Test p-value[a][b]	0.9520	
Hazard ratio(interaction)	0.979 (0.483, 1.984)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	36 (64.3%)	37 (56.9%)
Number of censored participants, n (%)	20 (35.7%)	28 (43.1%)
Proportionality Test p-value[a][b]	0.3578	
Hazard ratio(interaction)	1.438 (0.663, 3.119)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	13 (23.2%)	18 (27.7%)
Number of censored participants, n (%)	43 (76.8%)	47 (72.3%)
Proportionality Test p-value[a][b]	0.7580	
Hazard ratio(interaction)	1.174 (0.424, 3.250)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Pain (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	30 (53.6%)	35 (53.8%)
Number of censored participants, n (%)	26 (46.4%)	30 (46.2%)
Proportionality Test p-value[a][b]	0.9275	
Hazard ratio(interaction)	1.037 (0.473, 2.275)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	28 (50.0%)	21 (32.3%)
Number of censored participants, n (%)	28 (50.0%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.8834	
Hazard ratio(interaction)	1.054 (0.520, 2.139)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	25 (44.6%)	29 (44.6%)
Number of censored participants, n (%)	31 (55.4%)	36 (55.4%)
Proportionality Test p-value[a][b]	0.3940	
Hazard ratio(interaction)	0.693 (0.298, 1.610)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	17 (30.4%)	15 (23.1%)
Number of censored participants, n (%)	39 (69.6%)	50 (76.9%)
Proportionality Test p-value[a][b]	0.3251	
Hazard ratio(interaction)	1.672 (0.600, 4.657)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	11 (19.6%)	17 (26.2%)
Number of censored participants, n (%)	45 (80.4%)	48 (73.8%)
Proportionality Test p-value[a][b]	0.8894	
Hazard ratio(interaction)	0.936 (0.370, 2.367)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	15 (26.8%)	22 (33.8%)
Number of censored participants, n (%)	41 (73.2%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.3634	
Hazard ratio(interaction)	0.600 (0.200, 1.805)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	12 (21.4%)	14 (21.5%)
Number of censored participants, n (%)	44 (78.6%)	51 (78.5%)
Proportionality Test p-value[a][b]	0.4339	
Hazard ratio(interaction)	0.683 (0.262, 1.776)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	31 (38.8%)	26 (37.7%)
Number of censored participants, n (%)	49 (61.3%)	43 (62.3%)
Proportionality Test p-value[a][b]	0.1383	
Hazard ratio(interaction)	0.579 (0.281, 1.193)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	29 (36.3%)	22 (31.9%)
Number of censored participants, n (%)	51 (63.8%)	47 (68.1%)
Proportionality Test p-value[a][b]	0.7225	
Hazard ratio(interaction)	0.865 (0.387, 1.930)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	37 (46.3%)	27 (39.1%)
Number of censored participants, n (%)	43 (53.8%)	42 (60.9%)
Proportionality Test p-value[a][b]	0.8512	
Hazard ratio(interaction)	1.078 (0.490, 2.373)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	24 (30.0%)	26 (37.7%)
Number of censored participants, n (%)	56 (70.0%)	43 (62.3%)
Proportionality Test p-value[a][b]	0.6383	
Hazard ratio(interaction)	1.208 (0.550, 2.654)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	29 (36.3%)	28 (40.6%)
Number of censored participants, n (%)	51 (63.8%)	41 (59.4%)
Proportionality Test p-value[a][b]	0.7822	
Hazard ratio(interaction)	0.899 (0.423, 1.911)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	34 (42.5%)	26 (37.7%)
Number of censored participants, n (%)	46 (57.5%)	43 (62.3%)
Proportionality Test p-value[a][b]	0.0034	
Hazard ratio(interaction)	0.305 (0.138, 0.676)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	45 (56.3%)	33 (47.8%)
Number of censored participants, n (%)	35 (43.8%)	36 (52.2%)
Proportionality Test p-value[a][b]	0.3619	
Hazard ratio(interaction)	0.711 (0.342, 1.479)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	19 (23.8%)	16 (23.2%)
Number of censored participants, n (%)	61 (76.3%)	53 (76.8%)
Proportionality Test p-value[a][b]	0.0368	
Hazard ratio(interaction)	0.432 (0.196, 0.950)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Pain (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	37 (46.3%)	32 (46.4%)
Number of censored participants, n (%)	43 (53.8%)	37 (53.6%)
Proportionality Test p-value[a][b]	0.6754	
Hazard ratio(interaction)	0.876 (0.472, 1.626)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	21 (26.3%)	19 (27.5%)
Number of censored participants, n (%)	59 (73.8%)	50 (72.5%)
Proportionality Test p-value[a][b]	0.1514	
Hazard ratio(interaction)	0.553 (0.246, 1.242)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	32 (40.0%)	24 (34.8%)
Number of censored participants, n (%)	48 (60.0%)	45 (65.2%)
Proportionality Test p-value[a][b]	0.9311	
Hazard ratio(interaction)	0.964 (0.420, 2.210)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	19 (23.8%)	15 (21.7%)
Number of censored participants, n (%)	61 (76.3%)	54 (78.3%)
Proportionality Test p-value[a][b]	0.1222	
Hazard ratio(interaction)	0.498 (0.206, 1.205)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	23 (28.8%)	20 (29.0%)
Number of censored participants, n (%)	57 (71.3%)	49 (71.0%)
Proportionality Test p-value[a][b]	0.2619	
Hazard ratio(interaction)	0.633 (0.284, 1.408)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	18 (22.5%)	14 (20.3%)
Number of censored participants, n (%)	62 (77.5%)	55 (79.7%)
Proportionality Test p-value[a][b]	0.8723	
Hazard ratio(interaction)	0.919 (0.326, 2.586)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	21 (26.3%)	12 (17.4%)
Number of censored participants, n (%)	59 (73.8%)	57 (82.6%)
Proportionality Test p-value[a][b]	0.3653	
Hazard ratio(interaction)	0.666 (0.276, 1.606)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	38 (52.1%)	24 (33.3%)
Number of censored participants, n (%)	35 (47.9%)	48 (66.7%)
Proportionality Test p-value[a][b]	0.1500	
Hazard ratio(interaction)	0.548 (0.242, 1.243)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	30 (41.1%)	26 (36.1%)
Number of censored participants, n (%)	43 (58.9%)	46 (63.9%)
Proportionality Test p-value[a][b]	0.3792	
Hazard ratio(interaction)	0.725 (0.354, 1.485)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	39 (53.4%)	28 (38.9%)
Number of censored participants, n (%)	34 (46.6%)	44 (61.1%)
Proportionality Test p-value[a][b]	0.0393	
Hazard ratio(interaction)	0.444 (0.205, 0.961)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	24 (32.9%)	18 (25.0%)
Number of censored participants, n (%)	49 (67.1%)	54 (75.0%)
Proportionality Test p-value[a][b]	0.9813	
Hazard ratio(interaction)	1.011 (0.401, 2.550)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	36 (49.3%)	23 (31.9%)
Number of censored participants, n (%)	37 (50.7%)	49 (68.1%)
Proportionality Test p-value[a][b]	0.7495	
Hazard ratio(interaction)	0.872 (0.378, 2.016)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	35 (47.9%)	17 (23.6%)
Number of censored participants, n (%)	38 (52.1%)	55 (76.4%)
Proportionality Test p-value[a][b]	0.9858	
Hazard ratio(interaction)	1.008 (0.416, 2.441)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	45 (61.6%)	32 (44.4%)
Number of censored participants, n (%)	28 (38.4%)	40 (55.6%)
Proportionality Test p-value[a][b]	0.8811	
Hazard ratio(interaction)	0.941 (0.425, 2.082)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	21 (28.8%)	14 (19.4%)
Number of censored participants, n (%)	52 (71.2%)	58 (80.6%)
Proportionality Test p-value[a][b]	0.7318	
Hazard ratio(interaction)	0.847 (0.327, 2.191)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Pain (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	41 (56.2%)	25 (34.7%)
Number of censored participants, n (%)	32 (43.8%)	47 (65.3%)
Proportionality Test p-value[a][b]	0.0190	
Hazard ratio(interaction)	0.388 (0.176, 0.856)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	29 (39.7%)	21 (29.2%)
Number of censored participants, n (%)	44 (60.3%)	51 (70.8%)
Proportionality Test p-value[a][b]	0.2729	
Hazard ratio(interaction)	0.640 (0.288, 1.421)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	30 (41.1%)	15 (20.8%)
Number of censored participants, n (%)	43 (58.9%)	57 (79.2%)
Proportionality Test p-value[a][b]	0.9150	
Hazard ratio(interaction)	1.050 (0.427, 2.582)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	26 (35.6%)	16 (22.2%)
Number of censored participants, n (%)	47 (64.4%)	56 (77.8%)
Proportionality Test p-value[a][b]	0.0388	
Hazard ratio(interaction)	0.363 (0.139, 0.949)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	30 (41.1%)	23 (31.9%)
Number of censored participants, n (%)	43 (58.9%)	49 (68.1%)
Proportionality Test p-value[a][b]	0.7658	
Hazard ratio(interaction)	1.108 (0.563, 2.180)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	21 (28.8%)	12 (16.7%)
Number of censored participants, n (%)	52 (71.2%)	60 (83.3%)
Proportionality Test p-value[a][b]	0.8276	
Hazard ratio(interaction)	0.913 (0.402, 2.075)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	15 (20.5%)	7 (9.7%)
Number of censored participants, n (%)	58 (79.5%)	65 (90.3%)
Proportionality Test p-value[a][b]	0.6208	
Hazard ratio(interaction)	1.363 (0.400, 4.649)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	82 (47.1%)	65 (37.4%)
Number of censored participants, n (%)	92 (52.9%)	109 (62.6%)
Proportionality Test p-value[a][b]	0.0378	
Hazard ratio(interaction)	0.604 (0.375, 0.972)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	69 (39.7%)	58 (33.3%)
Number of censored participants, n (%)	105 (60.3%)	116 (66.7%)
Proportionality Test p-value[a][b]	0.2815	
Hazard ratio(interaction)	0.772 (0.482, 1.237)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	89 (51.1%)	70 (40.2%)
Number of censored participants, n (%)	85 (48.9%)	104 (59.8%)
Proportionality Test p-value[a][b]	0.0394	
Hazard ratio(interaction)	0.618 (0.391, 0.977)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	65 (37.4%)	58 (33.3%)
Number of censored participants, n (%)	109 (62.6%)	116 (66.7%)
Proportionality Test p-value[a][b]	0.2912	
Hazard ratio(interaction)	1.307 (0.795, 2.148)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	81 (46.6%)	71 (40.8%)
Number of censored participants, n (%)	93 (53.4%)	103 (59.2%)
Proportionality Test p-value[a][b]	0.6593	
Hazard ratio(interaction)	0.905 (0.580, 1.411)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	79 (45.4%)	67 (38.5%)
Number of censored participants, n (%)	95 (54.6%)	107 (61.5%)
Proportionality Test p-value[a][b]	0.0179	
Hazard ratio(interaction)	0.578 (0.367, 0.910)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	108 (62.1%)	83 (47.7%)
Number of censored participants, n (%)	66 (37.9%)	91 (52.3%)
Proportionality Test p-value[a][b]	0.5604	
Hazard ratio(interaction)	0.878 (0.565, 1.362)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	47 (27.0%)	35 (20.1%)
Number of censored participants, n (%)	127 (73.0%)	139 (79.9%)
Proportionality Test p-value[a][b]	0.1339	
Hazard ratio(interaction)	0.649 (0.369, 1.142)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Pain (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	92 (52.9%)	74 (42.5%)
Number of censored participants, n (%)	82 (47.1%)	100 (57.5%)
Proportionality Test p-value[a][b]	0.1294	
Hazard ratio(interaction)	0.725 (0.479, 1.099)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	67 (38.5%)	52 (29.9%)
Number of censored participants, n (%)	107 (61.5%)	122 (70.1%)
Proportionality Test p-value[a][b]	0.3000	
Hazard ratio(interaction)	0.783 (0.492, 1.244)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	71 (40.8%)	55 (31.6%)
Number of censored participants, n (%)	103 (59.2%)	119 (68.4%)
Proportionality Test p-value[a][b]	0.6586	
Hazard ratio(interaction)	0.894 (0.545, 1.468)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	54 (31.0%)	35 (20.1%)
Number of censored participants, n (%)	120 (69.0%)	139 (79.9%)
Proportionality Test p-value[a][b]	0.1188	
Hazard ratio(interaction)	0.637 (0.362, 1.123)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	55 (31.6%)	48 (27.6%)
Number of censored participants, n (%)	119 (68.4%)	126 (72.4%)
Proportionality Test p-value[a][b]	0.8363	
Hazard ratio(interaction)	0.953 (0.600, 1.511)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	43 (24.7%)	40 (23.0%)
Number of censored participants, n (%)	131 (75.3%)	134 (77.0%)
Proportionality Test p-value[a][b]	0.6190	
Hazard ratio(interaction)	0.858 (0.468, 1.570)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	40 (23.0%)	28 (16.1%)
Number of censored participants, n (%)	134 (77.0%)	146 (83.9%)
Proportionality Test p-value[a][b]	0.2131	
Hazard ratio(interaction)	0.671 (0.359, 1.257)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	15 (42.9%)	15 (46.9%)
Number of censored participants, n (%)	20 (57.1%)	17 (53.1%)
Proportionality Test p-value[a][b]	0.7967	
Hazard ratio(interaction)	1.200 (0.300, 4.805)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	10 (28.6%)	11 (34.4%)
Number of censored participants, n (%)	25 (71.4%)	21 (65.6%)
Proportionality Test p-value[a][b]	0.2967	
Hazard ratio(interaction)	2.033 (0.536, 7.706)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	16 (45.7%)	13 (40.6%)
Number of censored participants, n (%)	19 (54.3%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.2311	
Hazard ratio(interaction)	2.145 (0.615, 7.476)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	12 (34.3%)	13 (40.6%)
Number of censored participants, n (%)	23 (65.7%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.8656	
Hazard ratio(interaction)	0.901 (0.271, 3.001)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	14 (40.0%)	13 (40.6%)
Number of censored participants, n (%)	21 (60.0%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.3747	
Hazard ratio(interaction)	1.617 (0.560, 4.675)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	14 (40.0%)	12 (37.5%)
Number of censored participants, n (%)	21 (60.0%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.1572	
Hazard ratio(interaction)	3.263 (0.634, 16.797)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	18 (51.4%)	19 (59.4%)
Number of censored participants, n (%)	17 (48.6%)	13 (40.6%)
Proportionality Test p-value[a][b]	0.0589	
Hazard ratio(interaction)	5.071 (0.941, 27.324)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	6 (17.1%)	13 (40.6%)
Number of censored participants, n (%)	29 (82.9%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.1903	
Hazard ratio(interaction)	3.143 (0.566, 17.439)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Pain (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	16 (45.7%)	18 (56.3%)
Number of censored participants, n (%)	19 (54.3%)	14 (43.8%)
Proportionality Test p-value[a][b]	0.2845	
Hazard ratio(interaction)	0.527 (0.163, 1.703)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	11 (31.4%)	9 (28.1%)
Number of censored participants, n (%)	24 (68.6%)	23 (71.9%)
Proportionality Test p-value[a][b]	0.5785	
Hazard ratio(interaction)	0.706 (0.207, 2.410)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	16 (45.7%)	13 (40.6%)
Number of censored participants, n (%)	19 (54.3%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.1319	
Hazard ratio(interaction)	3.291 (0.699, 15.494)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	8 (22.9%)	11 (34.4%)
Number of censored participants, n (%)	27 (77.1%)	21 (65.6%)
Proportionality Test p-value[a][b]	0.7986	
Hazard ratio(interaction)	0.802 (0.147, 4.383)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	9 (25.7%)	12 (37.5%)
Number of censored participants, n (%)	26 (74.3%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.8622	
Hazard ratio(interaction)	1.112 (0.337, 3.668)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	11 (31.4%)	8 (25.0%)
Number of censored participants, n (%)	24 (68.6%)	24 (75.0%)
Proportionality Test p-value[a][b]	0.3189	
Hazard ratio(interaction)	0.429 (0.081, 2.263)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	8 (22.9%)	5 (15.6%)
Number of censored participants, n (%)	27 (77.1%)	27 (84.4%)
Proportionality Test p-value[a][b]	0.2807	
Hazard ratio(interaction)	2.191 (0.527, 9.114)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	10 (27.0%)	10 (32.3%)
Number of censored participants, n (%)	27 (73.0%)	21 (67.7%)
Proportionality Test p-value[a][b]	0.6856	
Hazard ratio(interaction)	0.753 (0.191, 2.975)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	9 (24.3%)	6 (19.4%)
Number of censored participants, n (%)	28 (75.7%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.3452	
Hazard ratio(interaction)	0.435 (0.077, 2.450)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	15 (40.5%)	11 (35.5%)
Number of censored participants, n (%)	22 (59.5%)	20 (64.5%)
Proportionality Test p-value[a][b]	0.2877	
Hazard ratio(interaction)	0.554 (0.186, 1.646)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	13 (35.1%)	9 (29.0%)
Number of censored participants, n (%)	24 (64.9%)	22 (71.0%)
Proportionality Test p-value[a][b]	0.6734	
Hazard ratio(interaction)	0.702 (0.135, 3.641)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	18 (48.6%)	9 (29.0%)
Number of censored participants, n (%)	19 (51.4%)	22 (71.0%)
Proportionality Test p-value[a][b]	0.0740	
Hazard ratio(interaction)	0.208 (0.037, 1.165)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	15 (40.5%)	12 (38.7%)
Number of censored participants, n (%)	22 (59.5%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.0527	
Hazard ratio(interaction)	0.124 (0.015, 1.025)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	19 (51.4%)	12 (38.7%)
Number of censored participants, n (%)	18 (48.6%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.4724	
Hazard ratio(interaction)	0.673 (0.229, 1.980)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	5 (13.5%)	4 (12.9%)
Number of censored participants, n (%)	32 (86.5%)	27 (87.1%)
Proportionality Test p-value[a][b]	0.4042	
Hazard ratio(interaction)	0.164 (0.002, 11.480)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Pain (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	14 (37.8%)	9 (29.0%)
Number of censored participants, n (%)	23 (62.2%)	22 (71.0%)
Proportionality Test p-value[a][b]	0.0605	
Hazard ratio(interaction)	0.269 (0.068, 1.060)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	10 (27.0%)	8 (25.8%)
Number of censored participants, n (%)	27 (73.0%)	23 (74.2%)
Proportionality Test p-value[a][b]	0.1355	
Hazard ratio(interaction)	0.332 (0.078, 1.412)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	14 (37.8%)	8 (25.8%)
Number of censored participants, n (%)	23 (62.2%)	23 (74.2%)
Proportionality Test p-value[a][b]	0.8009	
Hazard ratio(interaction)	0.847 (0.234, 3.067)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	7 (18.9%)	4 (12.9%)
Number of censored participants, n (%)	30 (81.1%)	27 (87.1%)
Proportionality Test p-value[a][b]	0.1730	
Hazard ratio(interaction)	0.098 (0.003, 2.765)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	12 (32.4%)	5 (16.1%)
Number of censored participants, n (%)	25 (67.6%)	26 (83.9%)
Proportionality Test p-value[a][b]	0.3237	
Hazard ratio(interaction)	0.501 (0.127, 1.978)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	10 (27.0%)	4 (12.9%)
Number of censored participants, n (%)	27 (73.0%)	27 (87.1%)
Proportionality Test p-value[a][b]	0.4387	
Hazard ratio(interaction)	0.398 (0.039, 4.100)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	6 (19.4%)
Number of censored participants, n (%)	33 (89.2%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.9468	
Hazard ratio(interaction)	1.070 (0.146, 7.861)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	45 (50.0%)	35 (38.9%)
Number of censored participants, n (%)	45 (50.0%)	55 (61.1%)
Proportionality Test p-value[a][b]	0.0370	
Hazard ratio(interaction)	0.525 (0.286, 0.962)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	37 (41.1%)	32 (35.6%)
Number of censored participants, n (%)	53 (58.9%)	58 (64.4%)
Proportionality Test p-value[a][b]	0.5663	
Hazard ratio(interaction)	0.829 (0.436, 1.575)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	52 (57.8%)	37 (41.1%)
Number of censored participants, n (%)	38 (42.2%)	53 (58.9%)
Proportionality Test p-value[a][b]	0.3750	
Hazard ratio(interaction)	0.740 (0.381, 1.439)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	36 (40.0%)	35 (38.9%)
Number of censored participants, n (%)	54 (60.0%)	55 (61.1%)
Proportionality Test p-value[a][b]	0.3626	
Hazard ratio(interaction)	1.334 (0.717, 2.481)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	46 (51.1%)	44 (48.9%)
Number of censored participants, n (%)	44 (48.9%)	46 (51.1%)
Proportionality Test p-value[a][b]	0.0896	
Hazard ratio(interaction)	1.699 (0.921, 3.134)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	47 (52.2%)	37 (41.1%)
Number of censored participants, n (%)	43 (47.8%)	53 (58.9%)
Proportionality Test p-value[a][b]	0.0394	
Hazard ratio(interaction)	0.515 (0.273, 0.968)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	62 (68.9%)	49 (54.4%)
Number of censored participants, n (%)	28 (31.1%)	41 (45.6%)
Proportionality Test p-value[a][b]	0.8798	
Hazard ratio(interaction)	0.955 (0.526, 1.733)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	28 (31.1%)	26 (28.9%)
Number of censored participants, n (%)	62 (68.9%)	64 (71.1%)
Proportionality Test p-value[a][b]	0.2939	
Hazard ratio(interaction)	0.700 (0.360, 1.363)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Pain (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	55 (61.1%)	48 (53.3%)
Number of censored participants, n (%)	35 (38.9%)	42 (46.7%)
Proportionality Test p-value[a][b]	0.4660	
Hazard ratio(interaction)	0.827 (0.497, 1.378)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	37 (41.1%)	24 (26.7%)
Number of censored participants, n (%)	53 (58.9%)	66 (73.3%)
Proportionality Test p-value[a][b]	0.3298	
Hazard ratio(interaction)	0.730 (0.388, 1.374)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	34 (37.8%)	33 (36.7%)
Number of censored participants, n (%)	56 (62.2%)	57 (63.3%)
Proportionality Test p-value[a][b]	0.6338	
Hazard ratio(interaction)	1.184 (0.591, 2.370)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	28 (31.1%)	23 (25.6%)
Number of censored participants, n (%)	62 (68.9%)	67 (74.4%)
Proportionality Test p-value[a][b]	0.3986	
Hazard ratio(interaction)	0.728 (0.349, 1.520)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	31 (34.4%)	31 (34.4%)
Number of censored participants, n (%)	59 (65.6%)	59 (65.6%)
Proportionality Test p-value[a][b]	0.3948	
Hazard ratio(interaction)	0.762 (0.407, 1.426)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	23 (25.6%)	29 (32.2%)
Number of censored participants, n (%)	67 (74.4%)	61 (67.8%)
Proportionality Test p-value[a][b]	0.1128	
Hazard ratio(interaction)	0.505 (0.217, 1.175)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	25 (27.8%)	14 (15.6%)
Number of censored participants, n (%)	65 (72.2%)	76 (84.4%)
Proportionality Test p-value[a][b]	0.2195	
Hazard ratio(interaction)	0.616 (0.285, 1.335)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	42 (51.2%)	35 (41.2%)
Number of censored participants, n (%)	40 (48.8%)	50 (58.8%)
Proportionality Test p-value[a][b]	0.9815	
Hazard ratio(interaction)	0.992 (0.521, 1.890)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	33 (40.2%)	31 (36.5%)
Number of censored participants, n (%)	49 (59.8%)	54 (63.5%)
Proportionality Test p-value[a][b]	0.5883	
Hazard ratio(interaction)	0.841 (0.450, 1.574)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	38 (46.3%)	35 (41.2%)
Number of censored participants, n (%)	44 (53.7%)	50 (58.8%)
Proportionality Test p-value[a][b]	0.4362	
Hazard ratio(interaction)	0.792 (0.441, 1.424)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	28 (34.1%)	27 (31.8%)
Number of censored participants, n (%)	54 (65.9%)	58 (68.2%)
Proportionality Test p-value[a][b]	0.3744	
Hazard ratio(interaction)	1.401 (0.666, 2.949)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	31 (37.8%)	31 (36.5%)
Number of censored participants, n (%)	51 (62.2%)	54 (63.5%)
Proportionality Test p-value[a][b]	0.4532	
Hazard ratio(interaction)	0.777 (0.402, 1.502)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	31 (37.8%)	30 (35.3%)
Number of censored participants, n (%)	51 (62.2%)	55 (64.7%)
Proportionality Test p-value[a][b]	0.3539	
Hazard ratio(interaction)	1.356 (0.712, 2.584)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	45 (54.9%)	41 (48.2%)
Number of censored participants, n (%)	37 (45.1%)	44 (51.8%)
Proportionality Test p-value[a][b]	0.8736	
Hazard ratio(interaction)	1.054 (0.552, 2.013)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	20 (24.4%)	18 (21.2%)
Number of censored participants, n (%)	62 (75.6%)	67 (78.8%)
Proportionality Test p-value[a][b]	0.9946	
Hazard ratio(interaction)	0.997 (0.465, 2.140)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Pain (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	39 (47.6%)	35 (41.2%)
Number of censored participants, n (%)	43 (52.4%)	50 (58.8%)
Proportionality Test p-value[a][b]	0.3110	
Hazard ratio(interaction)	0.735 (0.406, 1.333)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	31 (37.8%)	29 (34.1%)
Number of censored participants, n (%)	51 (62.2%)	56 (65.9%)
Proportionality Test p-value[a][b]	0.9763	
Hazard ratio(interaction)	0.991 (0.544, 1.805)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	39 (47.6%)	27 (31.8%)
Number of censored participants, n (%)	43 (52.4%)	58 (68.2%)
Proportionality Test p-value[a][b]	0.7585	
Hazard ratio(interaction)	0.895 (0.441, 1.816)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	27 (32.9%)	19 (22.4%)
Number of censored participants, n (%)	55 (67.1%)	66 (77.6%)
Proportionality Test p-value[a][b]	0.3382	
Hazard ratio(interaction)	0.704 (0.343, 1.444)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	21 (25.6%)	24 (28.2%)
Number of censored participants, n (%)	61 (74.4%)	61 (71.8%)
Proportionality Test p-value[a][b]	0.4524	
Hazard ratio(interaction)	1.276 (0.676, 2.406)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	21 (25.6%)	15 (17.6%)
Number of censored participants, n (%)	61 (74.4%)	70 (82.4%)
Proportionality Test p-value[a][b]	0.6725	
Hazard ratio(interaction)	1.182 (0.544, 2.567)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	19 (23.2%)	13 (15.3%)
Number of censored participants, n (%)	63 (76.8%)	72 (84.7%)
Proportionality Test p-value[a][b]	0.8786	
Hazard ratio(interaction)	1.081 (0.399, 2.923)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	92 (48.7%)	71 (37.6%)
Number of censored participants, n (%)	97 (51.3%)	118 (62.4%)
Proportionality Test p-value[a][b]	0.0552	
Hazard ratio(interaction)	0.655 (0.425, 1.010)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	73 (38.6%)	60 (31.7%)
Number of censored participants, n (%)	116 (61.4%)	129 (68.3%)
Proportionality Test p-value[a][b]	0.5525	
Hazard ratio(interaction)	0.871 (0.553, 1.373)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	97 (51.3%)	75 (39.7%)
Number of censored participants, n (%)	92 (48.7%)	114 (60.3%)
Proportionality Test p-value[a][b]	0.3028	
Hazard ratio(interaction)	0.798 (0.519, 1.226)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	74 (39.2%)	64 (33.9%)
Number of censored participants, n (%)	115 (60.8%)	125 (66.1%)
Proportionality Test p-value[a][b]	0.4224	
Hazard ratio(interaction)	1.211 (0.759, 1.932)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	89 (47.1%)	75 (39.7%)
Number of censored participants, n (%)	100 (52.9%)	114 (60.3%)
Proportionality Test p-value[a][b]	0.9280	
Hazard ratio(interaction)	1.019 (0.673, 1.545)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	87 (46.0%)	71 (37.6%)
Number of censored participants, n (%)	102 (54.0%)	118 (62.4%)
Proportionality Test p-value[a][b]	0.0144	
Hazard ratio(interaction)	0.584 (0.380, 0.899)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	118 (62.4%)	91 (48.1%)
Number of censored participants, n (%)	71 (37.6%)	98 (51.9%)
Proportionality Test p-value[a][b]	0.5270	
Hazard ratio(interaction)	0.871 (0.569, 1.335)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	51 (27.0%)	45 (23.8%)
Number of censored participants, n (%)	138 (73.0%)	144 (76.2%)
Proportionality Test p-value[a][b]	0.2112	
Hazard ratio(interaction)	0.723 (0.434, 1.202)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Pain (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	100 (52.9%)	84 (44.4%)
Number of censored participants, n (%)	89 (47.1%)	105 (55.6%)
Proportionality Test p-value[a][b]	0.1099	
Hazard ratio(interaction)	0.734 (0.502, 1.072)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	71 (37.6%)	56 (29.6%)
Number of censored participants, n (%)	118 (62.4%)	133 (70.4%)
Proportionality Test p-value[a][b]	0.1768	
Hazard ratio(interaction)	0.748 (0.491, 1.140)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	80 (42.3%)	61 (32.3%)
Number of censored participants, n (%)	109 (57.7%)	128 (67.7%)
Proportionality Test p-value[a][b]	0.7296	
Hazard ratio(interaction)	0.920 (0.574, 1.475)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	58 (30.7%)	40 (21.2%)
Number of censored participants, n (%)	131 (69.3%)	149 (78.8%)
Proportionality Test p-value[a][b]	0.0563	
Hazard ratio(interaction)	0.588 (0.341, 1.014)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	60 (31.7%)	54 (28.6%)
Number of censored participants, n (%)	129 (68.3%)	135 (71.4%)
Proportionality Test p-value[a][b]	0.4330	
Hazard ratio(interaction)	0.839 (0.541, 1.301)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	51 (27.0%)	44 (23.3%)
Number of censored participants, n (%)	138 (73.0%)	145 (76.7%)
Proportionality Test p-value[a][b]	0.3539	
Hazard ratio(interaction)	0.778 (0.458, 1.322)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	46 (24.3%)	32 (16.9%)
Number of censored participants, n (%)	143 (75.7%)	157 (83.1%)
Proportionality Test p-value[a][b]	0.2873	
Hazard ratio(interaction)	0.740 (0.425, 1.288)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	5 (25.0%)	9 (52.9%)
Number of censored participants, n (%)	15 (75.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.6053	
Hazard ratio(interaction)	2.080 (0.129, 33.460)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	6 (30.0%)	9 (52.9%)
Number of censored participants, n (%)	14 (70.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.2670	
Hazard ratio(interaction)	0.370 (0.064, 2.140)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	8 (40.0%)	8 (47.1%)
Number of censored participants, n (%)	12 (60.0%)	9 (52.9%)
Proportionality Test p-value[a][b]	0.2245	
Hazard ratio(interaction)	0.273 (0.034, 2.216)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	7 (41.2%)
Number of censored participants, n (%)	17 (85.0%)	10 (58.8%)
Proportionality Test p-value[a][b]	0.4934	
Hazard ratio(interaction)	176.97 (0.000, 4.79E8)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	6 (30.0%)	9 (52.9%)
Number of censored participants, n (%)	14 (70.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.7687	
Hazard ratio(interaction)	1.352 (0.181, 10.111)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	6 (30.0%)	8 (47.1%)
Number of censored participants, n (%)	14 (70.0%)	9 (52.9%)
Proportionality Test p-value[a][b]	0.8913	
Hazard ratio(interaction)	0.865 (0.108, 6.913)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	8 (40.0%)	11 (64.7%)
Number of censored participants, n (%)	12 (60.0%)	6 (35.3%)
Proportionality Test p-value[a][b]	0.3477	
Hazard ratio(interaction)	191.35 (0.003, 1.11E7)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	3 (17.6%)
Number of censored participants, n (%)	18 (90.0%)	14 (82.4%)
Proportionality Test p-value[a][b]	0.4797	
Hazard ratio(interaction)	0.311 (0.012, 7.925)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Pain (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	8 (40.0%)	8 (47.1%)
Number of censored participants, n (%)	12 (60.0%)	9 (52.9%)
Proportionality Test p-value[a][b]	0.1764	
Hazard ratio(interaction)	0.148 (0.009, 2.361)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	7 (35.0%)	5 (29.4%)
Number of censored participants, n (%)	13 (65.0%)	12 (70.6%)
Proportionality Test p-value[a][b]	0.9965	
Hazard ratio(interaction)	0.000 (0.000, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	7 (35.0%)	7 (41.2%)
Number of censored participants, n (%)	13 (65.0%)	10 (58.8%)
Proportionality Test p-value[a][b]	0.8809	
Hazard ratio(interaction)	0.733 (0.013, 42.284)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	4 (20.0%)	6 (35.3%)
Number of censored participants, n (%)	16 (80.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	0.4557	
Hazard ratio(interaction)	0.430 (0.047, 3.948)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	4 (20.0%)	6 (35.3%)
Number of censored participants, n (%)	16 (80.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	0.2385	
Hazard ratio(interaction)	8.165 (0.249, 268.05)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	4 (23.5%)
Number of censored participants, n (%)	17 (85.0%)	13 (76.5%)
Proportionality Test p-value[a][b]	0.6748	
Hazard ratio(interaction)	0.394 (0.005, 30.521)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	1 (5.9%)
Number of censored participants, n (%)	18 (90.0%)	16 (94.1%)
Proportionality Test p-value[a][b]	0.9974	
Hazard ratio(interaction)	0.000 (0.000, NE)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	77 (46.4%)	65 (36.7%)
Number of censored participants, n (%)	89 (53.6%)	112 (63.3%)
Proportionality Test p-value[a][b]	0.1111	
Hazard ratio(interaction)	0.692 (0.440, 1.088)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	63 (38.0%)	54 (30.5%)
Number of censored participants, n (%)	103 (62.0%)	123 (69.5%)
Proportionality Test p-value[a][b]	0.4426	
Hazard ratio(interaction)	0.830 (0.515, 1.336)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	80 (48.2%)	67 (37.9%)
Number of censored participants, n (%)	86 (51.8%)	110 (62.1%)
Proportionality Test p-value[a][b]	0.4084	
Hazard ratio(interaction)	0.830 (0.534, 1.291)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	59 (35.5%)	62 (35.0%)
Number of censored participants, n (%)	107 (64.5%)	115 (65.0%)
Proportionality Test p-value[a][b]	0.4343	
Hazard ratio(interaction)	1.216 (0.745, 1.984)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	77 (46.4%)	68 (38.4%)
Number of censored participants, n (%)	89 (53.6%)	109 (61.6%)
Proportionality Test p-value[a][b]	0.7772	
Hazard ratio(interaction)	1.063 (0.696, 1.625)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	76 (45.8%)	66 (37.3%)
Number of censored participants, n (%)	90 (54.2%)	111 (62.7%)
Proportionality Test p-value[a][b]	0.0267	
Hazard ratio(interaction)	0.591 (0.371, 0.941)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	100 (60.2%)	83 (46.9%)
Number of censored participants, n (%)	66 (39.8%)	94 (53.1%)
Proportionality Test p-value[a][b]	0.6323	
Hazard ratio(interaction)	0.900 (0.585, 1.384)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	43 (25.9%)	42 (23.7%)
Number of censored participants, n (%)	123 (74.1%)	135 (76.3%)
Proportionality Test p-value[a][b]	0.1474	
Hazard ratio(interaction)	0.670 (0.389, 1.152)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Pain (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	88 (53.0%)	77 (43.5%)
Number of censored participants, n (%)	78 (47.0%)	100 (56.5%)
Proportionality Test p-value[a][b]	0.1239	
Hazard ratio(interaction)	0.736 (0.498, 1.088)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	63 (38.0%)	47 (26.6%)
Number of censored participants, n (%)	103 (62.0%)	130 (73.4%)
Proportionality Test p-value[a][b]	0.0725	
Hazard ratio(interaction)	0.643 (0.397, 1.041)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	64 (38.6%)	53 (29.9%)
Number of censored participants, n (%)	102 (61.4%)	124 (70.1%)
Proportionality Test p-value[a][b]	0.8405	
Hazard ratio(interaction)	1.054 (0.631, 1.759)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	47 (28.3%)	36 (20.3%)
Number of censored participants, n (%)	119 (71.7%)	141 (79.7%)
Proportionality Test p-value[a][b]	0.0077	
Hazard ratio(interaction)	0.449 (0.249, 0.809)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	55 (33.1%)	52 (29.4%)
Number of censored participants, n (%)	111 (66.9%)	125 (70.6%)
Proportionality Test p-value[a][b]	0.8231	
Hazard ratio(interaction)	0.951 (0.615, 1.472)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	42 (25.3%)	37 (20.9%)
Number of censored participants, n (%)	124 (74.7%)	140 (79.1%)
Proportionality Test p-value[a][b]	0.1746	
Hazard ratio(interaction)	0.662 (0.365, 1.201)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	41 (24.7%)	25 (14.1%)
Number of censored participants, n (%)	125 (75.3%)	152 (85.9%)
Proportionality Test p-value[a][b]	0.2170	
Hazard ratio(interaction)	0.676 (0.363, 1.259)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	20 (46.5%)	15 (51.7%)
Number of censored participants, n (%)	23 (53.5%)	14 (48.3%)
Proportionality Test p-value[a][b]	0.6239	
Hazard ratio(interaction)	0.765 (0.262, 2.235)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	16 (37.2%)	15 (51.7%)
Number of censored participants, n (%)	27 (62.8%)	14 (48.3%)
Proportionality Test p-value[a][b]	0.7099	
Hazard ratio(interaction)	0.827 (0.305, 2.247)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	25 (58.1%)	16 (55.2%)
Number of censored participants, n (%)	18 (41.9%)	13 (44.8%)
Proportionality Test p-value[a][b]	0.1025	
Hazard ratio(interaction)	0.391 (0.126, 1.207)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	18 (41.9%)	9 (31.0%)
Number of censored participants, n (%)	25 (58.1%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.3036	
Hazard ratio(interaction)	2.076 (0.516, 8.347)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	18 (41.9%)	16 (55.2%)
Number of censored participants, n (%)	25 (58.1%)	13 (44.8%)
Proportionality Test p-value[a][b]	0.9077	
Hazard ratio(interaction)	0.933 (0.288, 3.022)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	17 (39.5%)	13 (44.8%)
Number of censored participants, n (%)	26 (60.5%)	16 (55.2%)
Proportionality Test p-value[a][b]	0.8654	
Hazard ratio(interaction)	1.078 (0.452, 2.573)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	26 (60.5%)	19 (65.5%)
Number of censored participants, n (%)	17 (39.5%)	10 (34.5%)
Proportionality Test p-value[a][b]	0.3915	
Hazard ratio(interaction)	1.718 (0.498, 5.927)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	10 (23.3%)	6 (20.7%)
Number of censored participants, n (%)	33 (76.7%)	23 (79.3%)
Proportionality Test p-value[a][b]	0.3471	
Hazard ratio(interaction)	1.924 (0.492, 7.531)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Pain (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	20 (46.5%)	15 (51.7%)
Number of censored participants, n (%)	23 (53.5%)	14 (48.3%)
Proportionality Test p-value[a][b]	0.3925	
Hazard ratio(interaction)	0.606 (0.192, 1.911)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	15 (34.9%)	14 (48.3%)
Number of censored participants, n (%)	28 (65.1%)	15 (51.7%)
Proportionality Test p-value[a][b]	0.6491	
Hazard ratio(interaction)	1.209 (0.534, 2.739)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	23 (53.5%)	15 (51.7%)
Number of censored participants, n (%)	20 (46.5%)	14 (48.3%)
Proportionality Test p-value[a][b]	0.5652	
Hazard ratio(interaction)	0.741 (0.267, 2.058)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	15 (34.9%)	10 (34.5%)
Number of censored participants, n (%)	28 (65.1%)	19 (65.5%)
Proportionality Test p-value[a][b]	0.1764	
Hazard ratio(interaction)	2.054 (0.723, 5.831)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	9 (20.9%)	8 (27.6%)
Number of censored participants, n (%)	34 (79.1%)	21 (72.4%)
Proportionality Test p-value[a][b]	0.5735	
Hazard ratio(interaction)	0.673 (0.169, 2.673)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	12 (27.9%)	11 (37.9%)
Number of censored participants, n (%)	31 (72.1%)	18 (62.1%)
Proportionality Test p-value[a][b]	0.3245	
Hazard ratio(interaction)	1.818 (0.554, 5.971)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	7 (16.3%)	8 (27.6%)
Number of censored participants, n (%)	36 (83.7%)	21 (72.4%)
Proportionality Test p-value[a][b]	0.4295	
Hazard ratio(interaction)	1.714 (0.450, 6.527)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	56 (42.1%)	54 (41.2%)
Number of censored participants, n (%)	77 (57.9%)	77 (58.8%)
Proportionality Test p-value[a][b]	0.0698	
Hazard ratio(interaction)	0.601 (0.347, 1.042)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	38 (28.6%)	40 (30.5%)
Number of censored participants, n (%)	95 (71.4%)	91 (69.5%)
Proportionality Test p-value[a][b]	0.4454	
Hazard ratio(interaction)	0.776 (0.404, 1.490)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	63 (47.4%)	56 (42.7%)
Number of censored participants, n (%)	70 (52.6%)	75 (57.3%)
Proportionality Test p-value[a][b]	0.0975	
Hazard ratio(interaction)	0.652 (0.392, 1.082)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	43 (32.3%)	44 (33.6%)
Number of censored participants, n (%)	90 (67.7%)	87 (66.4%)
Proportionality Test p-value[a][b]	0.8701	
Hazard ratio(interaction)	1.055 (0.557, 1.998)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	54 (40.6%)	52 (39.7%)
Number of censored participants, n (%)	79 (59.4%)	79 (60.3%)
Proportionality Test p-value[a][b]	0.5486	
Hazard ratio(interaction)	0.860 (0.524, 1.409)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	53 (39.8%)	48 (36.6%)
Number of censored participants, n (%)	80 (60.2%)	83 (63.4%)
Proportionality Test p-value[a][b]	0.0192	
Hazard ratio(interaction)	0.529 (0.311, 0.901)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	76 (57.1%)	70 (53.4%)
Number of censored participants, n (%)	57 (42.9%)	61 (46.6%)
Proportionality Test p-value[a][b]	0.2444	
Hazard ratio(interaction)	1.408 (0.791, 2.505)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	34 (25.6%)	28 (21.4%)
Number of censored participants, n (%)	99 (74.4%)	103 (78.6%)
Proportionality Test p-value[a][b]	0.2317	
Hazard ratio(interaction)	0.678 (0.359, 1.282)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Pain (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	64 (48.1%)	60 (45.8%)
Number of censored participants, n (%)	69 (51.9%)	71 (54.2%)
Proportionality Test p-value[a][b]	0.0920	
Hazard ratio(interaction)	0.638 (0.378, 1.076)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	45 (33.8%)	39 (29.8%)
Number of censored participants, n (%)	88 (66.2%)	92 (70.2%)
Proportionality Test p-value[a][b]	0.9369	
Hazard ratio(interaction)	0.977 (0.549, 1.737)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	57 (42.9%)	43 (32.8%)
Number of censored participants, n (%)	76 (57.1%)	88 (67.2%)
Proportionality Test p-value[a][b]	0.2048	
Hazard ratio(interaction)	0.687 (0.384, 1.228)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	38 (28.6%)	27 (20.6%)
Number of censored participants, n (%)	95 (71.4%)	104 (79.4%)
Proportionality Test p-value[a][b]	0.1985	
Hazard ratio(interaction)	0.659 (0.348, 1.245)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	38 (28.6%)	38 (29.0%)
Number of censored participants, n (%)	95 (71.4%)	93 (71.0%)
Proportionality Test p-value[a][b]	0.2210	
Hazard ratio(interaction)	0.702 (0.398, 1.237)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	31 (23.3%)	32 (24.4%)
Number of censored participants, n (%)	102 (76.7%)	99 (75.6%)
Proportionality Test p-value[a][b]	0.5514	
Hazard ratio(interaction)	0.816 (0.419, 1.592)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	21 (15.8%)	21 (16.0%)
Number of censored participants, n (%)	112 (84.2%)	110 (84.0%)
Proportionality Test p-value[a][b]	0.8031	
Hazard ratio(interaction)	1.107 (0.497, 2.466)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	41 (53.9%)	26 (34.7%)
Number of censored participants, n (%)	35 (46.1%)	49 (65.3%)
Proportionality Test p-value[a][b]	0.6169	
Hazard ratio(interaction)	0.838 (0.418, 1.677)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	41 (53.9%)	29 (38.7%)
Number of censored participants, n (%)	35 (46.1%)	46 (61.3%)
Proportionality Test p-value[a][b]	0.8169	
Hazard ratio(interaction)	1.075 (0.581, 1.990)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	42 (55.3%)	27 (36.0%)
Number of censored participants, n (%)	34 (44.7%)	48 (64.0%)
Proportionality Test p-value[a][b]	0.9962	
Hazard ratio(interaction)	1.002 (0.473, 2.120)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	34 (44.7%)	27 (36.0%)
Number of censored participants, n (%)	42 (55.3%)	48 (64.0%)
Proportionality Test p-value[a][b]	0.1468	
Hazard ratio(interaction)	1.642 (0.840, 3.211)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	41 (53.9%)	32 (42.7%)
Number of censored participants, n (%)	35 (46.1%)	43 (57.3%)
Proportionality Test p-value[a][b]	0.2014	
Hazard ratio(interaction)	1.582 (0.783, 3.199)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	40 (52.6%)	31 (41.3%)
Number of censored participants, n (%)	36 (47.4%)	44 (58.7%)
Proportionality Test p-value[a][b]	0.9758	
Hazard ratio(interaction)	0.989 (0.499, 1.961)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	50 (65.8%)	32 (42.7%)
Number of censored participants, n (%)	26 (34.2%)	43 (57.3%)
Proportionality Test p-value[a][b]	0.4330	
Hazard ratio(interaction)	0.769 (0.400, 1.482)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	19 (25.0%)	20 (26.7%)
Number of censored participants, n (%)	57 (75.0%)	55 (73.3%)
Proportionality Test p-value[a][b]	0.8566	
Hazard ratio(interaction)	0.928 (0.413, 2.085)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Pain (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	44 (57.9%)	32 (42.7%)
Number of censored participants, n (%)	32 (42.1%)	43 (57.3%)
Proportionality Test p-value[a][b]	0.5507	
Hazard ratio(interaction)	0.840 (0.474, 1.488)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	33 (43.4%)	22 (29.3%)
Number of censored participants, n (%)	43 (56.6%)	53 (70.7%)
Proportionality Test p-value[a][b]	0.0904	
Hazard ratio(interaction)	0.533 (0.257, 1.104)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	30 (39.5%)	25 (33.3%)
Number of censored participants, n (%)	46 (60.5%)	50 (66.7%)
Proportionality Test p-value[a][b]	0.1058	
Hazard ratio(interaction)	2.007 (0.863, 4.670)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	24 (31.6%)	19 (25.3%)
Number of censored participants, n (%)	52 (68.4%)	56 (74.7%)
Proportionality Test p-value[a][b]	0.4658	
Hazard ratio(interaction)	0.730 (0.314, 1.699)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	26 (34.2%)	22 (29.3%)
Number of censored participants, n (%)	50 (65.8%)	53 (70.7%)
Proportionality Test p-value[a][b]	0.3833	
Hazard ratio(interaction)	1.339 (0.694, 2.583)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	23 (30.3%)	16 (21.3%)
Number of censored participants, n (%)	53 (69.7%)	59 (78.7%)
Proportionality Test p-value[a][b]	0.5411	
Hazard ratio(interaction)	0.748 (0.294, 1.899)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	27 (35.5%)	12 (16.0%)
Number of censored participants, n (%)	49 (64.5%)	63 (84.0%)
Proportionality Test p-value[a][b]	0.0524	
Hazard ratio(interaction)	0.311 (0.095, 1.012)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	56 (44.8%)	45 (38.5%)
Number of censored participants, n (%)	69 (55.2%)	72 (61.5%)
Proportionality Test p-value[a][b]	0.6859	
Hazard ratio(interaction)	0.884 (0.487, 1.606)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	43 (34.4%)	38 (32.5%)
Number of censored participants, n (%)	82 (65.6%)	79 (67.5%)
Proportionality Test p-value[a][b]	0.3297	
Hazard ratio(interaction)	0.755 (0.429, 1.329)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	64 (51.2%)	42 (35.9%)
Number of censored participants, n (%)	61 (48.8%)	75 (64.1%)
Proportionality Test p-value[a][b]	0.0960	
Hazard ratio(interaction)	0.611 (0.342, 1.092)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	45 (36.0%)	38 (32.5%)
Number of censored participants, n (%)	80 (64.0%)	79 (67.5%)
Proportionality Test p-value[a][b]	0.4481	
Hazard ratio(interaction)	1.294 (0.665, 2.520)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	59 (47.2%)	48 (41.0%)
Number of censored participants, n (%)	66 (52.8%)	69 (59.0%)
Proportionality Test p-value[a][b]	0.9014	
Hazard ratio(interaction)	0.965 (0.547, 1.702)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	52 (41.6%)	42 (35.9%)
Number of censored participants, n (%)	73 (58.4%)	75 (64.1%)
Proportionality Test p-value[a][b]	0.5637	
Hazard ratio(interaction)	0.823 (0.424, 1.596)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	72 (57.6%)	55 (47.0%)
Number of censored participants, n (%)	53 (42.4%)	62 (53.0%)
Proportionality Test p-value[a][b]	0.9728	
Hazard ratio(interaction)	0.990 (0.568, 1.727)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	30 (24.0%)	24 (20.5%)
Number of censored participants, n (%)	95 (76.0%)	93 (79.5%)
Proportionality Test p-value[a][b]	0.9925	
Hazard ratio(interaction)	0.997 (0.511, 1.946)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Pain (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	62 (49.6%)	51 (43.6%)
Number of censored participants, n (%)	63 (50.4%)	66 (56.4%)
Proportionality Test p-value[a][b]	0.0814	
Hazard ratio(interaction)	0.635 (0.381, 1.058)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	44 (35.2%)	33 (28.2%)
Number of censored participants, n (%)	81 (64.8%)	84 (71.8%)
Proportionality Test p-value[a][b]	0.1852	
Hazard ratio(interaction)	0.682 (0.388, 1.201)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	52 (41.6%)	42 (35.9%)
Number of censored participants, n (%)	73 (58.4%)	75 (64.1%)
Proportionality Test p-value[a][b]	0.9253	
Hazard ratio(interaction)	0.969 (0.506, 1.858)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	38 (30.4%)	26 (22.2%)
Number of censored participants, n (%)	87 (69.6%)	91 (77.8%)
Proportionality Test p-value[a][b]	0.2789	
Hazard ratio(interaction)	0.703 (0.372, 1.330)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	38 (30.4%)	34 (29.1%)
Number of censored participants, n (%)	87 (69.6%)	83 (70.9%)
Proportionality Test p-value[a][b]	0.7371	
Hazard ratio(interaction)	1.095 (0.645, 1.859)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	33 (26.4%)	33 (28.2%)
Number of censored participants, n (%)	92 (73.6%)	84 (71.8%)
Proportionality Test p-value[a][b]	0.9898	
Hazard ratio(interaction)	1.004 (0.521, 1.937)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	27 (21.6%)	17 (14.5%)
Number of censored participants, n (%)	98 (78.4%)	100 (85.5%)
Proportionality Test p-value[a][b]	0.6510	
Hazard ratio(interaction)	0.816 (0.338, 1.971)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	41 (48.8%)	35 (39.3%)
Number of censored participants, n (%)	43 (51.2%)	54 (60.7%)
Proportionality Test p-value[a][b]	0.1057	
Hazard ratio(interaction)	0.568 (0.287, 1.127)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	36 (42.9%)	31 (34.8%)
Number of censored participants, n (%)	48 (57.1%)	58 (65.2%)
Proportionality Test p-value[a][b]	0.4626	
Hazard ratio(interaction)	0.778 (0.398, 1.521)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	41 (48.8%)	41 (46.1%)
Number of censored participants, n (%)	43 (51.2%)	48 (53.9%)
Proportionality Test p-value[a][b]	0.5481	
Hazard ratio(interaction)	0.824 (0.438, 1.550)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	32 (38.1%)	33 (37.1%)
Number of censored participants, n (%)	52 (61.9%)	56 (62.9%)
Proportionality Test p-value[a][b]	0.8048	
Hazard ratio(interaction)	1.085 (0.569, 2.068)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	36 (42.9%)	36 (40.4%)
Number of censored participants, n (%)	48 (57.1%)	53 (59.6%)
Proportionality Test p-value[a][b]	0.6574	
Hazard ratio(interaction)	1.157 (0.606, 2.209)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	41 (48.8%)	37 (41.6%)
Number of censored participants, n (%)	43 (51.2%)	52 (58.4%)
Proportionality Test p-value[a][b]	0.0428	
Hazard ratio(interaction)	0.530 (0.286, 0.980)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	54 (64.3%)	47 (52.8%)
Number of censored participants, n (%)	30 (35.7%)	42 (47.2%)
Proportionality Test p-value[a][b]	0.7238	
Hazard ratio(interaction)	0.879 (0.430, 1.798)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	23 (27.4%)	24 (27.0%)
Number of censored participants, n (%)	61 (72.6%)	65 (73.0%)
Proportionality Test p-value[a][b]	0.1822	
Hazard ratio(interaction)	0.571 (0.251, 1.301)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Pain (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	46 (54.8%)	41 (46.1%)
Number of censored participants, n (%)	38 (45.2%)	48 (53.9%)
Proportionality Test p-value[a][b]	0.2067	
Hazard ratio(interaction)	0.668 (0.357, 1.250)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	34 (40.5%)	28 (31.5%)
Number of censored participants, n (%)	50 (59.5%)	61 (68.5%)
Proportionality Test p-value[a][b]	0.1722	
Hazard ratio(interaction)	0.607 (0.296, 1.243)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	35 (41.7%)	26 (29.2%)
Number of censored participants, n (%)	49 (58.3%)	63 (70.8%)
Proportionality Test p-value[a][b]	0.5137	
Hazard ratio(interaction)	0.788 (0.386, 1.610)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	24 (28.6%)	20 (22.5%)
Number of censored participants, n (%)	60 (71.4%)	69 (77.5%)
Proportionality Test p-value[a][b]	0.0609	
Hazard ratio(interaction)	0.426 (0.175, 1.040)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	26 (31.0%)	26 (29.2%)
Number of censored participants, n (%)	58 (69.0%)	63 (70.8%)
Proportionality Test p-value[a][b]	0.3871	
Hazard ratio(interaction)	0.731 (0.359, 1.488)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	21 (25.0%)	15 (16.9%)
Number of censored participants, n (%)	63 (75.0%)	74 (83.1%)
Proportionality Test p-value[a][b]	0.2766	
Hazard ratio(interaction)	0.612 (0.253, 1.482)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

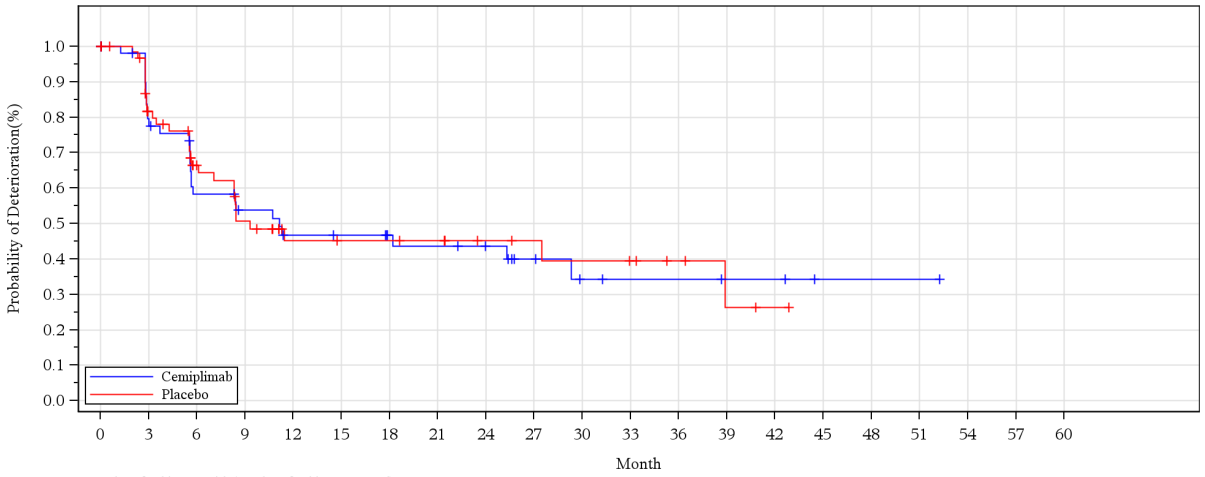
High risk feature: Non-Nodal
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	21 (25.0%)	16 (18.0%)
Number of censored participants, n (%)	63 (75.0%)	73 (82.0%)
Proportionality Test p-value[a][b]	0.5610	
Hazard ratio(interaction)	0.808 (0.395, 1.656)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	39 (7)	27 (9)	23 (11)	19 (12)	18 (13)	15 (16)	14 (16)	12 (18)	8 (21)	5 (23)	4 (24)	4 (24)	3 (25)	3 (25)	1 (27)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)
Placebo	65 (0)	45 (9)	31 (15)	22 (17)	14 (23)	13 (24)	13 (24)	12 (25)	9 (28)	8 (29)	7 (29)	6 (30)	4 (32)	2 (33)	1 (34)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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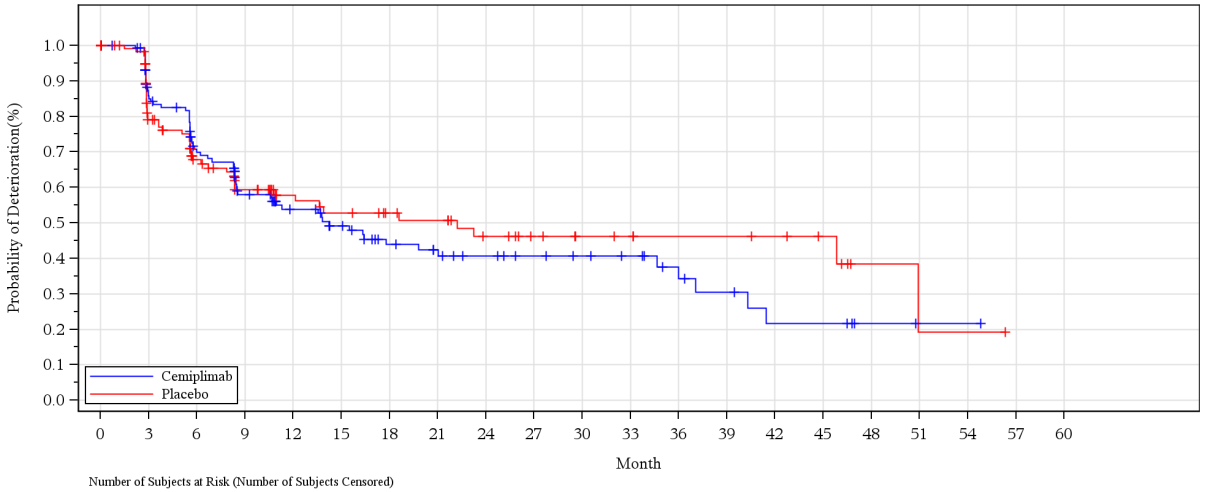
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	105 (30)	80 (36)	61 (42)	48 (51)	40 (55)	30 (61)	26 (64)	22 (67)	19 (70)	17 (72)	15 (74)	10 (77)	8 (78)	5 (79)	5 (79)	2 (82)	1 (83)	1 (83)	0 (84)	0 (84)
Placebo	141 (0)	82 (36)	60 (47)	46 (54)	35 (64)	31 (65)	27 (69)	25 (70)	19 (74)	15 (78)	12 (81)	11 (82)	9 (84)	9 (84)	8 (85)	6 (87)	2 (90)	1 (90)	1 (90)	0 (91)	0 (91)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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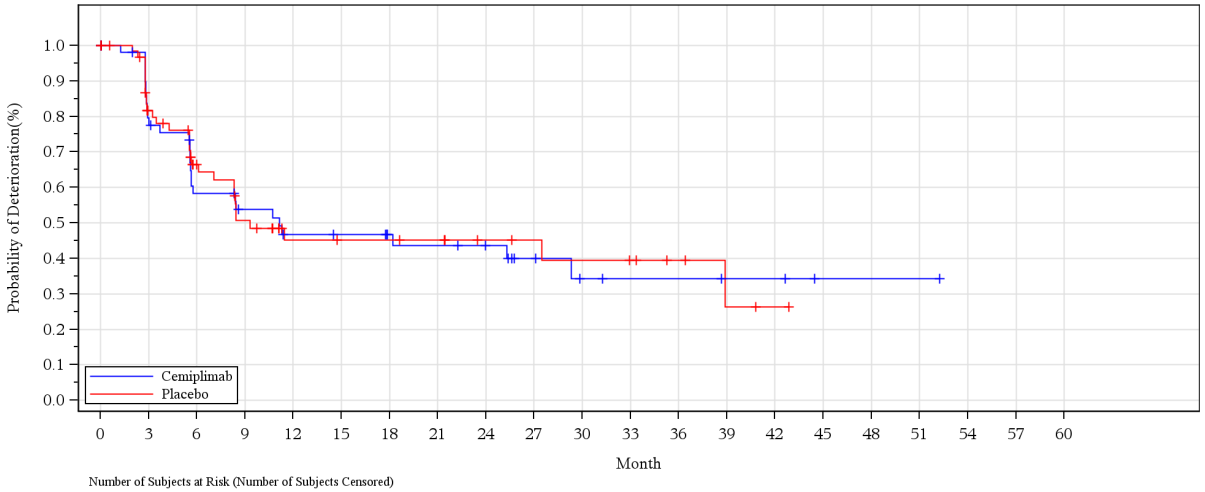
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	39 (7)	27 (9)	23 (11)	19 (12)	18 (13)	15 (16)	14 (16)	12 (18)	8 (21)	5 (23)	4 (24)	4 (24)	3 (25)	3 (25)	1 (27)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)
Placebo	65 (0)	45 (9)	31 (15)	22 (17)	14 (23)	13 (24)	13 (24)	12 (25)	9 (28)	8 (29)	7 (29)	6 (30)	4 (32)	2 (33)	1 (34)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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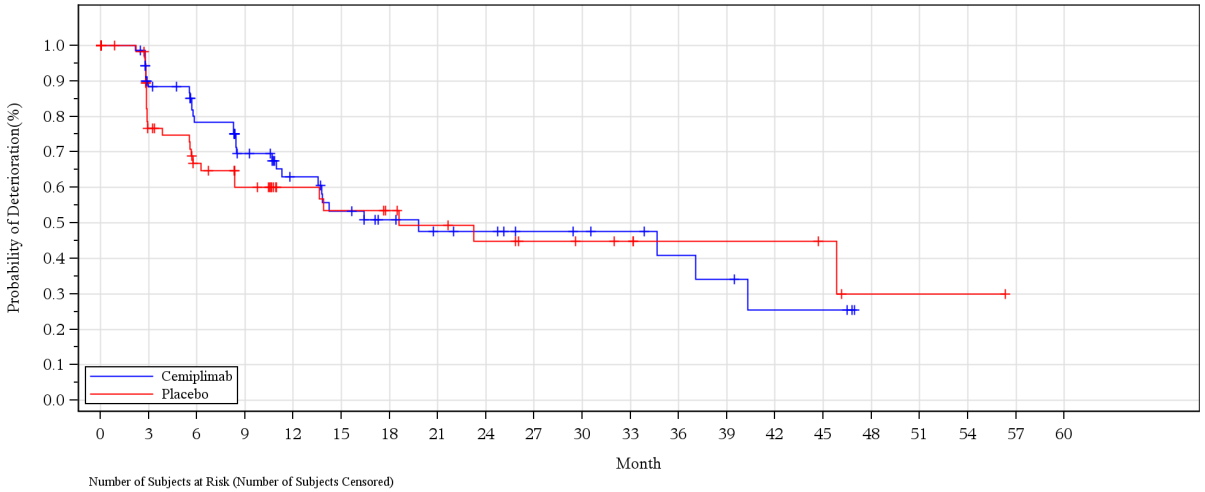
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	57 (15)	47 (19)	36 (25)	27 (31)	22 (32)	17 (36)	14 (38)	13 (39)	10 (42)	9 (43)	8 (44)	6 (45)	5 (45)	3 (46)	3 (46)	0 (49)	0 (49)	0 (49)	0 (49)	0 (49)
Placebo	69 (0)	41 (15)	32 (19)	26 (22)	18 (30)	16 (30)	14 (32)	12 (33)	10 (34)	8 (36)	7 (37)	6 (38)	4 (40)	4 (40)	4 (40)	3 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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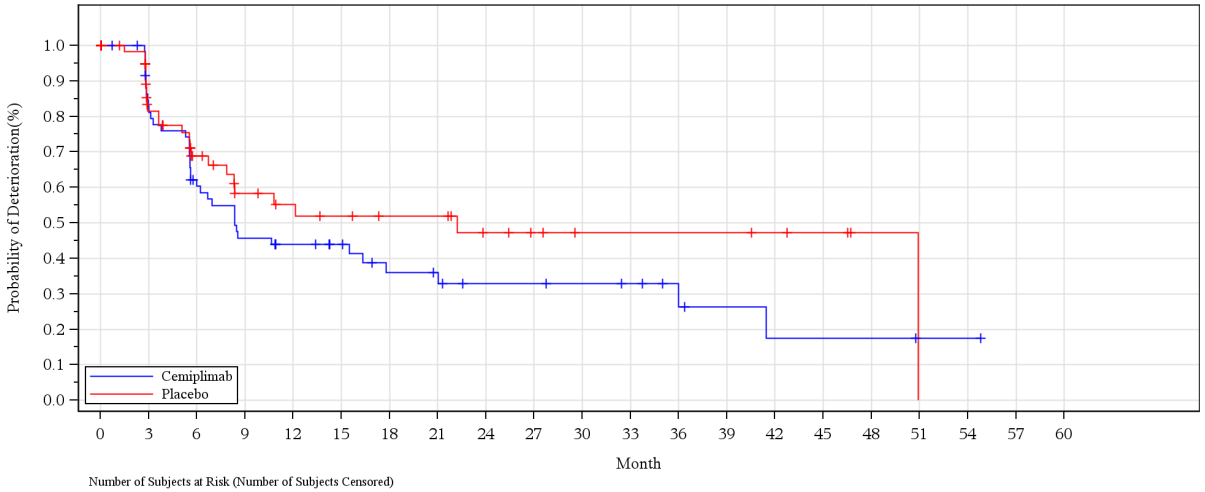
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	48 (15)	33 (17)	25 (17)	21 (20)	18 (23)	13 (25)	12 (26)	9 (28)	9 (28)	8 (29)	7 (30)	4 (32)	3 (33)	2 (33)	2 (33)	2 (33)	1 (34)	1 (34)	0 (35)	0 (35)
Placebo	72 (0)	41 (21)	28 (28)	20 (32)	17 (34)	15 (35)	13 (37)	13 (37)	9 (40)	7 (42)	5 (44)	5 (44)	5 (44)	5 (44)	4 (45)	3 (46)	1 (48)	0 (48)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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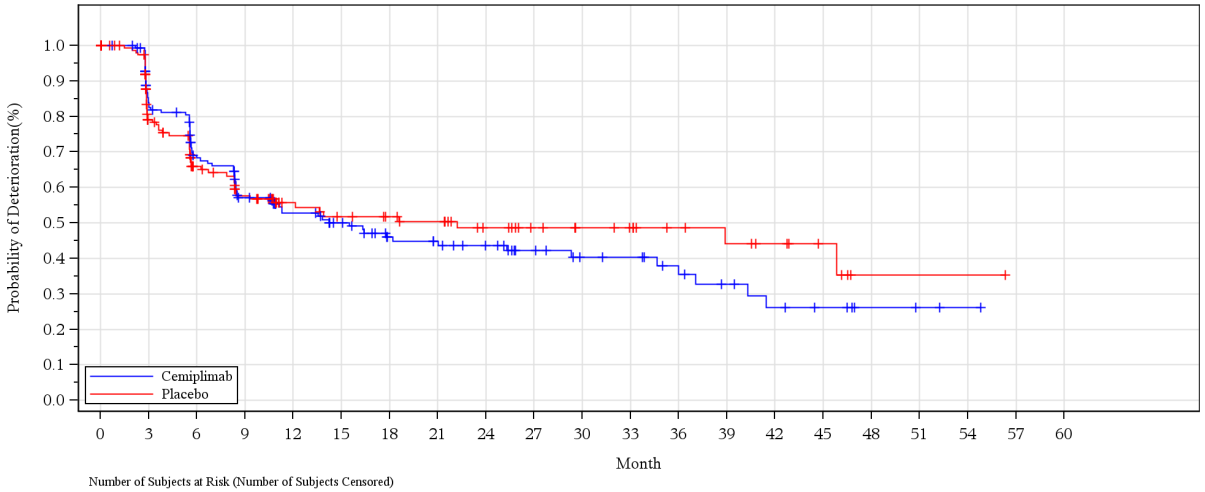
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	122 (28)	93 (35)	73 (40)	60 (48)	52 (53)	40 (61)	37 (63)	32 (67)	25 (73)	20 (77)	19 (78)	14 (81)	11 (83)	8 (84)	6 (86)	3 (89)	2 (90)	1 (91)	0 (92)	0 (92)
Placebo	174 (0)	106 (38)	75 (52)	61 (57)	44 (72)	39 (74)	36 (77)	33 (79)	26 (85)	21 (90)	18 (93)	16 (95)	12 (99)	10 (100)	8 (102)	5 (105)	1 (108)	1 (108)	1 (108)	0 (109)	0 (109)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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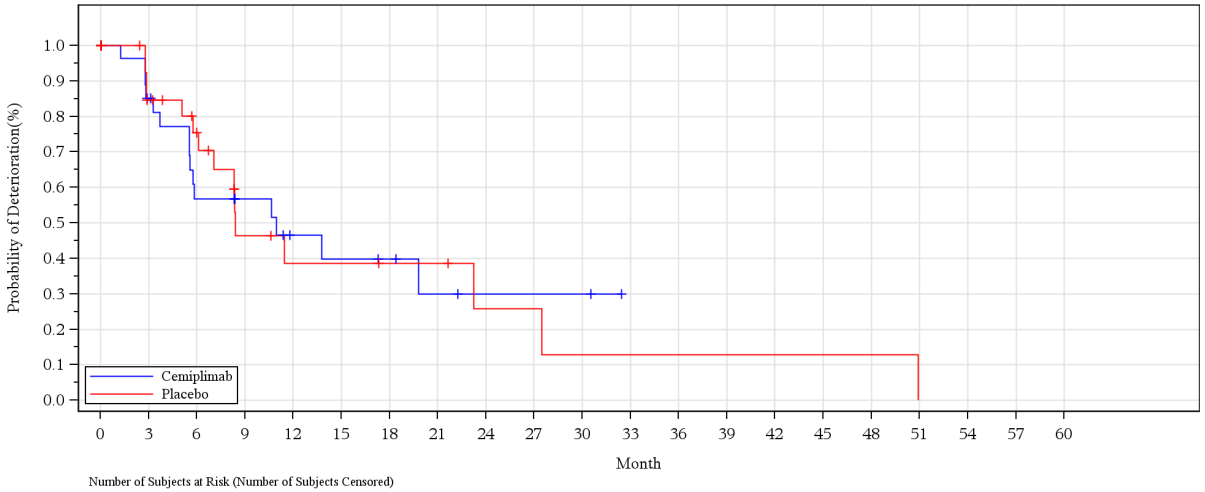
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	22 (9)	14 (10)	11 (13)	7 (15)	6 (15)	5 (16)	3 (17)	2 (18)	2 (18)	2 (18)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	32 (0)	21 (7)	16 (10)	7 (14)	5 (15)	5 (15)	4 (16)	4 (16)	2 (17)	2 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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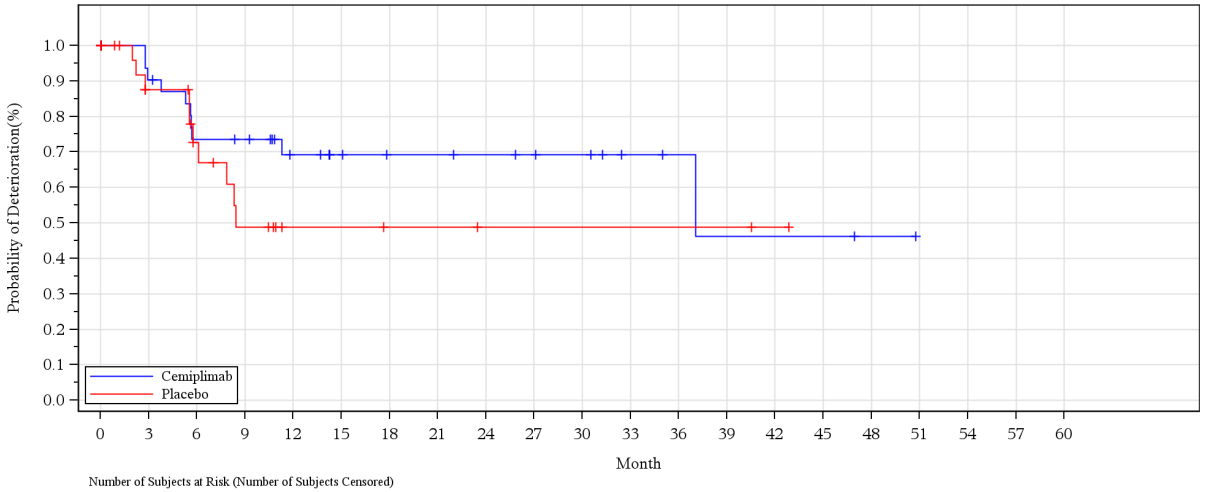
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	28 (6)	22 (7)	21 (8)	15 (13)	12 (16)	10 (18)	10 (18)	9 (19)	8 (20)	7 (21)	4 (24)	3 (25)	2 (25)	2 (25)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	31 (0)	19 (9)	13 (12)	8 (13)	4 (17)	4 (17)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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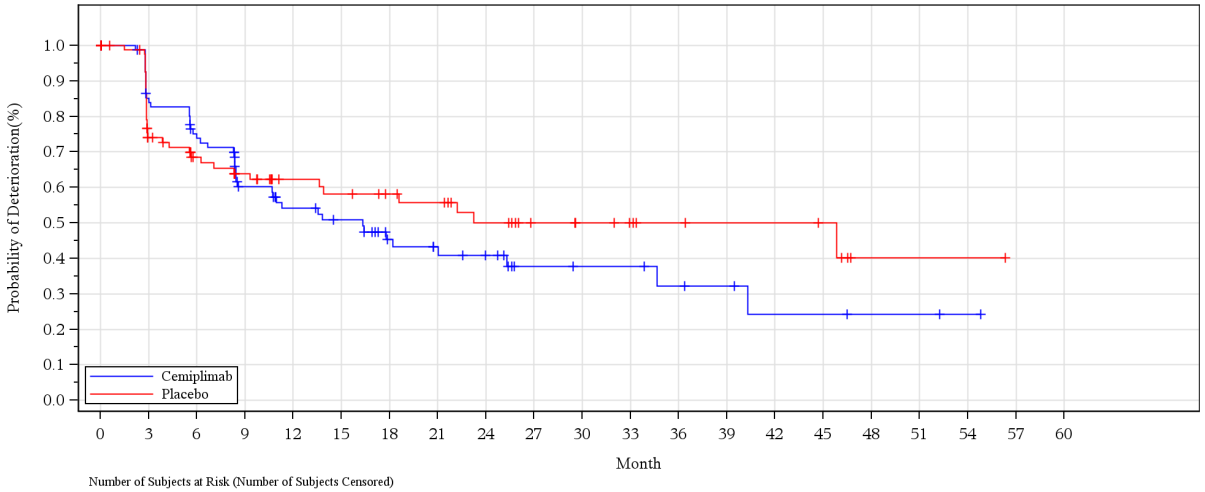
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



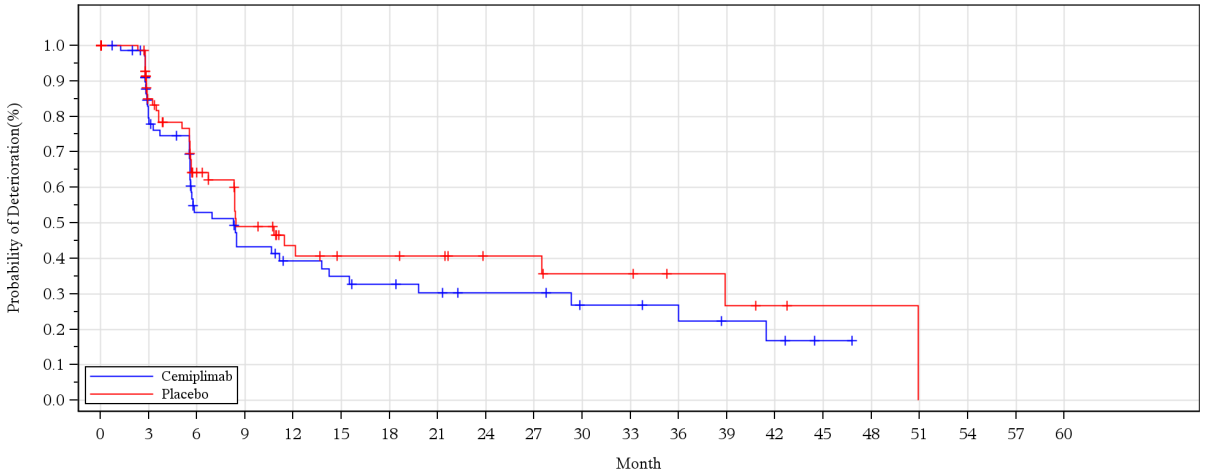
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	68 (10)	57 (12)	41 (18)	34 (21)	30 (23)	21 (29)	18 (31)	15 (33)	9 (38)	8 (39)	8 (39)	6 (40)	5 (41)	3 (42)	3 (42)	2 (43)	2 (43)	1 (44)	0 (45)	0 (45)
Placebo	90 (0)	56 (13)	45 (20)	38 (24)	30 (31)	28 (31)	25 (34)	23 (35)	18 (38)	13 (43)	11 (45)	9 (47)	7 (49)	6 (50)	6 (50)	5 (51)	1 (54)	1 (54)	1 (54)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



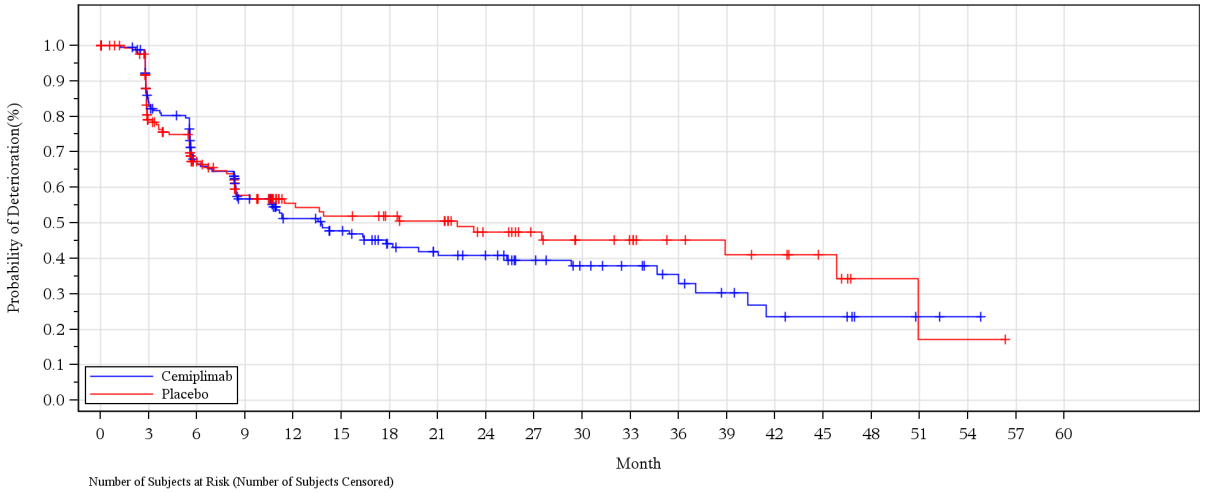
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	48 (21)	28 (26)	22 (27)	18 (29)	16 (29)	14 (30)	12 (31)	10 (33)	10 (33)	7 (35)	7 (35)	5 (36)	4 (37)	3 (37)	1 (39)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)
Placebo	85 (0)	52 (23)	33 (30)	22 (34)	15 (39)	12 (41)	12 (41)	11 (42)	8 (45)	8 (45)	6 (46)	6 (46)	4 (48)	3 (48)	2 (49)	1 (50)	1 (50)	0 (50)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	134 (29)	99 (37)	77 (45)	62 (53)	54 (57)	42 (65)	37 (68)	33 (71)	26 (77)	21 (81)	18 (84)	13 (87)	10 (89)	7 (90)	6 (91)	3 (94)	2 (95)	1 (96)	0 (97)	0 (97)
Placebo	189 (0)	113 (44)	82 (59)	63 (67)	46 (82)	43 (82)	39 (86)	36 (88)	27 (95)	22 (100)	18 (103)	16 (105)	12 (109)	10 (110)	9 (111)	6 (114)	2 (117)	1 (117)	1 (117)	0 (118)	0 (118)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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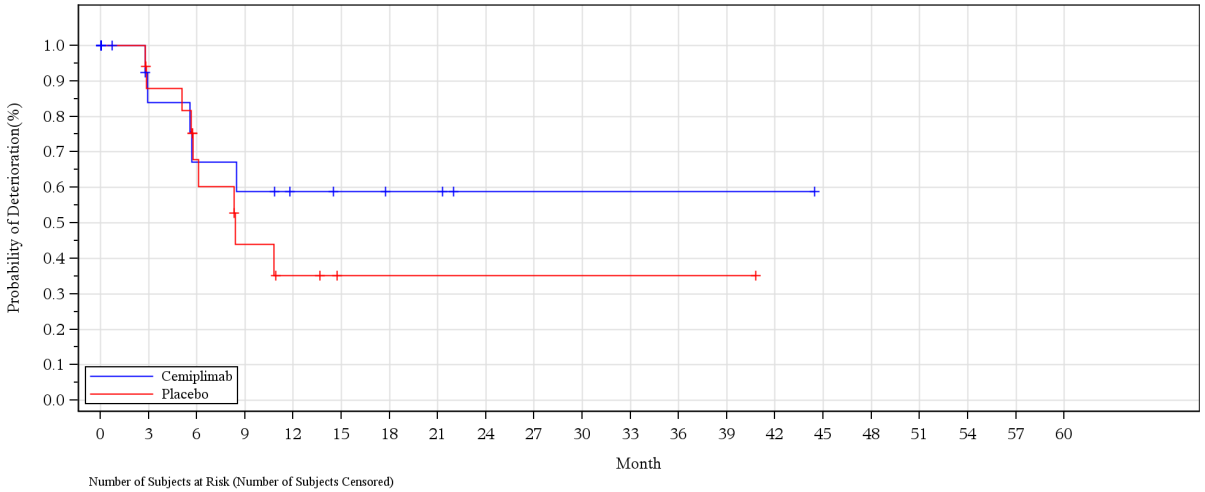
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Race: Non-white



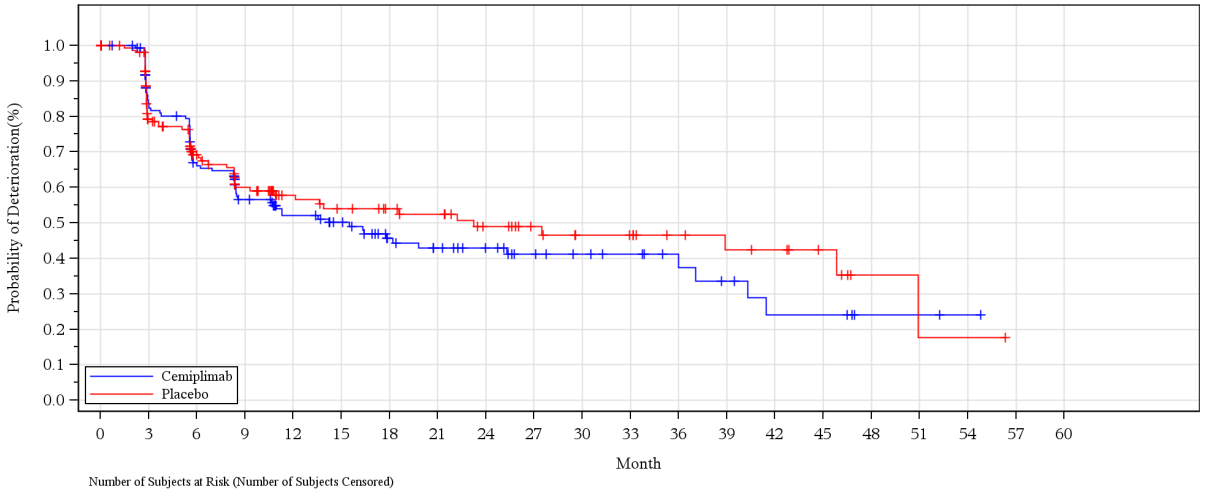
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	10 (8)	8 (8)	7 (8)	5 (10)	4 (11)	3 (12)	3 (12)	1 (14)	1 (14)	1 (14)	1 (14)	1 (14)	1 (14)	1 (14)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)
Placebo	17 (0)	14 (1)	9 (3)	5 (4)	3 (5)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



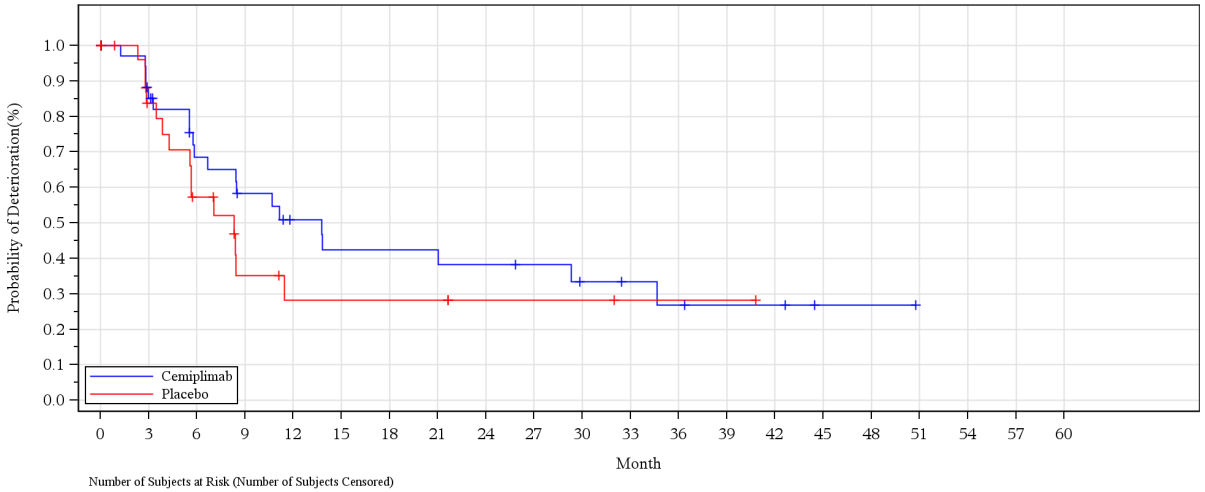
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	116 (27)	87 (32)	68 (39)	55 (47)	48 (52)	35 (61)	30 (64)	25 (69)	19 (74)	16 (77)	14 (79)	10 (82)	8 (83)	5 (84)	5 (84)	2 (87)	2 (87)	1 (88)	0 (89)	0 (89)
Placebo	177 (0)	108 (39)	79 (55)	62 (62)	45 (77)	40 (79)	36 (83)	33 (85)	26 (90)	21 (95)	17 (98)	16 (99)	12 (103)	10 (104)	9 (105)	6 (108)	2 (111)	1 (111)	1 (111)	0 (112)	0 (112)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



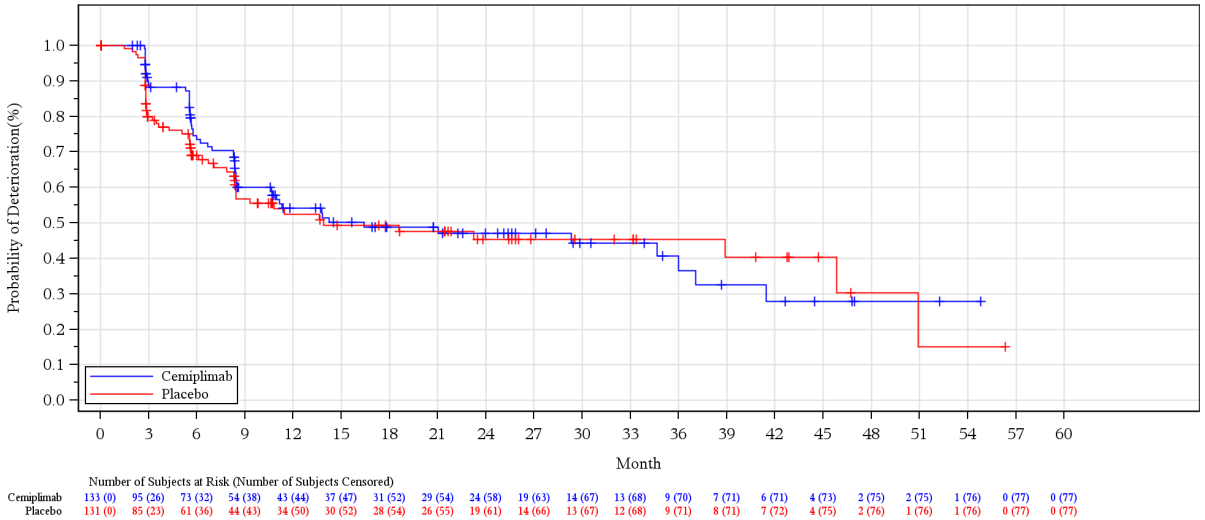
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	28 (10)	20 (13)	16 (14)	12 (16)	10 (16)	10 (16)	10 (16)	9 (16)	8 (17)	6 (18)	5 (19)	4 (19)	3 (20)	3 (20)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	29 (0)	19 (6)	12 (7)	6 (9)	4 (10)	4 (10)	4 (10)	4 (10)	2 (12)	2 (12)	2 (12)	1 (13)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



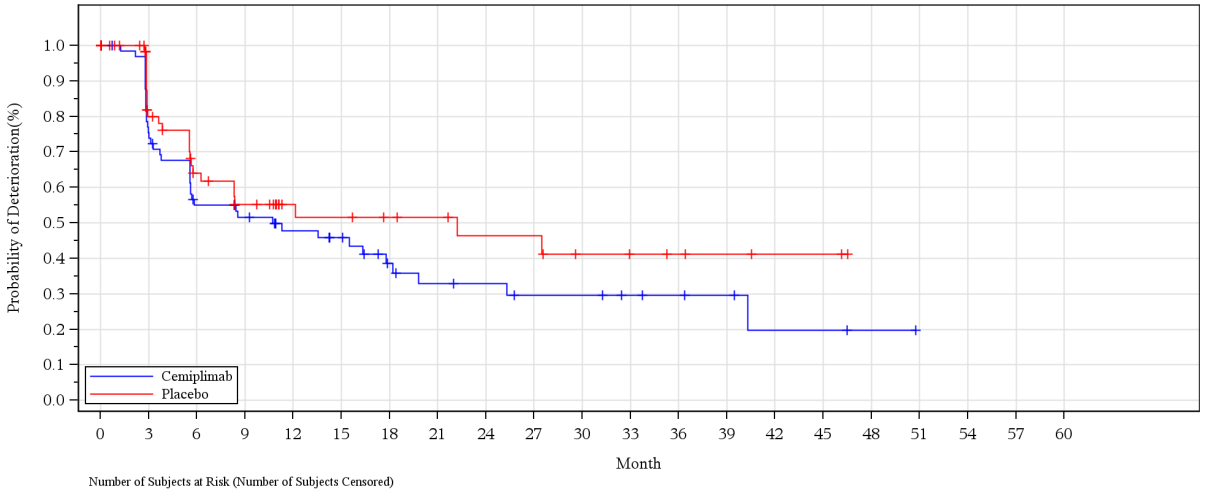
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	95 (26)	73 (32)	54 (38)	43 (44)	37 (47)	31 (52)	29 (54)	24 (58)	19 (63)	14 (67)	13 (68)	9 (70)	7 (71)	6 (71)	4 (73)	2 (75)	2 (75)	1 (76)	0 (77)	0 (77)
Placebo	131 (0)	85 (23)	61 (36)	44 (43)	34 (50)	30 (52)	28 (54)	26 (55)	19 (61)	14 (66)	13 (67)	12 (68)	9 (71)	8 (71)	7 (72)	4 (75)	2 (76)	1 (76)	1 (76)	0 (77)	0 (77)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



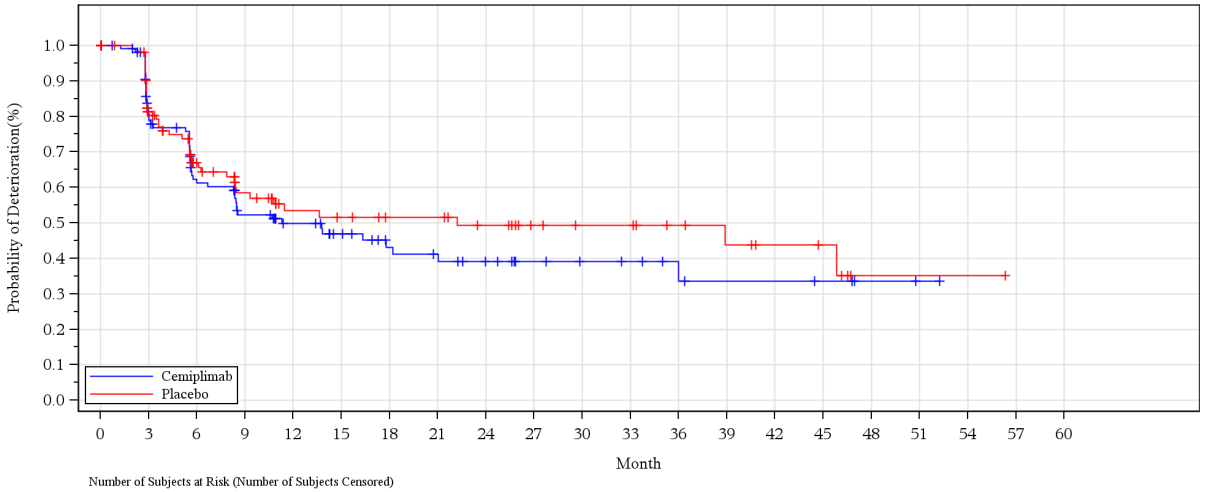
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	49 (11)	34 (13)	30 (15)	24 (19)	21 (21)	14 (25)	11 (26)	10 (27)	8 (28)	8 (28)	6 (30)	5 (31)	4 (32)	2 (33)	2 (33)	1 (34)	0 (35)	0 (35)	0 (35)	0 (35)
Placebo	75 (0)	42 (22)	30 (26)	24 (28)	15 (37)	14 (37)	12 (39)	11 (40)	9 (41)	9 (41)	6 (43)	5 (44)	4 (45)	3 (46)	2 (47)	2 (47)	0 (49)	0 (49)	0 (49)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:15 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	82 (23)	58 (28)	45 (33)	36 (40)	29 (45)	22 (50)	20 (51)	16 (54)	12 (58)	10 (60)	9 (61)	6 (63)	5 (64)	5 (64)	4 (65)	2 (67)	1 (68)	0 (69)	0 (69)	0 (69)
Placebo	117 (0)	78 (20)	52 (33)	39 (40)	29 (47)	27 (48)	24 (51)	24 (51)	20 (54)	15 (59)	13 (61)	13 (61)	10 (64)	8 (65)	6 (67)	5 (68)	1 (71)	1 (71)	1 (71)	0 (72)	0 (72)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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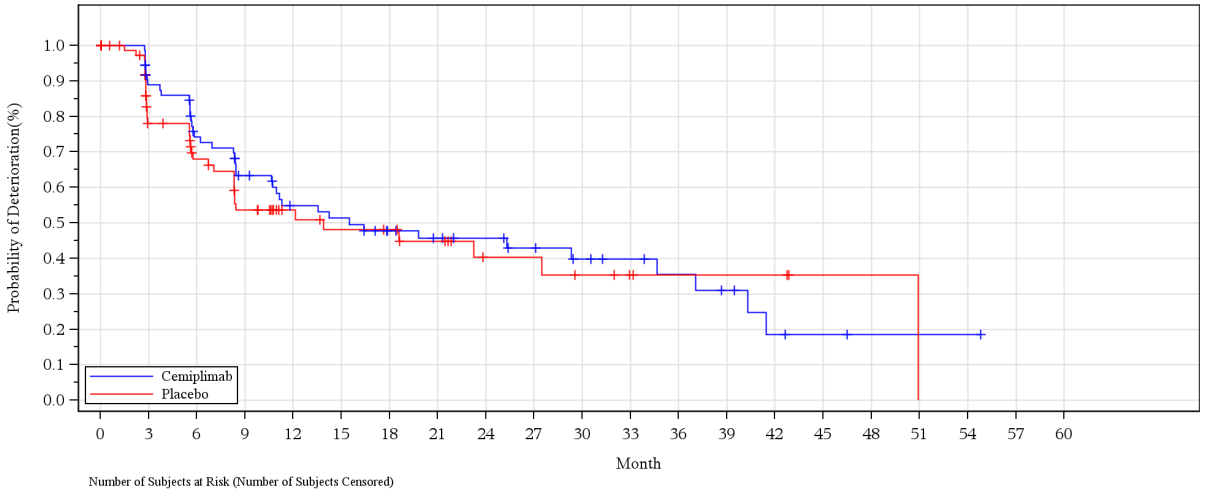
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	62 (14)	49 (17)	39 (20)	31 (23)	29 (23)	23 (27)	20 (29)	18 (31)	15 (33)	12 (35)	10 (37)	8 (38)	6 (39)	3 (40)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)
Placebo	89 (0)	49 (25)	39 (29)	29 (31)	20 (40)	17 (41)	16 (42)	13 (44)	8 (48)	8 (48)	6 (49)	4 (51)	3 (52)	3 (52)	3 (52)	1 (54)	1 (54)	0 (54)	0 (54)	0 (54)	0 (54)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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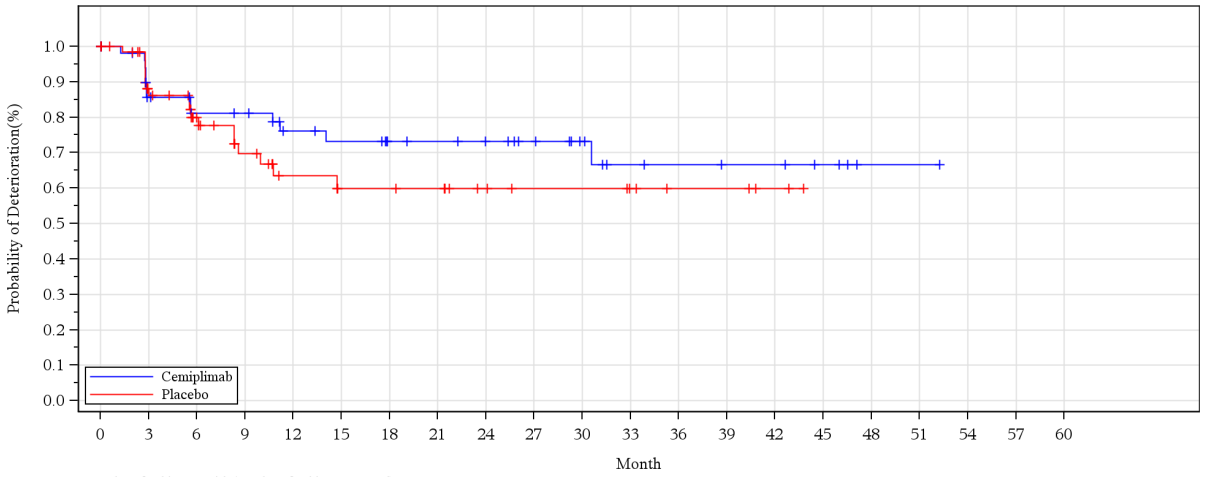
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	40 (9)	35 (12)	34 (13)	28 (17)	26 (18)	22 (22)	21 (23)	19 (25)	16 (28)	12 (32)	8 (35)	7 (36)	6 (37)	6 (37)	4 (39)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)
Placebo	65 (0)	47 (11)	35 (19)	25 (25)	18 (30)	15 (32)	15 (32)	14 (33)	10 (37)	8 (39)	8 (39)	6 (41)	4 (43)	4 (43)	2 (45)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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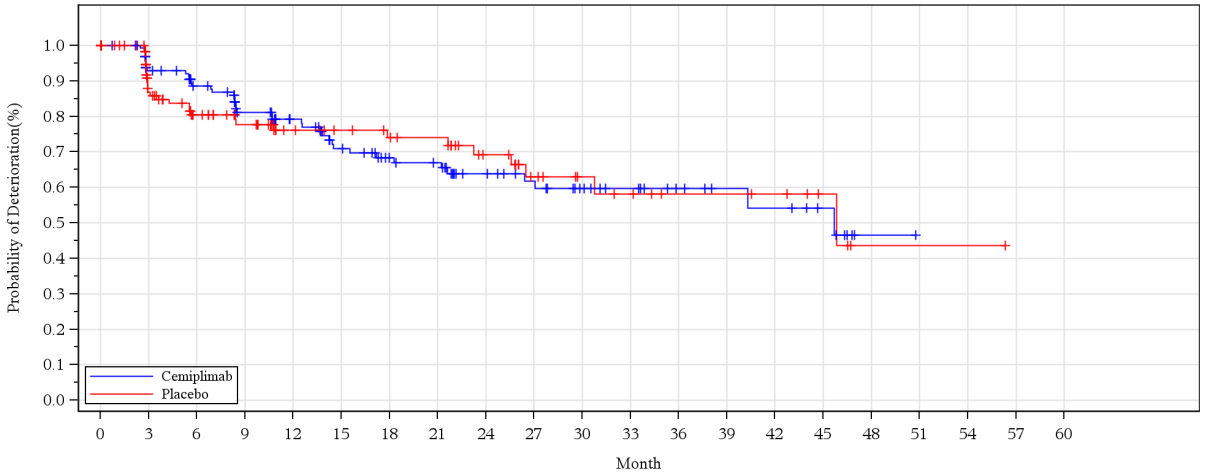
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



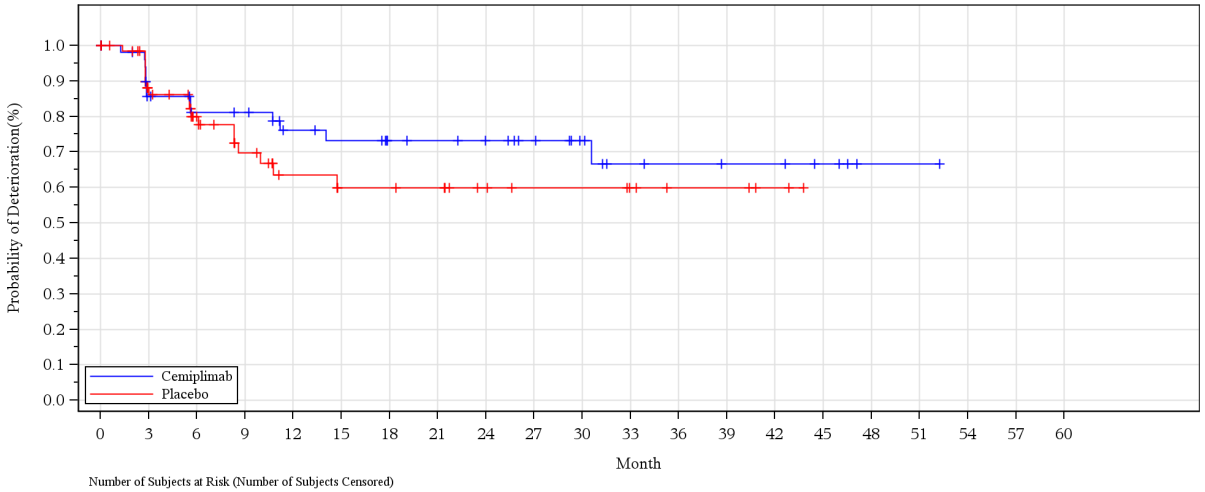
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	114 (30)	100 (39)	82 (49)	71 (58)	58 (64)	48 (72)	45 (74)	34 (83)	29 (87)	23 (92)	19 (96)	14 (101)	11 (104)	10 (104)	7 (107)	1 (112)	0 (113)	0 (113)	0 (113)	0 (113)
Placebo	141 (0)	87 (40)	68 (53)	57 (62)	43 (75)	39 (79)	36 (81)	34 (83)	25 (90)	17 (96)	13 (100)	11 (101)	8 (104)	8 (104)	7 (105)	4 (108)	1 (110)	1 (110)	1 (110)	0 (111)	0 (111)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



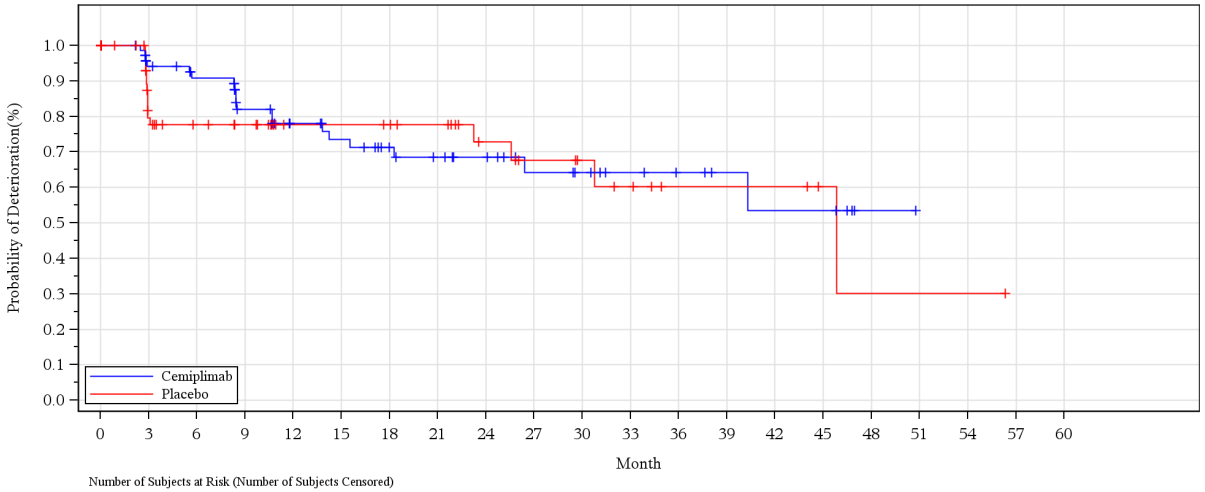
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	40 (9)	35 (12)	34 (13)	28 (17)	26 (18)	22 (22)	21 (23)	19 (25)	16 (28)	12 (32)	8 (35)	7 (36)	6 (37)	6 (37)	4 (39)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)
Placebo	65 (0)	47 (11)	35 (19)	25 (25)	18 (30)	15 (32)	15 (32)	14 (33)	10 (37)	8 (39)	8 (39)	6 (41)	4 (43)	4 (43)	2 (45)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



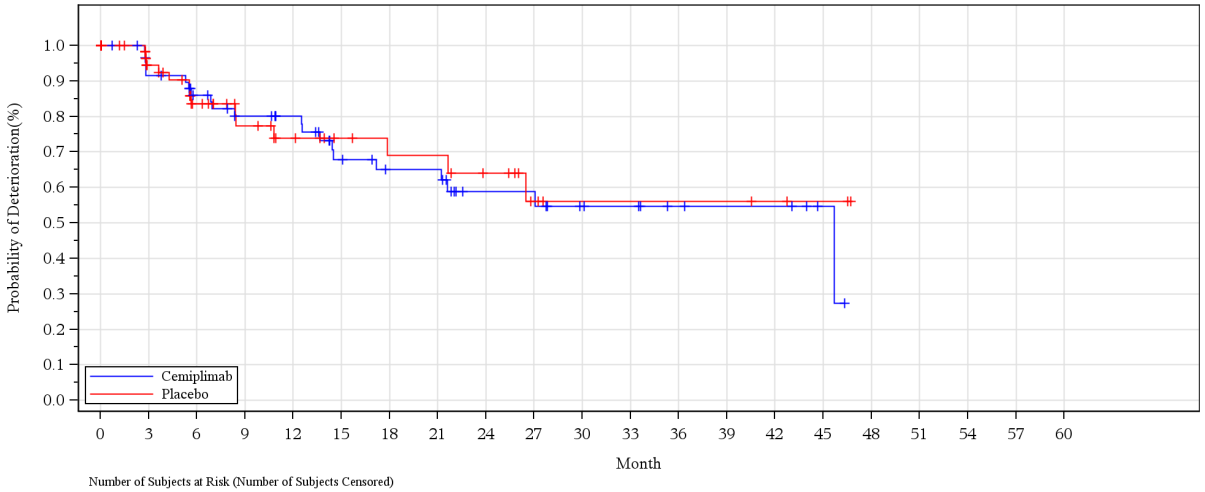
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	61 (15)	55 (19)	43 (26)	36 (31)	32 (33)	26 (38)	23 (40)	20 (43)	15 (47)	13 (49)	10 (52)	8 (54)	6 (56)	5 (56)	5 (56)	1 (60)	0 (61)	0 (61)	0 (61)	0 (61)
Placebo	69 (0)	41 (17)	35 (22)	32 (25)	23 (34)	23 (34)	22 (35)	20 (37)	14 (42)	11 (44)	9 (46)	7 (47)	4 (50)	4 (50)	4 (50)	2 (52)	1 (52)	1 (52)	1 (52)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



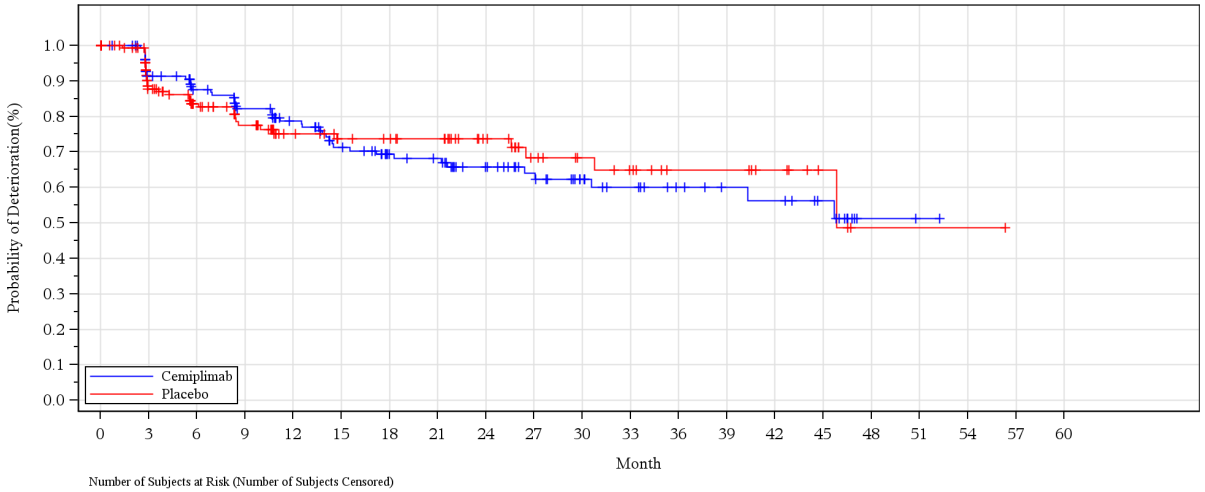
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	53 (15)	45 (20)	39 (23)	35 (27)	26 (31)	22 (34)	22 (34)	14 (40)	14 (40)	10 (43)	9 (44)	6 (47)	5 (48)	5 (48)	2 (51)	0 (52)	0 (52)	0 (52)	0 (52)	0 (52)
Placebo	72 (0)	46 (23)	33 (31)	25 (37)	20 (41)	16 (45)	14 (46)	14 (46)	11 (48)	6 (52)	4 (54)	4 (54)	4 (54)	4 (54)	3 (55)	2 (56)	0 (58)	0 (58)	0 (58)	0 (58)	0 (58)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Gender group: Male



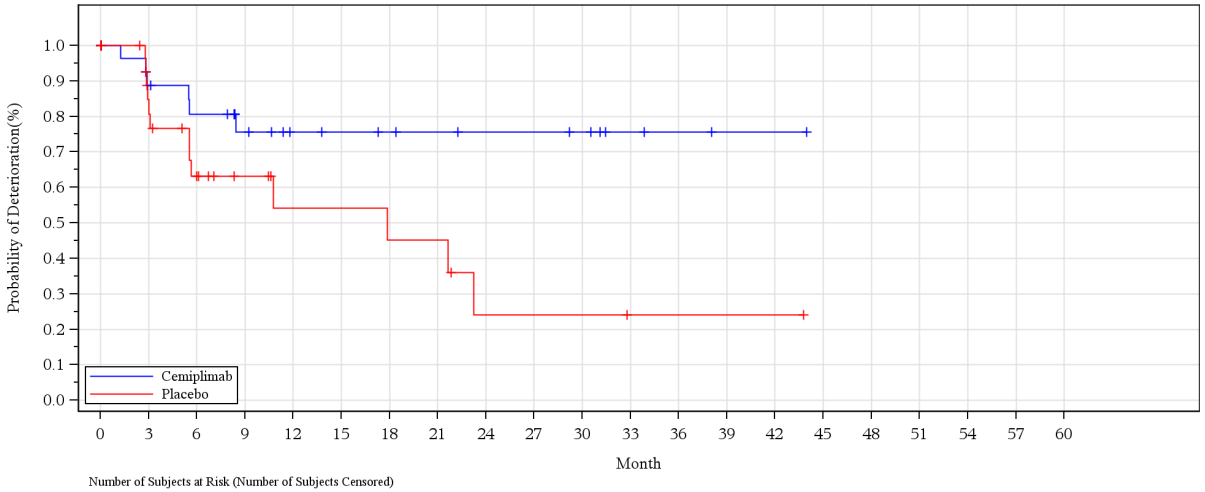
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	131 (30)	115 (41)	101 (48)	88 (57)	74 (63)	61 (74)	58 (76)	46 (86)	38 (93)	29 (101)	24 (105)	19 (110)	16 (113)	15 (113)	11 (117)	2 (125)	1 (126)	0 (127)	0 (127)	0 (127)
Placebo	174 (0)	113 (44)	89 (63)	73 (73)	55 (89)	48 (95)	46 (97)	43 (100)	33 (110)	23 (118)	19 (122)	16 (124)	11 (129)	11 (129)	8 (132)	4 (136)	1 (138)	1 (138)	1 (138)	0 (139)	0 (139)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Gender group: Female



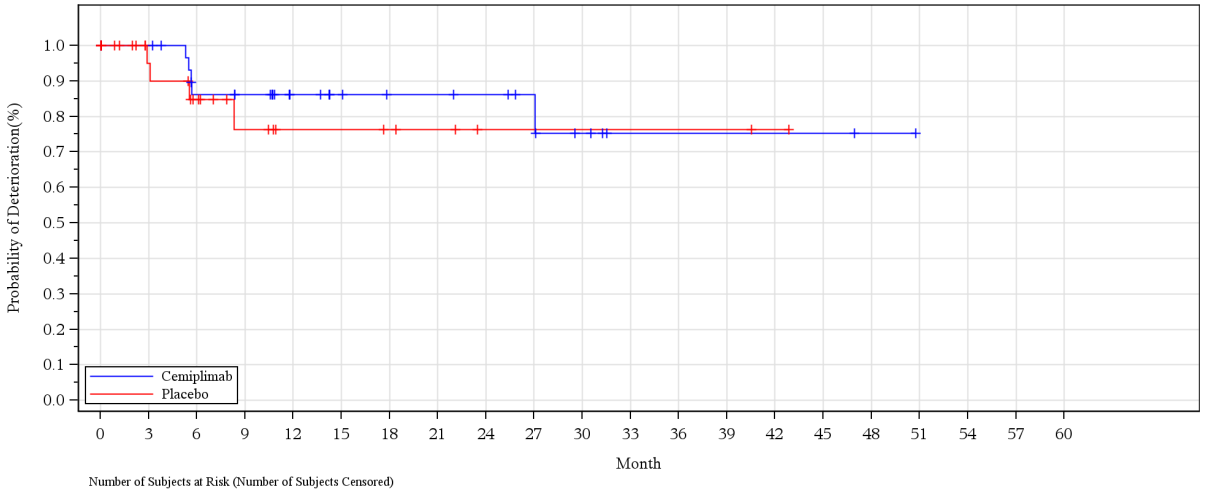
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	23 (9)	20 (10)	15 (14)	11 (18)	10 (19)	9 (20)	8 (21)	7 (22)	7 (22)	6 (23)	3 (26)	2 (27)	1 (28)	1 (28)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)
Placebo	32 (0)	21 (7)	14 (9)	9 (14)	6 (16)	6 (16)	5 (16)	5 (16)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



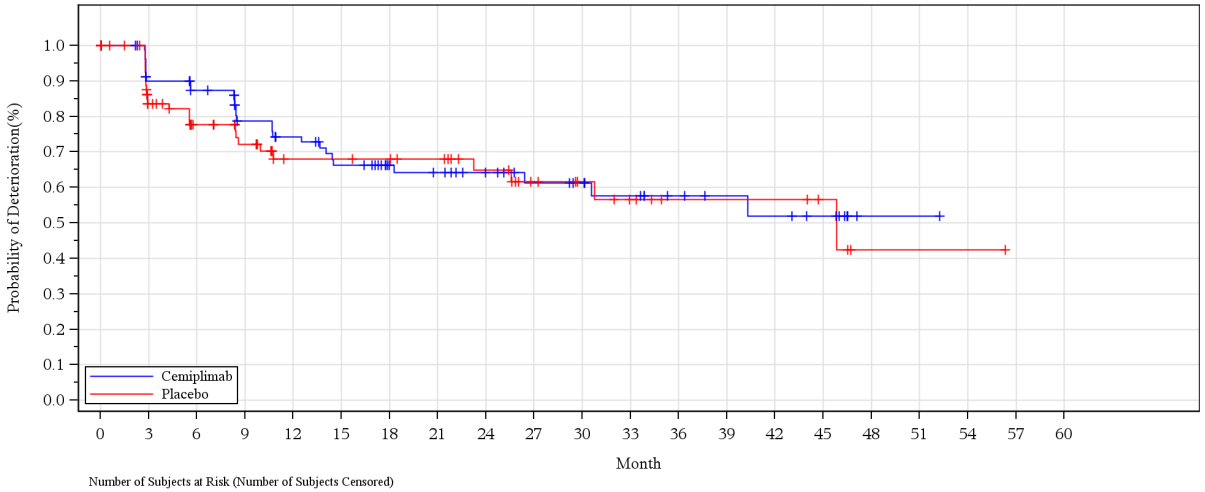
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	31 (6)	24 (9)	22 (11)	16 (17)	13 (20)	11 (22)	11 (22)	10 (23)	8 (25)	5 (27)	2 (30)	2 (30)	2 (30)	2 (30)	2 (30)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	31 (0)	19 (11)	14 (14)	9 (18)	6 (21)	6 (21)	5 (22)	4 (23)	2 (25)	2 (25)	2 (25)	2 (25)	2 (25)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



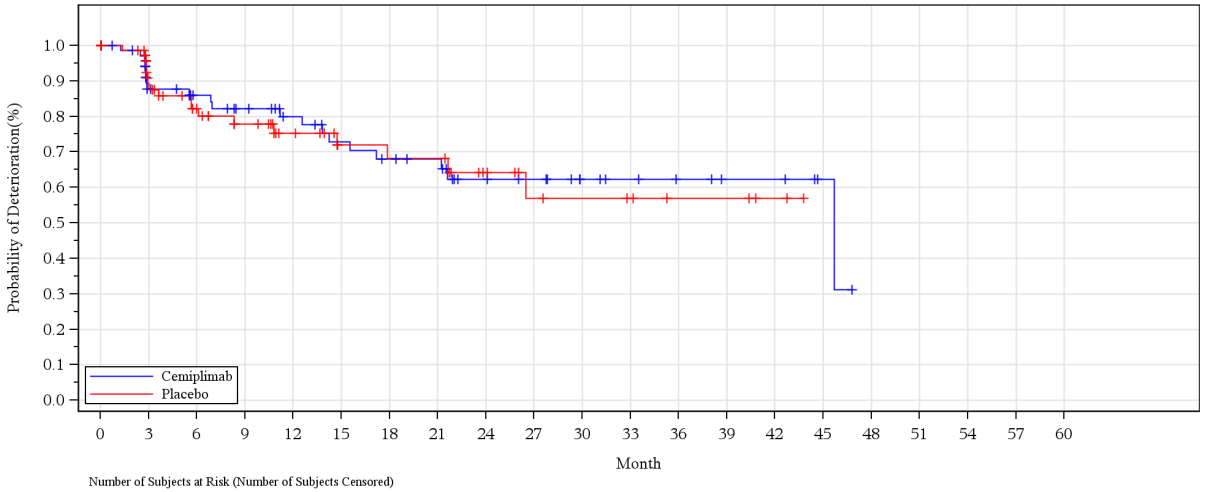
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	70 (12)	65 (15)	53 (21)	48 (23)	41 (25)	32 (34)	30 (35)	25 (40)	21 (43)	19 (45)	16 (47)	12 (51)	10 (53)	9 (53)	7 (55)	1 (61)	1 (61)	0 (62)	0 (62)	0 (62)
Placebo	90 (0)	61 (16)	47 (26)	39 (31)	29 (39)	29 (39)	28 (40)	26 (42)	21 (46)	15 (51)	12 (54)	9 (56)	6 (59)	6 (59)	6 (59)	4 (61)	1 (63)	1 (63)	1 (63)	0 (64)	0 (64)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



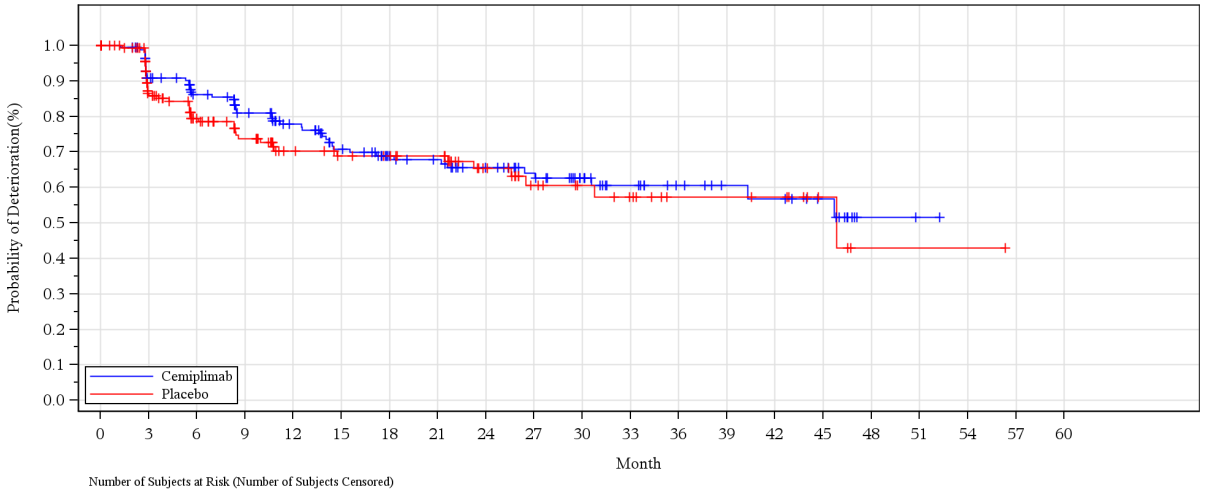
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	53 (21)	46 (27)	41 (30)	35 (35)	30 (37)	27 (38)	25 (40)	18 (45)	16 (47)	11 (52)	9 (54)	7 (56)	5 (58)	5 (58)	2 (61)	0 (62)	0 (62)	0 (62)	0 (62)	0 (62)
Placebo	85 (0)	54 (24)	42 (32)	34 (38)	26 (45)	19 (51)	18 (51)	18 (51)	12 (56)	8 (59)	7 (60)	6 (61)	4 (63)	4 (63)	2 (65)	0 (67)	0 (67)	0 (67)	0 (67)	0 (67)	0 (67)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Race: White



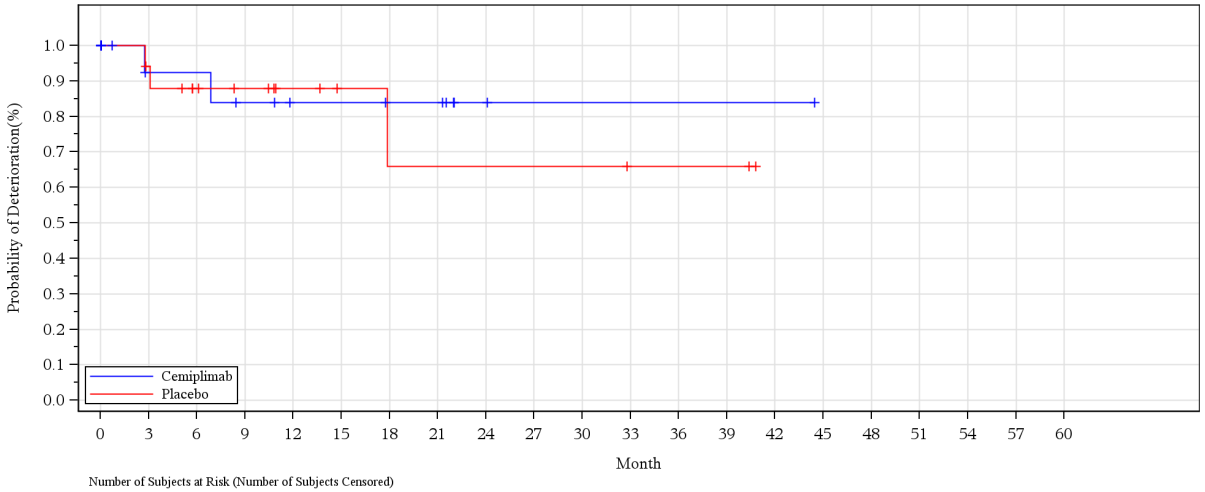
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	143 (31)	124 (43)	107 (53)	92 (64)	77 (71)	64 (82)	60 (85)	51 (92)	44 (98)	34 (107)	26 (114)	20 (120)	16 (124)	15 (124)	11 (128)	2 (136)	1 (137)	0 (138)	0 (138)	0 (138)
Placebo	189 (0)	119 (50)	92 (68)	73 (81)	55 (96)	50 (100)	48 (102)	45 (105)	32 (116)	22 (124)	18 (128)	15 (130)	10 (135)	10 (135)	9 (136)	4 (141)	1 (143)	1 (143)	1 (143)	0 (144)	0 (144)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (8)	11 (8)	9 (9)	7 (11)	7 (11)	6 (12)	6 (12)	2 (16)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	17 (0)	15 (1)	11 (4)	9 (6)	6 (9)	4 (11)	3 (11)	3 (11)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	2 (12)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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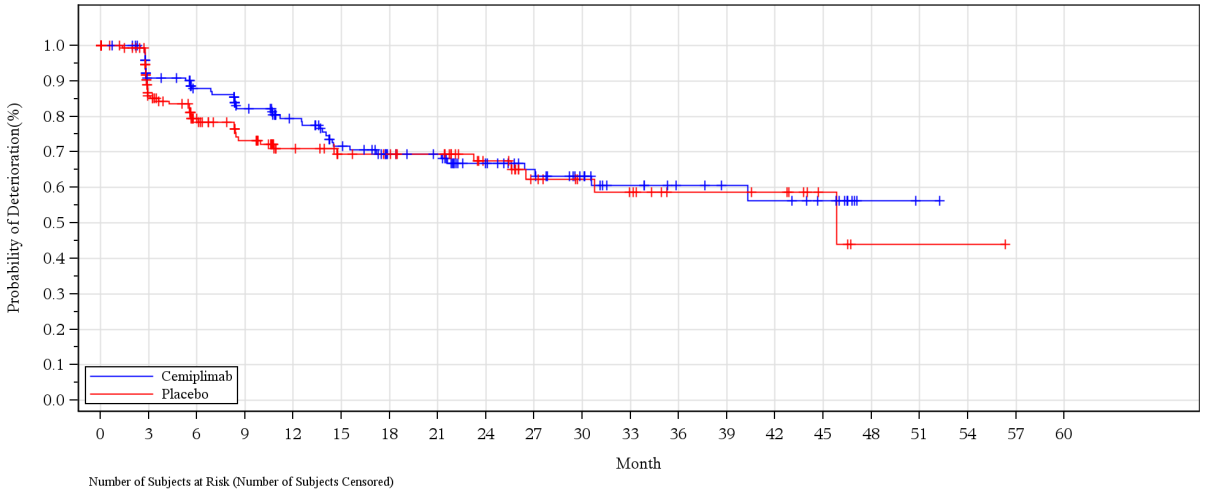
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	124 (29)	112 (37)	97 (45)	84 (55)	70 (61)	58 (71)	55 (74)	42 (85)	35 (91)	27 (98)	20 (104)	16 (108)	14 (110)	13 (110)	10 (113)	2 (121)	1 (122)	0 (123)	0 (123)	0 (123)
Placebo	177 (0)	113 (44)	87 (62)	70 (73)	53 (88)	46 (94)	44 (96)	41 (99)	30 (109)	21 (116)	17 (120)	15 (121)	10 (126)	10 (126)	9 (127)	4 (132)	1 (134)	1 (134)	1 (134)	0 (135)	0 (135)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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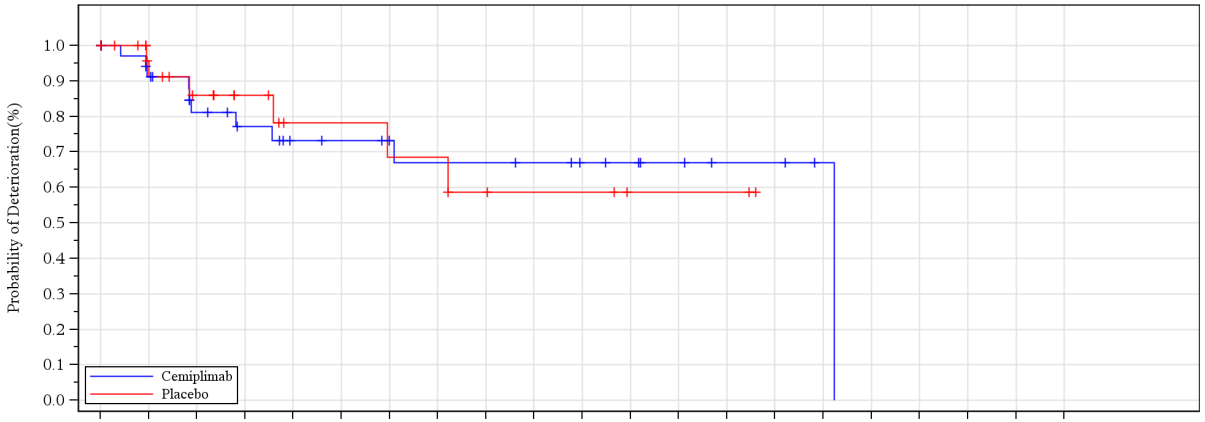
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	30 (10)	23 (14)	19 (17)	15 (20)	14 (21)	12 (23)	11 (23)	11 (23)	10 (24)	8 (26)	7 (27)	5 (29)	3 (31)	3 (31)	1 (33)	0 (33)	0 (33)	0 (33)	0 (33)
Placebo	29 (0)	21 (7)	16 (10)	12 (14)	8 (17)	8 (17)	7 (17)	7 (17)	5 (18)	4 (19)	4 (19)	2 (21)	2 (21)	2 (21)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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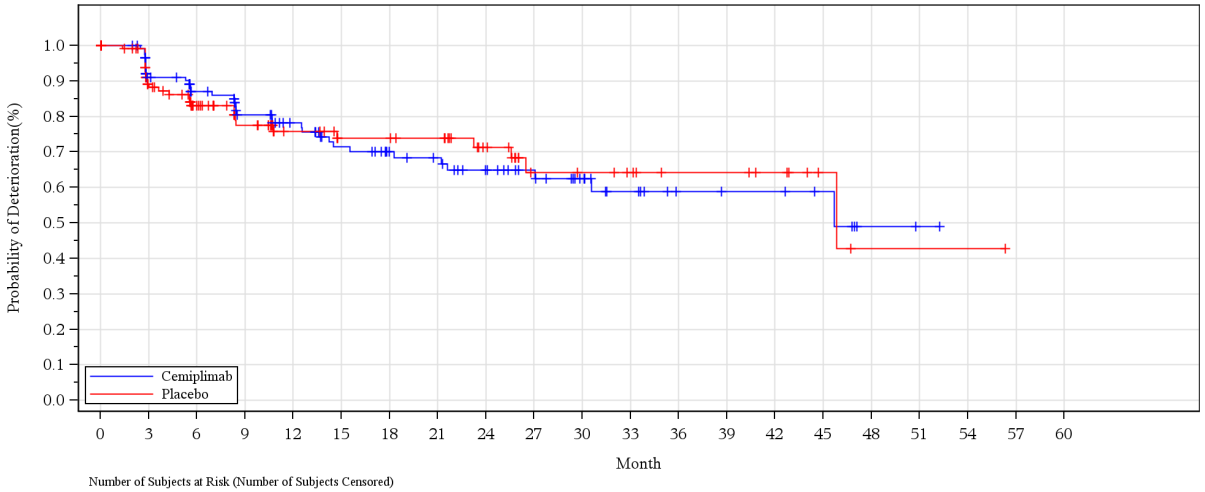
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



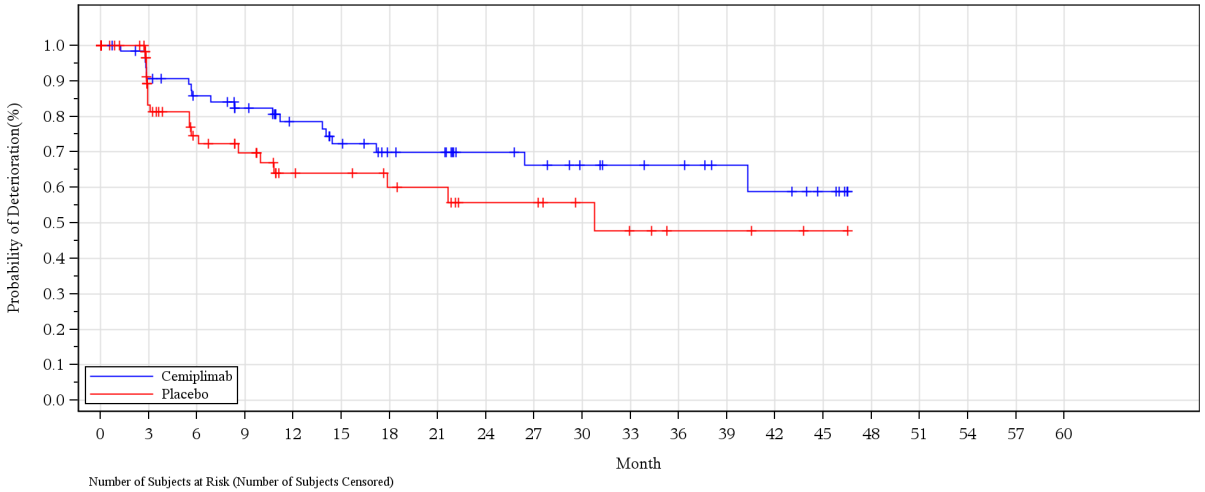
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	96 (27)	83 (36)	70 (43)	61 (50)	51 (55)	43 (62)	40 (64)	33 (69)	27 (75)	20 (81)	14 (86)	9 (91)	8 (92)	8 (92)	6 (94)	2 (97)	1 (98)	0 (99)	0 (99)	0 (99)
Placebo	131 (0)	92 (27)	71 (42)	55 (54)	42 (66)	36 (71)	36 (71)	34 (73)	25 (81)	15 (89)	14 (90)	12 (92)	9 (95)	9 (95)	7 (97)	3 (101)	1 (102)	1 (102)	1 (102)	0 (103)	0 (103)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



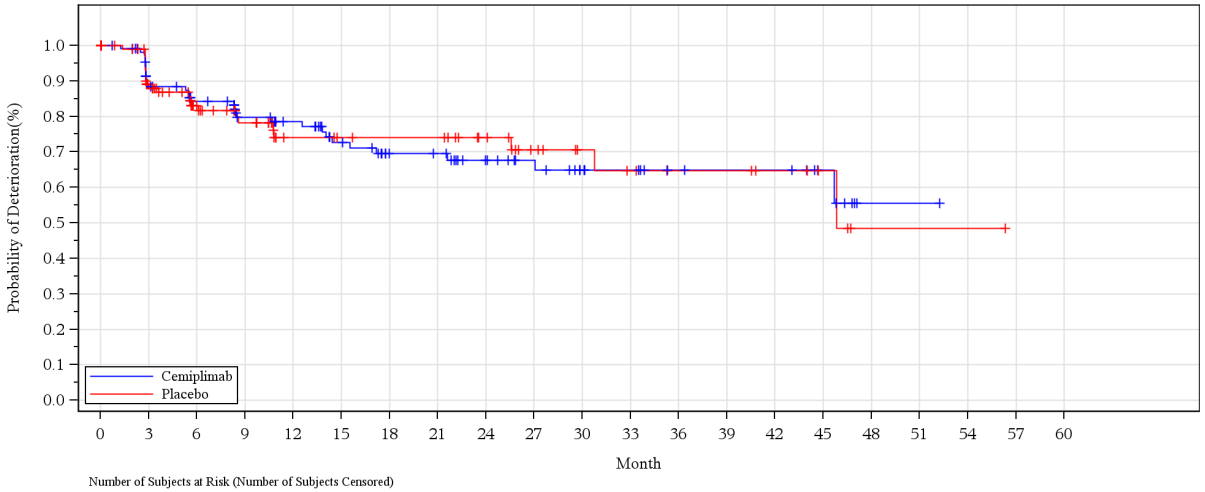
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	58 (12)	52 (15)	46 (19)	38 (25)	33 (27)	27 (32)	26 (33)	20 (39)	18 (40)	15 (43)	13 (45)	12 (46)	9 (49)	8 (49)	5 (52)	0 (57)	0 (57)	0 (57)	0 (57)	0 (57)
Placebo	75 (0)	42 (24)	32 (30)	27 (33)	19 (39)	18 (40)	15 (42)	14 (43)	10 (46)	10 (46)	7 (49)	5 (50)	3 (52)	3 (52)	2 (53)	1 (54)	0 (55)	0 (55)	0 (55)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



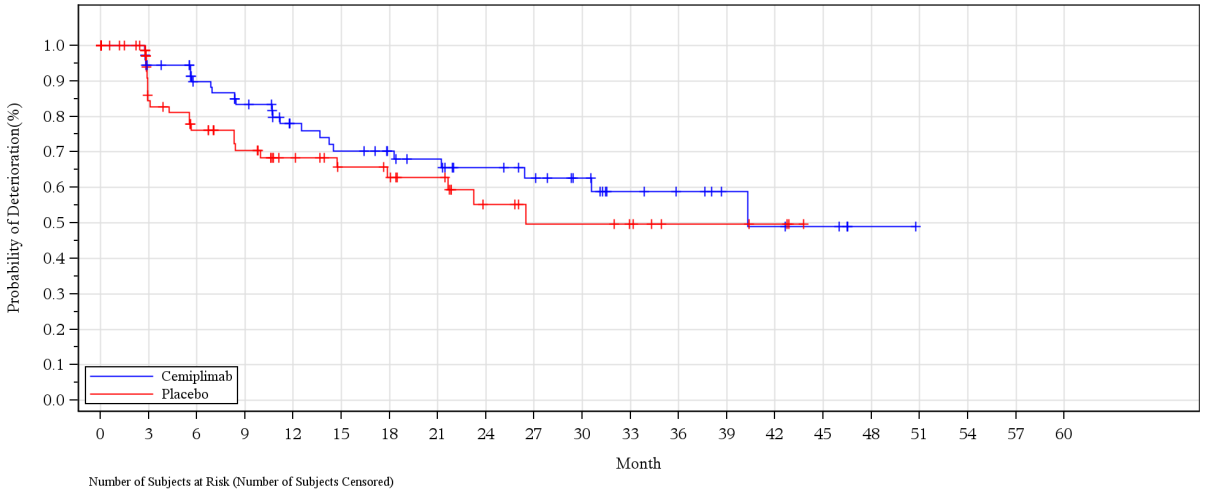
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	89 (24)	79 (30)	66 (39)	59 (45)	48 (52)	38 (60)	37 (61)	29 (68)	24 (73)	18 (78)	16 (80)	12 (84)	11 (85)	11 (85)	7 (89)	1 (94)	1 (94)	0 (95)	0 (95)	0 (95)
Placebo	117 (0)	82 (24)	59 (42)	45 (53)	32 (64)	30 (66)	29 (67)	29 (67)	23 (73)	16 (79)	12 (83)	10 (84)	8 (86)	8 (86)	6 (88)	4 (90)	1 (92)	1 (92)	1 (92)	0 (93)	0 (93)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



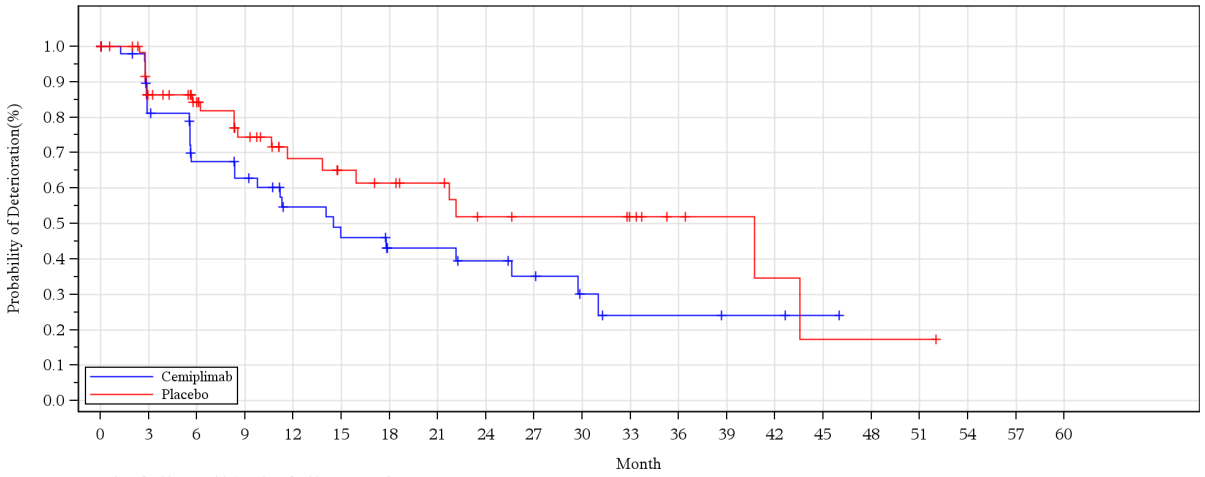
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	65 (15)	56 (21)	50 (23)	40 (30)	36 (30)	32 (34)	29 (36)	24 (40)	21 (42)	17 (46)	11 (51)	9 (53)	6 (56)	5 (56)	4 (57)	1 (60)	0 (61)	0 (61)	0 (61)	0 (61)
Placebo	89 (0)	52 (27)	44 (30)	37 (34)	29 (41)	24 (45)	22 (46)	19 (49)	12 (54)	9 (56)	9 (56)	7 (58)	4 (61)	4 (61)	3 (62)	0 (65)	0 (65)	0 (65)	0 (65)	0 (65)	0 (65)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



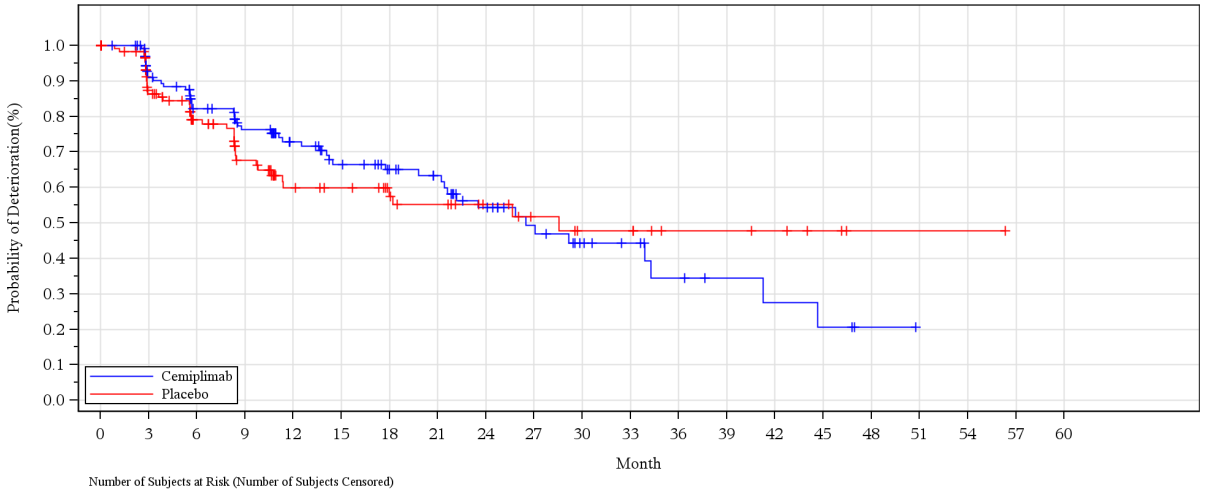
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (9)	29 (12)	26 (13)	19 (17)	16 (17)	12 (20)	12 (20)	10 (21)	8 (22)	5 (24)	3 (25)	3 (25)	2 (26)	2 (26)	1 (27)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	65 (0)	47 (10)	38 (18)	29 (23)	21 (29)	18 (31)	16 (32)	14 (34)	10 (36)	9 (37)	9 (37)	7 (39)	4 (42)	3 (43)	2 (43)	1 (43)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	107 (35)	89 (43)	75 (51)	60 (63)	50 (68)	42 (75)	37 (79)	27 (84)	20 (89)	14 (93)	11 (96)	7 (98)	5 (100)	4 (100)	3 (100)	1 (102)	0 (103)	0 (103)	0 (103)	0 (103)
Placebo	141 (0)	90 (36)	68 (51)	49 (61)	34 (71)	31 (74)	25 (79)	22 (81)	17 (86)	13 (89)	10 (91)	10 (91)	6 (95)	6 (95)	5 (96)	3 (98)	1 (100)	1 (100)	1 (100)	0 (101)	0 (101)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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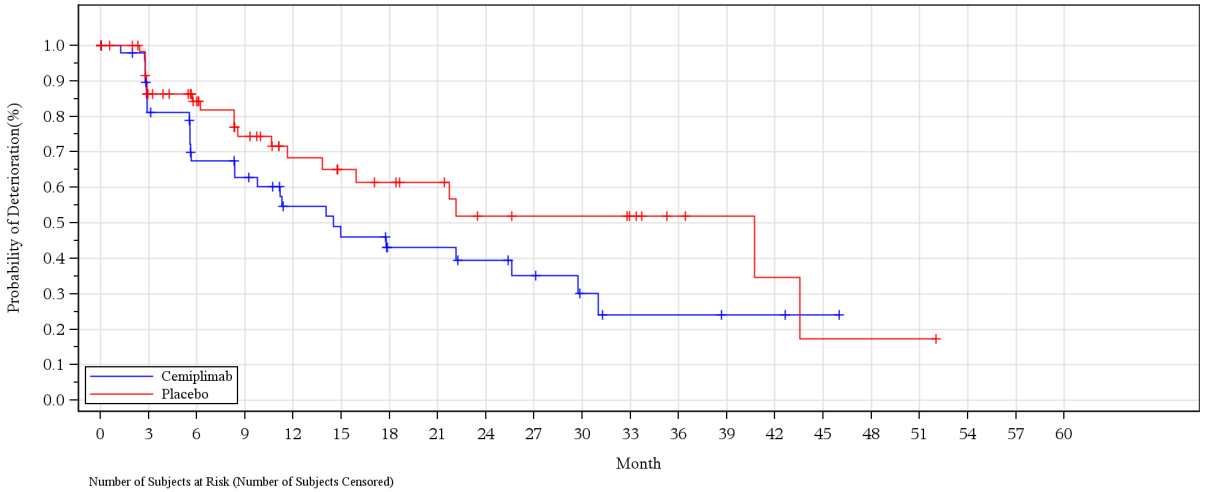
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



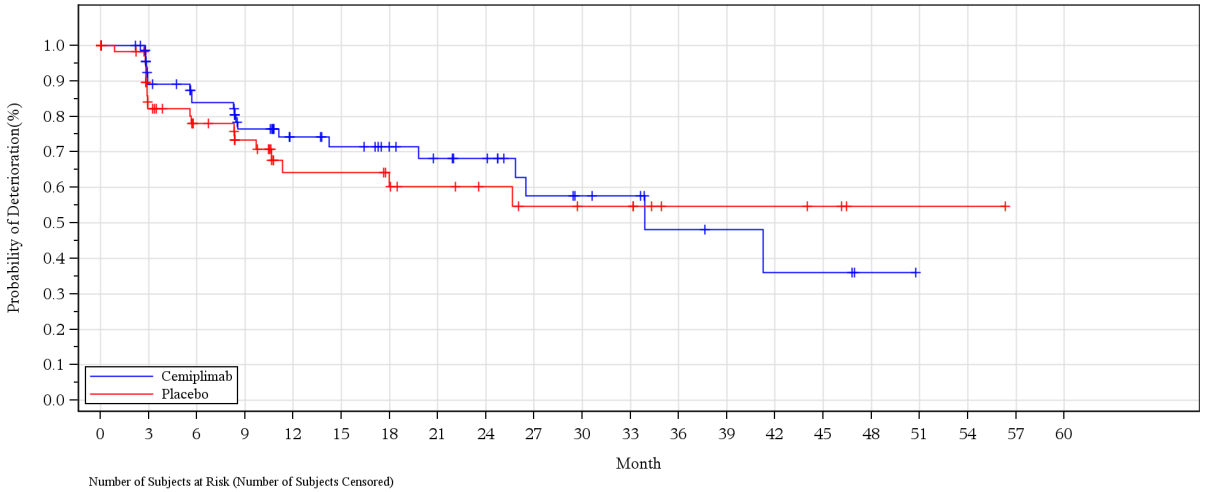
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (9)	29 (12)	26 (13)	19 (17)	16 (17)	12 (20)	12 (20)	10 (21)	8 (22)	5 (24)	3 (25)	3 (25)	2 (26)	2 (26)	1 (27)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	65 (0)	47 (10)	38 (18)	29 (23)	21 (29)	18 (31)	16 (32)	14 (34)	10 (36)	9 (37)	9 (37)	7 (39)	4 (42)	3 (43)	2 (43)	1 (43)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



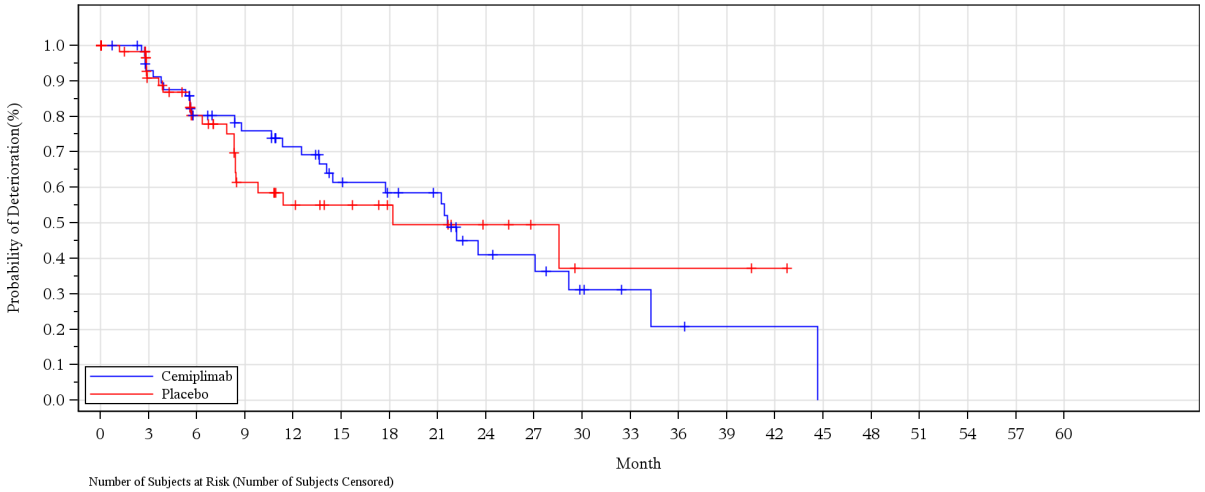
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	55 (18)	48 (22)	39 (27)	30 (35)	27 (37)	22 (42)	19 (44)	17 (46)	11 (50)	9 (52)	8 (53)	5 (55)	4 (56)	3 (56)	3 (56)	1 (58)	0 (59)	0 (59)	0 (59)	0 (59)
Placebo	69 (0)	44 (15)	35 (22)	28 (27)	18 (34)	18 (34)	15 (36)	13 (38)	11 (40)	9 (41)	8 (42)	8 (42)	4 (46)	4 (46)	4 (46)	3 (47)	1 (49)	1 (49)	1 (49)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



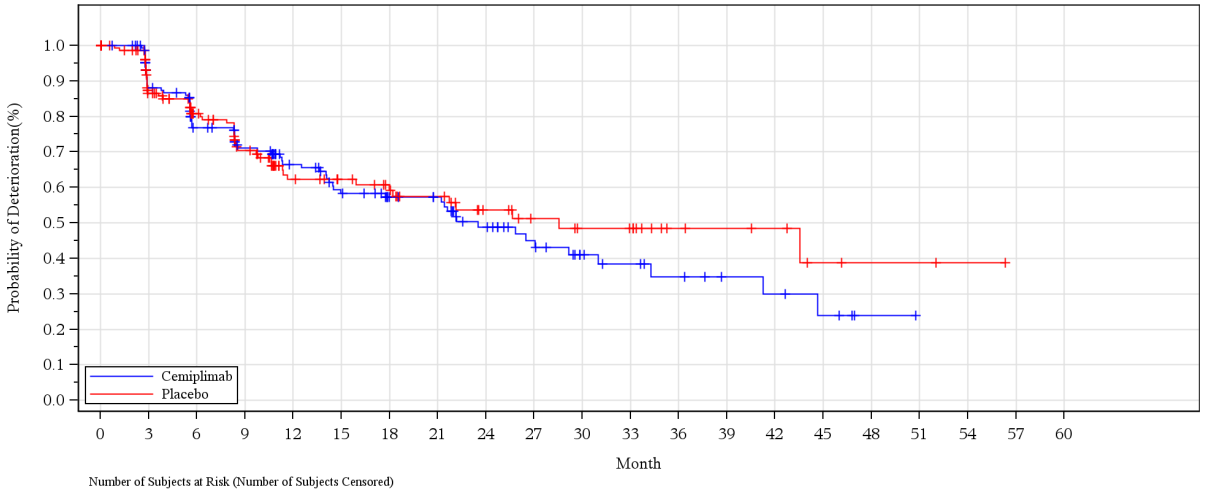
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	52 (17)	41 (21)	36 (24)	30 (28)	23 (31)	20 (33)	18 (35)	10 (38)	9 (39)	5 (41)	3 (43)	2 (43)	1 (44)	1 (44)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)
Placebo	72 (0)	46 (21)	33 (29)	21 (34)	16 (37)	13 (40)	10 (43)	9 (43)	6 (46)	4 (48)	2 (49)	2 (49)	2 (49)	2 (49)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	123 (34)	98 (44)	84 (51)	68 (62)	56 (66)	46 (75)	43 (78)	32 (83)	24 (89)	16 (95)	13 (97)	10 (99)	7 (102)	6 (102)	4 (103)	1 (106)	0 (107)	0 (107)	0 (107)	0 (107)
Placebo	174 (0)	115 (40)	90 (58)	70 (67)	48 (82)	43 (87)	37 (91)	32 (95)	24 (101)	19 (105)	16 (107)	15 (108)	8 (115)	7 (116)	6 (117)	3 (119)	2 (120)	2 (120)	1 (121)	0 (122)	0 (122)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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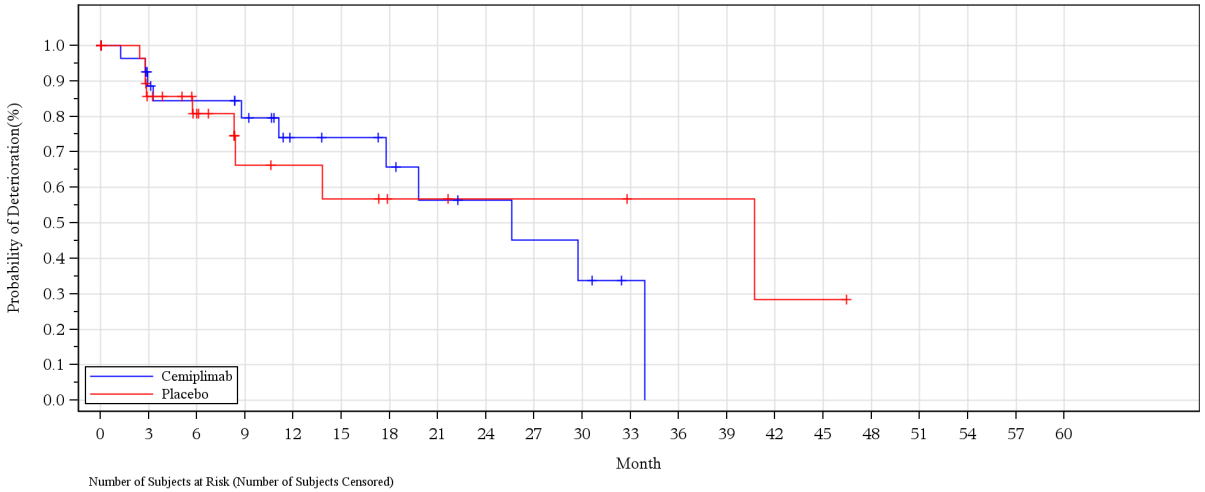
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	22 (10)	20 (11)	17 (13)	11 (18)	10 (19)	8 (20)	6 (21)	5 (22)	4 (22)	3 (22)	1 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)
Placebo	32 (0)	22 (6)	16 (11)	8 (17)	7 (18)	6 (18)	4 (20)	4 (20)	3 (21)	3 (21)	3 (21)	2 (22)	2 (22)	2 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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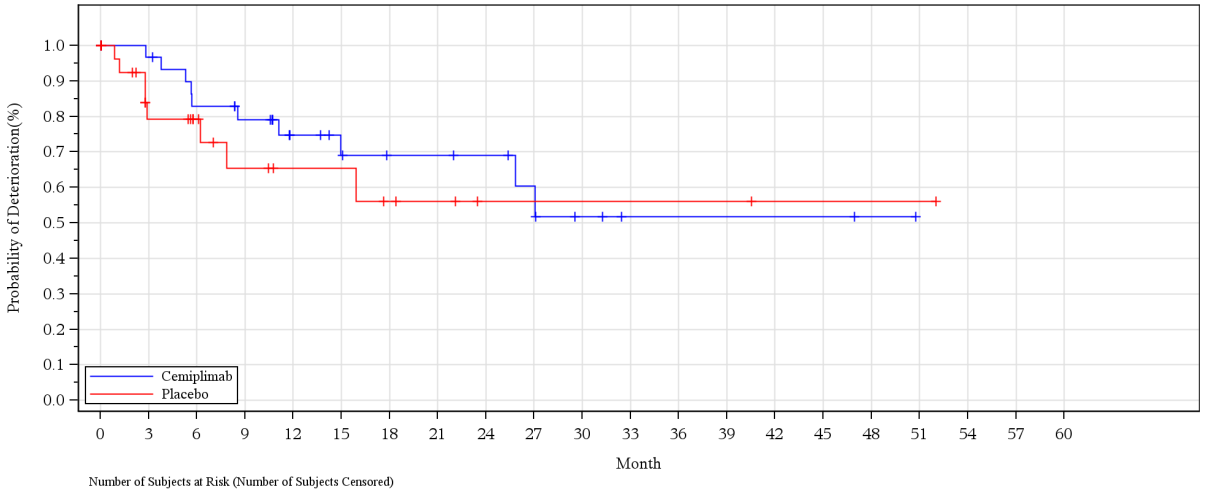
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (7)	24 (8)	21 (10)	15 (15)	12 (17)	10 (19)	10 (19)	9 (20)	7 (21)	4 (23)	2 (25)	2 (25)	2 (25)	2 (25)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	31 (0)	17 (9)	13 (13)	9 (15)	7 (17)	7 (17)	5 (18)	4 (19)	2 (21)	2 (21)	2 (21)	2 (21)	2 (21)	2 (21)	1 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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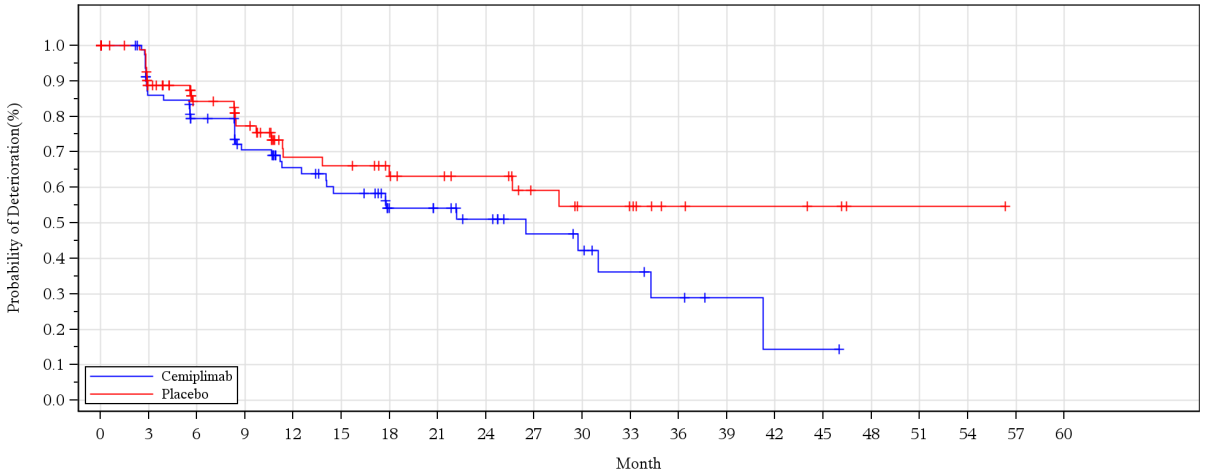
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



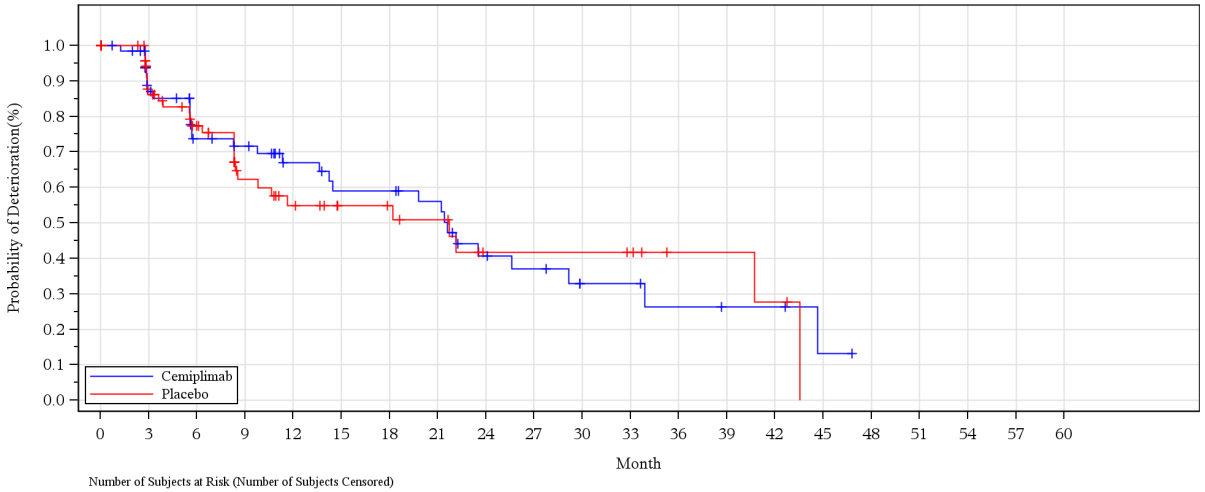
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	66 (13)	57 (17)	46 (22)	38 (27)	32 (29)	22 (37)	20 (39)	16 (42)	11 (46)	9 (47)	6 (49)	4 (50)	2 (52)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)	0 (53)	0 (53)
Placebo	90 (0)	67 (14)	52 (26)	43 (31)	28 (42)	27 (42)	22 (46)	20 (48)	18 (50)	13 (54)	10 (56)	9 (57)	5 (61)	4 (62)	4 (62)	3 (63)	1 (65)	1 (65)	1 (65)	0 (66)	0 (66)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	50 (24)	37 (30)	34 (32)	26 (38)	22 (39)	22 (39)	19 (41)	12 (43)	10 (44)	6 (47)	6 (47)	4 (48)	3 (49)	3 (49)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	85 (0)	53 (23)	41 (30)	26 (38)	20 (41)	15 (46)	14 (47)	12 (48)	7 (51)	7 (51)	7 (51)	6 (52)	3 (55)	3 (55)	2 (55)	0 (56)	0 (56)	0 (56)	0 (56)	0 (56)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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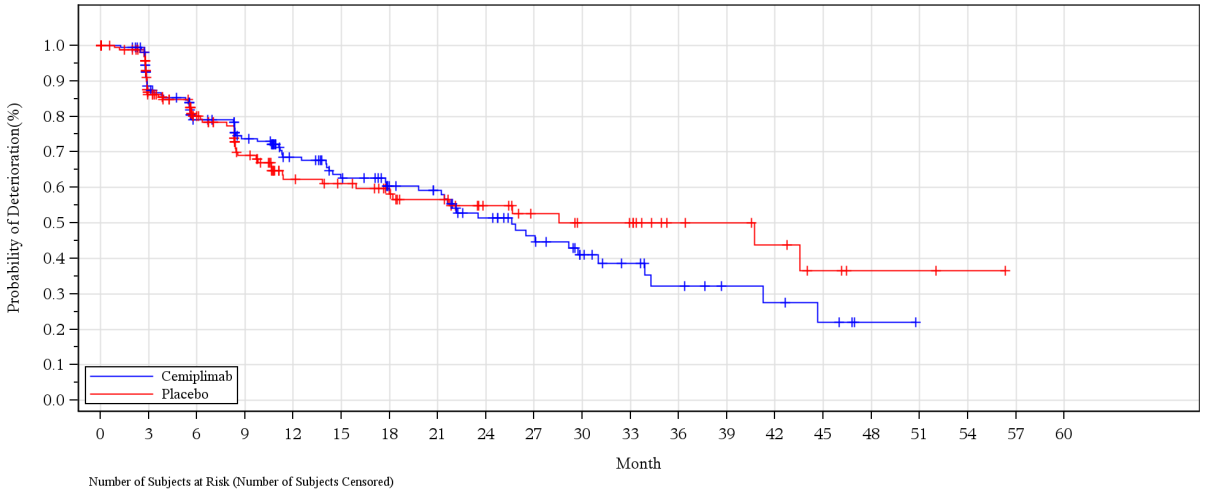
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	133 (36)	110 (47)	94 (56)	73 (71)	62 (76)	51 (85)	47 (88)	36 (93)	28 (98)	19 (104)	14 (108)	10 (110)	7 (113)	6 (113)	4 (114)	1 (117)	0 (118)	0 (118)	0 (118)	0 (118)
Placebo	189 (0)	123 (45)	95 (65)	70 (78)	50 (92)	46 (95)	39 (100)	34 (104)	26 (111)	21 (115)	18 (117)	17 (118)	10 (125)	9 (126)	7 (127)	4 (129)	2 (131)	2 (131)	1 (132)	0 (133)	0 (133)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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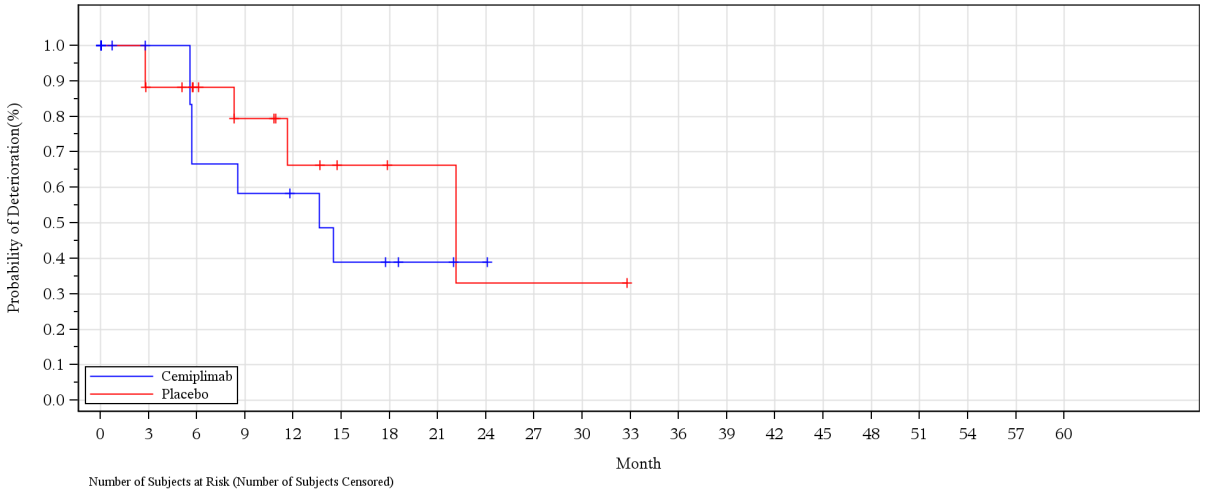
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Race: Non-white



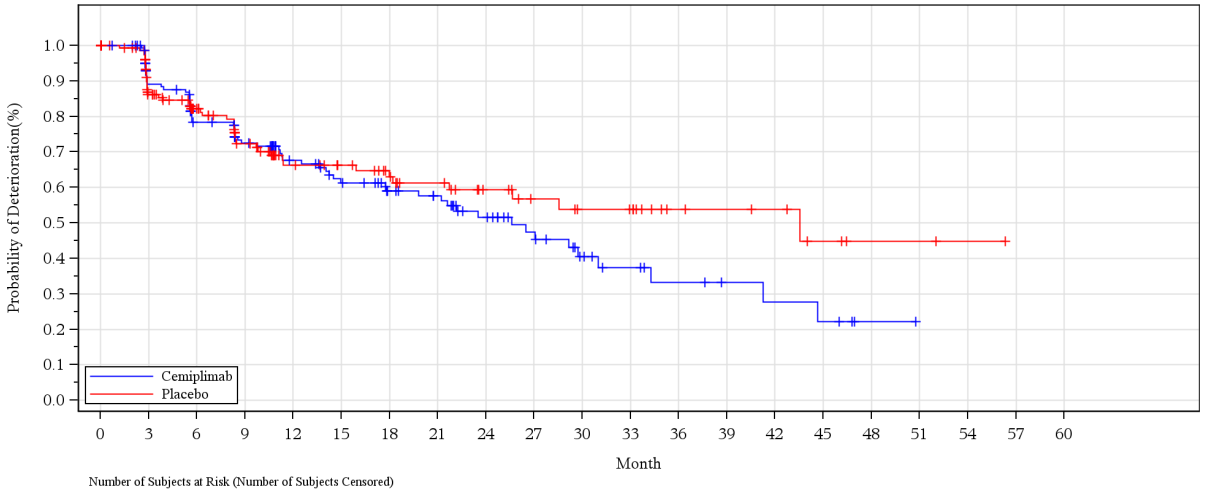
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	12 (8)	8 (8)	7 (8)	6 (9)	4 (9)	3 (10)	2 (11)	1 (12)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)
Placebo	17 (0)	14 (1)	11 (4)	8 (6)	5 (8)	3 (10)	2 (11)	2 (11)	1 (11)	1 (11)	1 (11)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	119 (32)	98 (39)	84 (46)	67 (58)	57 (62)	46 (71)	41 (75)	31 (81)	23 (87)	15 (92)	11 (95)	8 (97)	6 (99)	5 (99)	4 (99)	1 (102)	0 (103)	0 (103)	0 (103)	0 (103)
Placebo	177 (0)	117 (40)	91 (61)	69 (73)	49 (88)	44 (93)	37 (98)	32 (102)	25 (108)	20 (112)	17 (114)	16 (115)	9 (122)	8 (123)	7 (124)	4 (126)	2 (128)	2 (128)	1 (129)	0 (130)	0 (130)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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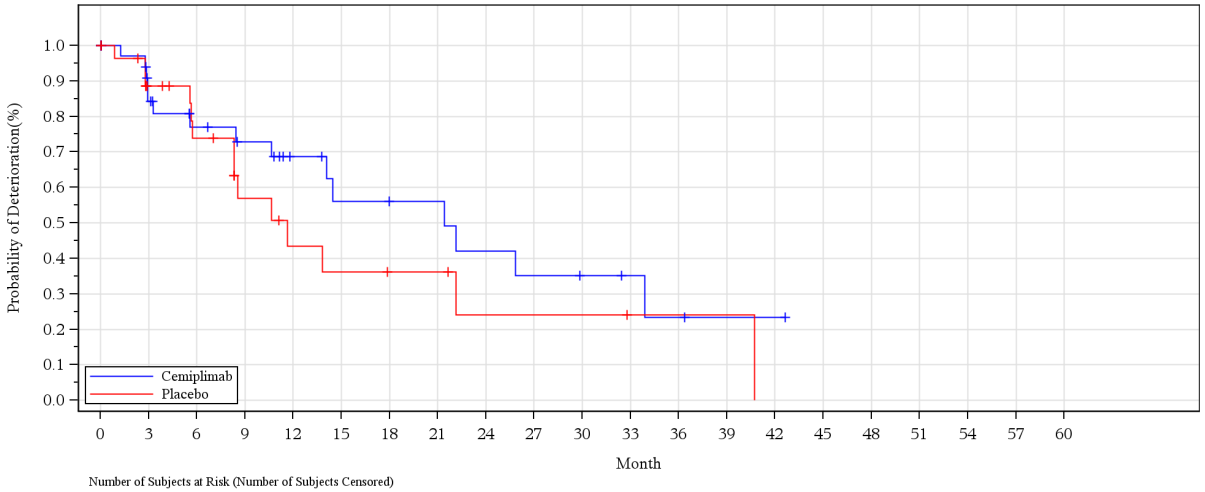
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	26 (12)	20 (16)	17 (18)	12 (22)	9 (23)	8 (24)	8 (24)	6 (24)	5 (24)	4 (25)	3 (26)	2 (26)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	29 (0)	20 (6)	15 (8)	9 (11)	6 (12)	5 (12)	4 (13)	4 (13)	2 (14)	2 (14)	2 (14)	1 (15)	1 (15)	1 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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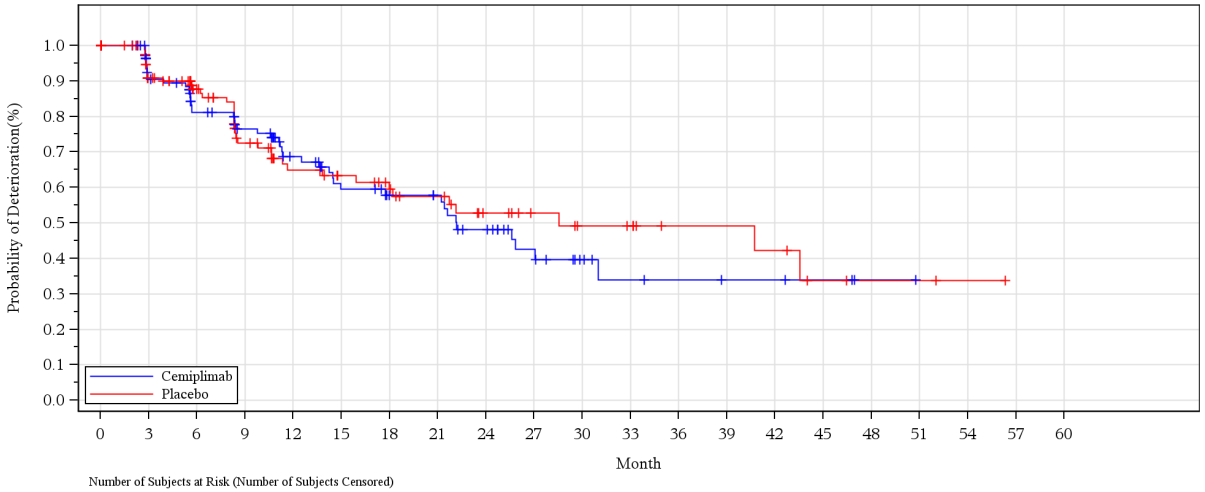
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	92 (31)	75 (39)	64 (46)	48 (56)	38 (60)	32 (65)	30 (67)	23 (69)	15 (75)	9 (80)	6 (82)	5 (83)	4 (84)	4 (84)	3 (85)	1 (87)	0 (88)	0 (88)	0 (88)	0 (88)
Placebo	131 (0)	95 (26)	76 (42)	53 (53)	40 (61)	35 (65)	30 (68)	26 (71)	19 (76)	15 (80)	12 (82)	11 (83)	7 (87)	7 (87)	6 (87)	3 (89)	2 (90)	2 (90)	1 (91)	0 (92)	0 (92)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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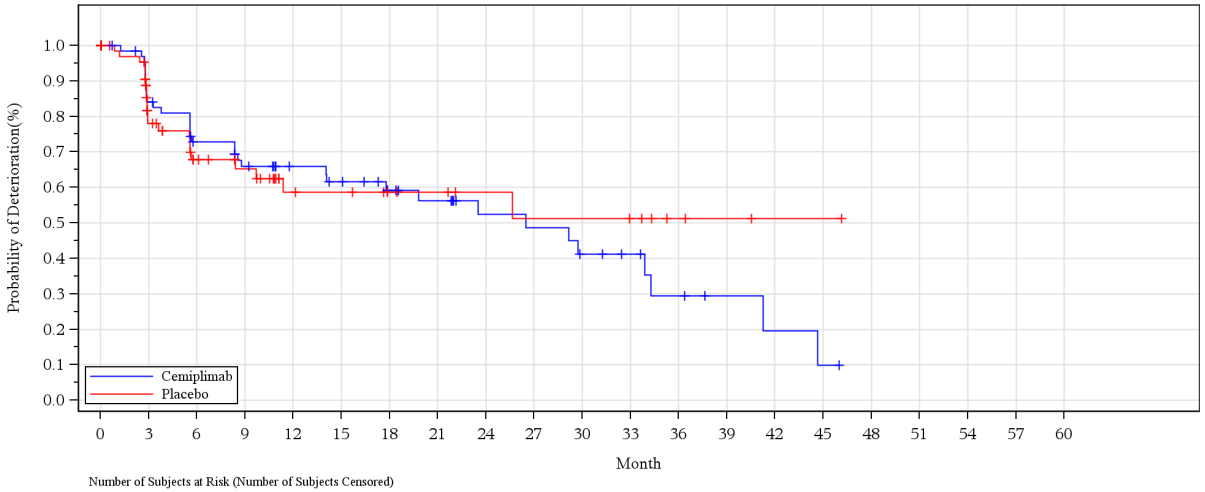
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



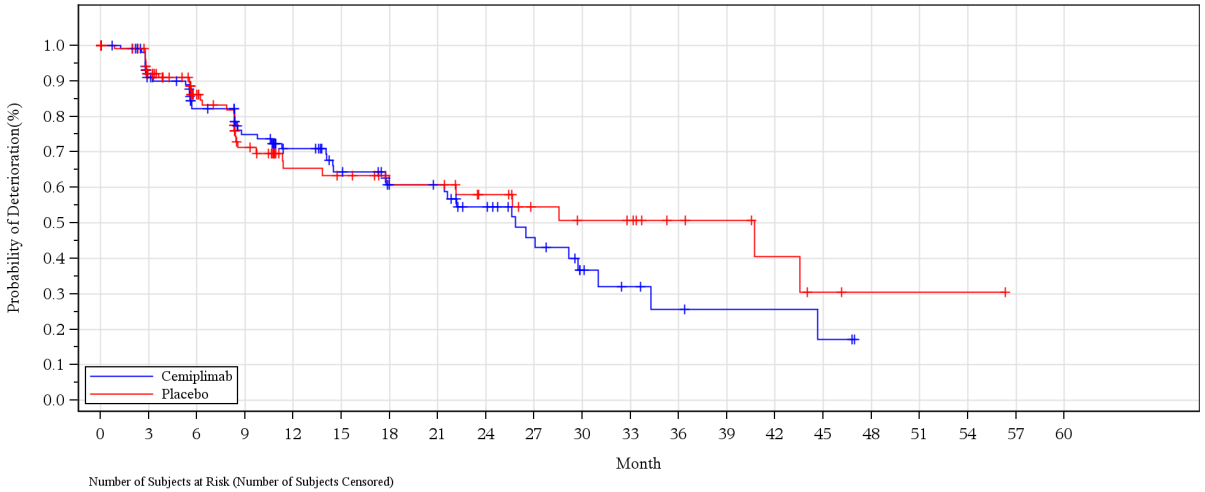
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	53 (13)	43 (16)	37 (18)	31 (24)	28 (25)	22 (30)	19 (32)	14 (36)	13 (36)	10 (37)	8 (39)	5 (40)	3 (42)	2 (42)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	75 (0)	42 (20)	30 (27)	25 (31)	15 (39)	14 (40)	11 (43)	10 (44)	8 (46)	7 (46)	7 (46)	6 (47)	3 (50)	2 (51)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



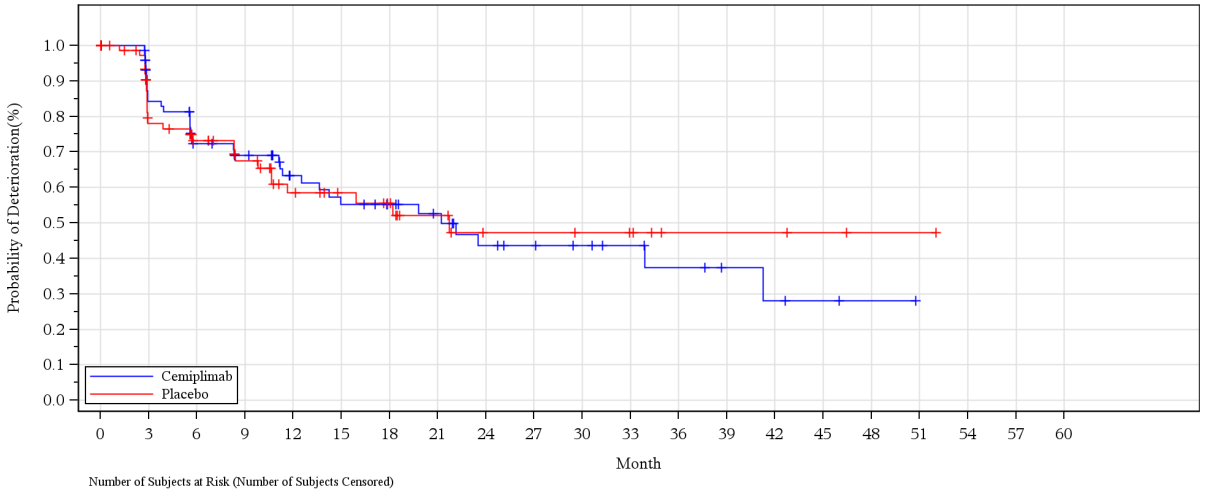
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	87 (29)	72 (36)	60 (42)	48 (51)	39 (56)	31 (62)	30 (63)	23 (67)	16 (71)	9 (75)	6 (77)	4 (78)	3 (79)	3 (79)	2 (79)	0 (81)	0 (81)	0 (81)	0 (81)	0 (81)
Placebo	117 (0)	87 (22)	64 (40)	44 (50)	31 (60)	29 (61)	24 (65)	24 (65)	19 (69)	14 (73)	12 (74)	11 (75)	7 (79)	6 (80)	4 (81)	2 (82)	1 (83)	1 (83)	1 (83)	0 (84)	0 (84)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



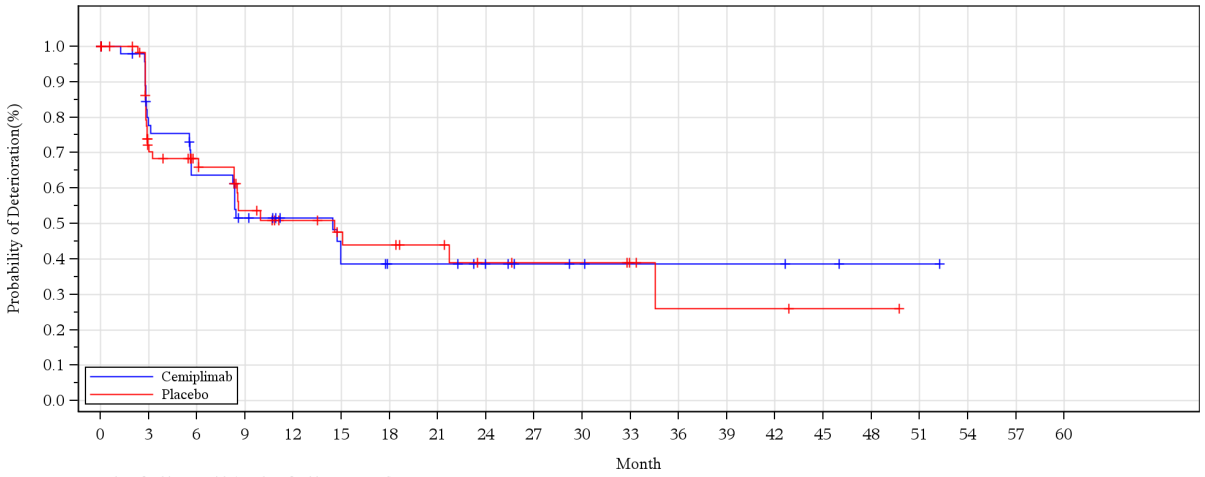
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	58 (15)	46 (19)	41 (22)	31 (29)	27 (29)	23 (33)	19 (36)	14 (38)	12 (40)	10 (42)	8 (44)	6 (45)	4 (47)	3 (47)	2 (48)	1 (49)	0 (50)	0 (50)	0 (50)	0 (50)
Placebo	89 (0)	50 (24)	42 (29)	34 (34)	24 (40)	20 (44)	17 (46)	12 (50)	8 (53)	8 (53)	7 (54)	6 (55)	3 (58)	3 (58)	3 (58)	2 (59)	1 (60)	1 (60)	0 (61)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	34 (12)	27 (13)	20 (15)	16 (19)	12 (19)	10 (21)	10 (21)	7 (24)	5 (26)	4 (27)	3 (28)	3 (28)	3 (28)	3 (28)	2 (29)	1 (30)	1 (30)	0 (31)	0 (31)	0 (31)
Placebo	65 (0)	38 (11)	30 (17)	21 (20)	16 (24)	13 (26)	12 (26)	10 (28)	7 (30)	6 (31)	6 (31)	4 (33)	2 (34)	2 (34)	2 (34)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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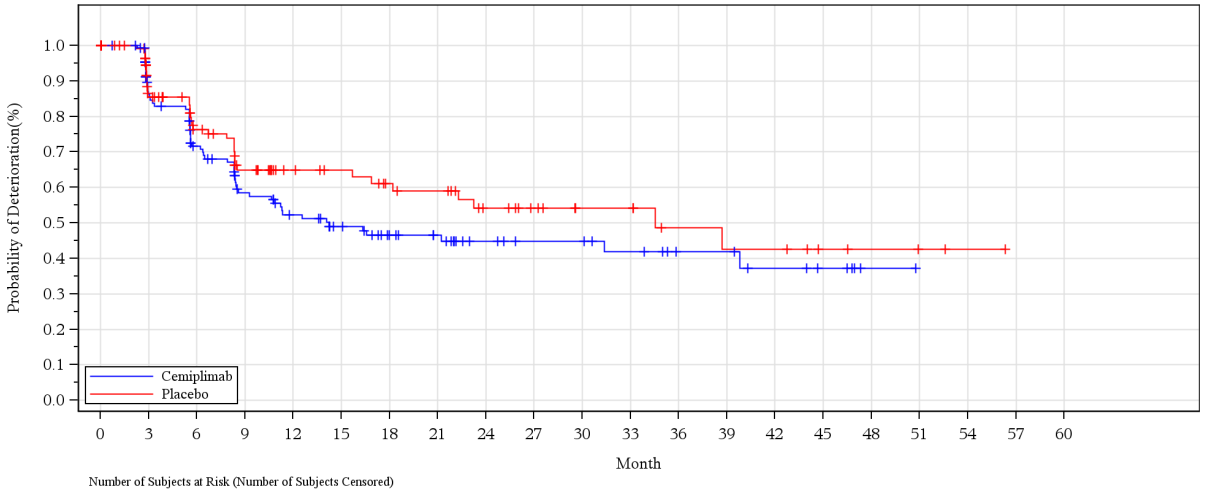
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	103 (33)	79 (40)	59 (46)	49 (50)	41 (55)	32 (62)	28 (66)	20 (73)	17 (76)	17 (76)	14 (78)	10 (82)	10 (82)	7 (84)	5 (86)	1 (90)	0 (91)	0 (91)	0 (91)	0 (91)
Placebo	141 (0)	83 (43)	64 (54)	48 (61)	37 (72)	34 (75)	29 (78)	27 (79)	20 (84)	16 (88)	12 (92)	12 (92)	8 (95)	7 (95)	7 (95)	4 (98)	3 (99)	2 (100)	1 (101)	0 (102)	0 (102)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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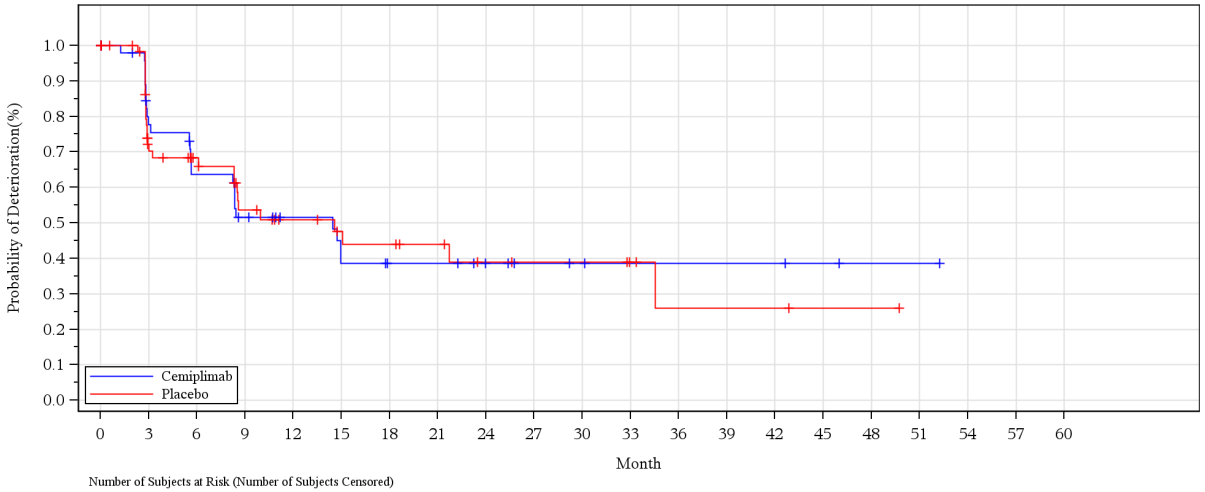
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



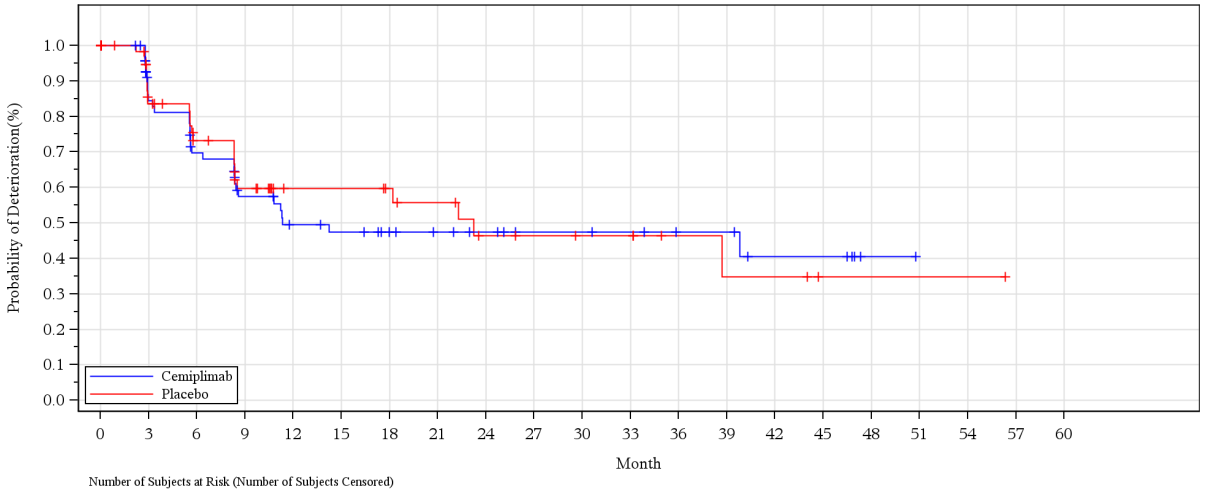
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	34 (12)	27 (13)	20 (15)	16 (19)	12 (19)	10 (21)	10 (21)	7 (24)	5 (26)	4 (27)	3 (28)	3 (28)	3 (28)	3 (28)	2 (29)	1 (30)	1 (30)	0 (31)	0 (31)	0 (31)
Placebo	65 (0)	38 (11)	30 (17)	21 (20)	16 (24)	13 (26)	12 (26)	10 (28)	7 (30)	6 (31)	6 (31)	4 (33)	2 (34)	2 (34)	2 (34)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



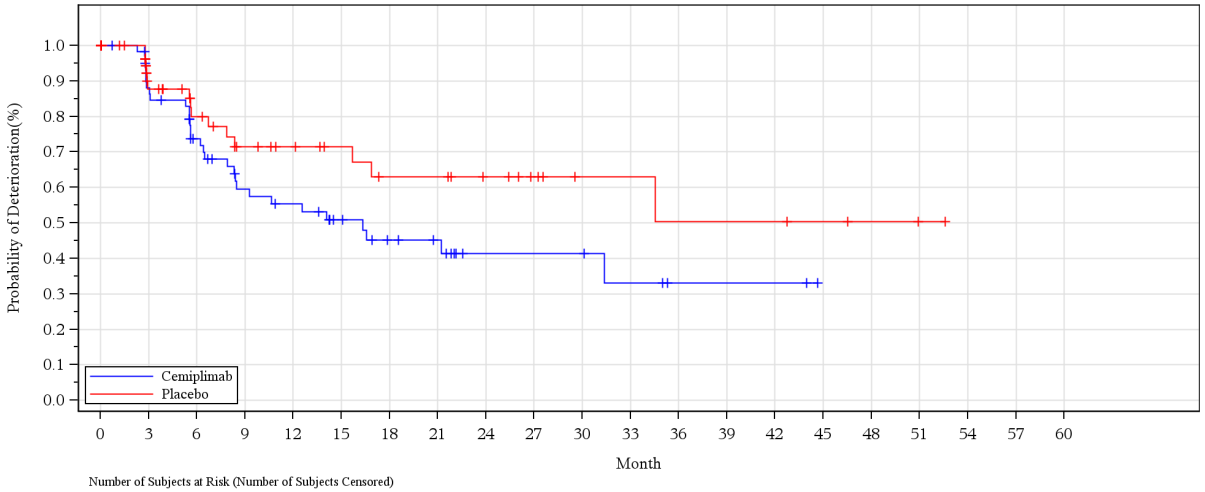
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	52 (18)	41 (20)	31 (23)	24 (26)	22 (27)	18 (31)	16 (33)	14 (35)	11 (38)	11 (38)	10 (39)	8 (41)	8 (41)	5 (43)	5 (43)	1 (47)	0 (48)	0 (48)	0 (48)	0 (48)
Placebo	69 (0)	44 (16)	34 (21)	25 (24)	17 (32)	17 (32)	15 (34)	13 (35)	9 (37)	8 (38)	7 (39)	7 (39)	4 (42)	3 (42)	3 (42)	1 (44)	1 (44)	1 (44)	1 (44)	0 (45)	0 (45)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



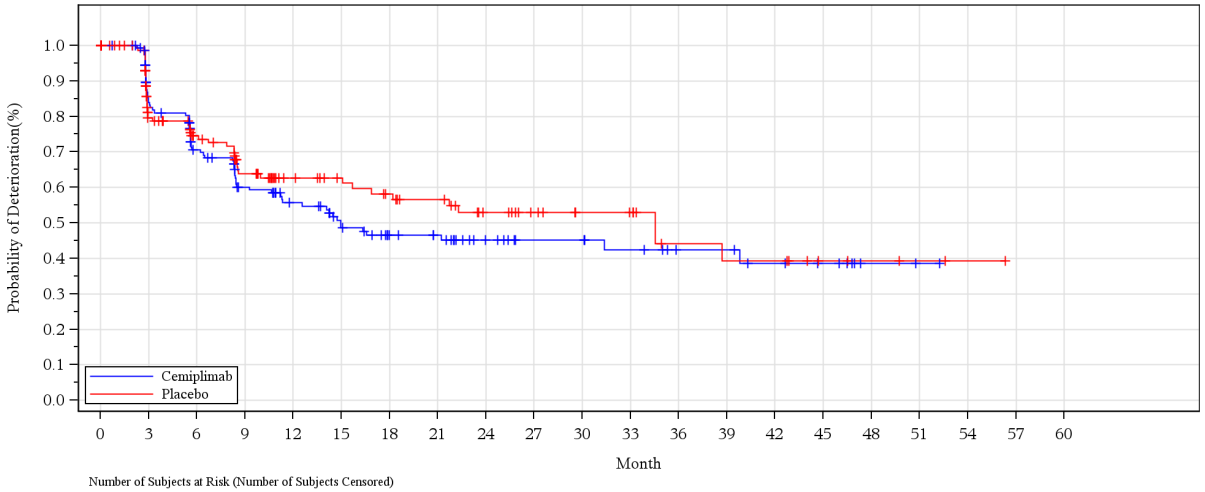
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	51 (15)	38 (20)	28 (23)	25 (24)	19 (28)	14 (31)	12 (33)	6 (38)	6 (38)	6 (38)	4 (39)	2 (41)	2 (41)	2 (41)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	72 (0)	39 (27)	30 (33)	23 (37)	20 (40)	17 (43)	14 (44)	14 (44)	11 (47)	8 (50)	5 (53)	5 (53)	4 (53)	4 (53)	4 (53)	3 (54)	2 (55)	1 (56)	0 (57)	0 (57)	0 (57)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Gender group: Male



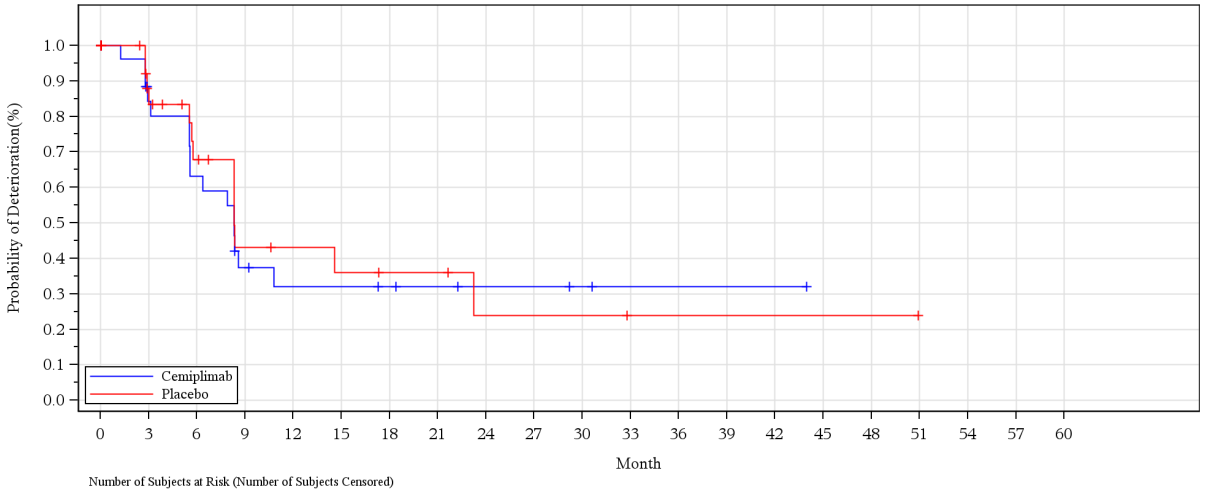
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	117 (34)	91 (42)	71 (49)	59 (56)	47 (61)	37 (69)	34 (72)	24 (81)	19 (86)	19 (86)	16 (88)	12 (92)	12 (92)	9 (94)	7 (96)	2 (101)	1 (102)	0 (103)	0 (103)	0 (103)
Placebo	174 (0)	101 (45)	81 (59)	62 (67)	47 (81)	42 (86)	37 (88)	33 (91)	25 (97)	20 (102)	16 (106)	15 (107)	9 (111)	8 (111)	8 (111)	4 (115)	3 (116)	2 (117)	1 (118)	0 (119)	0 (119)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Gender group: Female



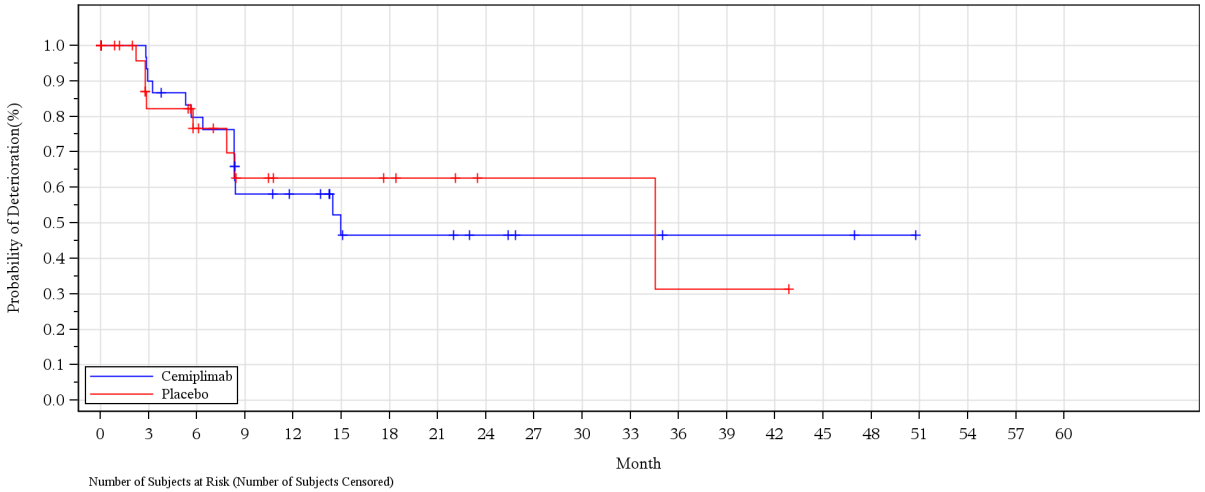
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	20 (11)	15 (11)	8 (12)	6 (13)	6 (13)	5 (14)	4 (15)	3 (16)	3 (16)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	32 (0)	20 (9)	13 (12)	7 (14)	6 (15)	5 (15)	4 (16)	4 (16)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



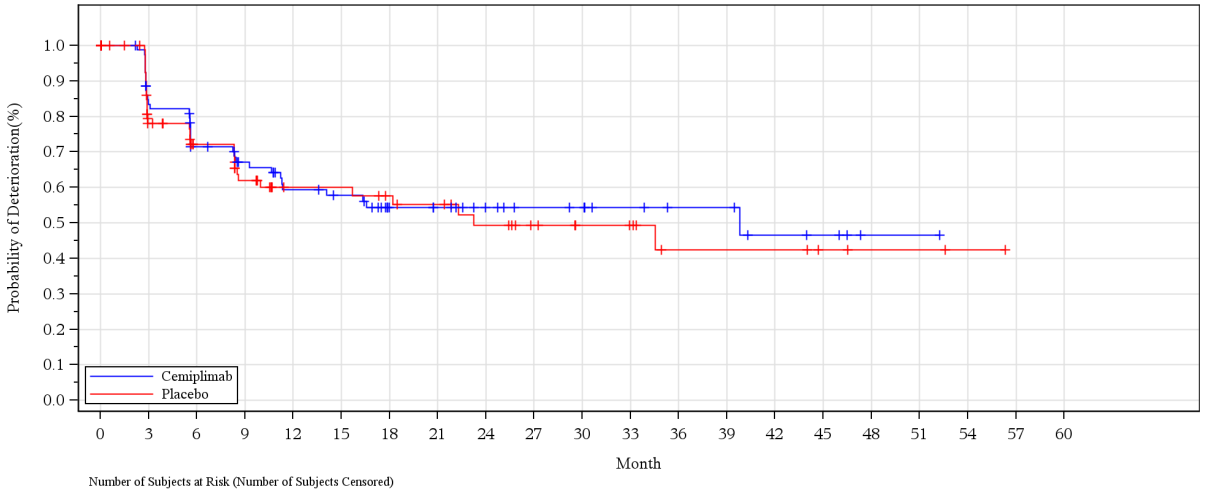
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	27 (7)	23 (8)	15 (10)	13 (12)	8 (15)	7 (16)	7 (16)	5 (18)	3 (20)	3 (20)	3 (20)	2 (21)	2 (21)	2 (21)	2 (21)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	31 (0)	17 (10)	13 (13)	8 (16)	6 (18)	6 (18)	5 (19)	4 (20)	2 (22)	2 (22)	2 (22)	2 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



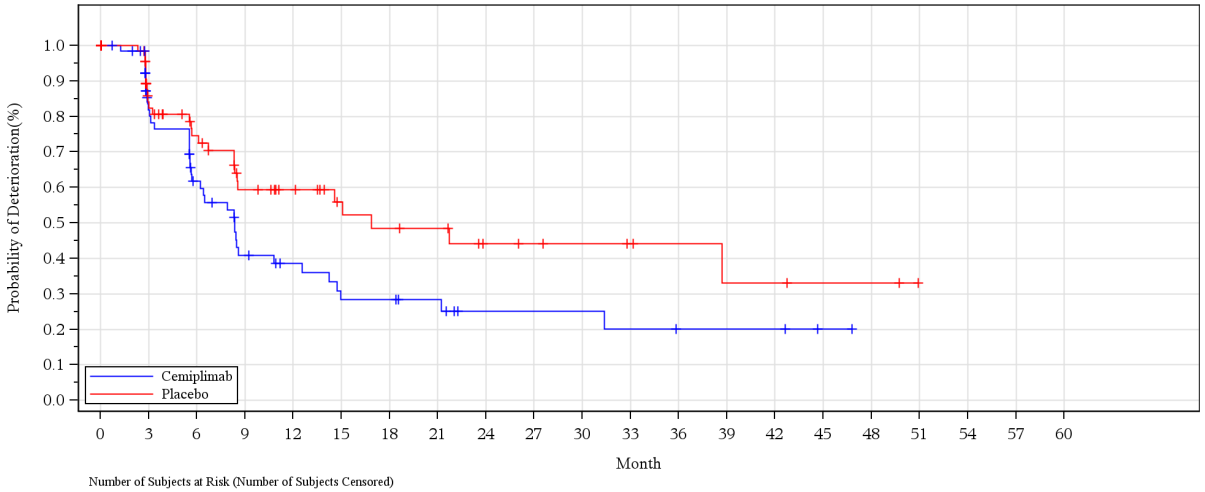
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	64 (13)	52 (16)	45 (20)	37 (23)	34 (25)	24 (33)	22 (35)	17 (40)	14 (43)	13 (44)	10 (47)	8 (49)	8 (49)	5 (51)	4 (52)	1 (55)	1 (55)	0 (56)	0 (56)	0 (56)
Placebo	90 (0)	56 (17)	44 (25)	35 (28)	26 (36)	26 (36)	23 (38)	21 (39)	17 (41)	13 (45)	10 (48)	9 (49)	5 (52)	5 (52)	5 (52)	3 (54)	2 (55)	2 (55)	1 (56)	0 (57)	0 (57)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



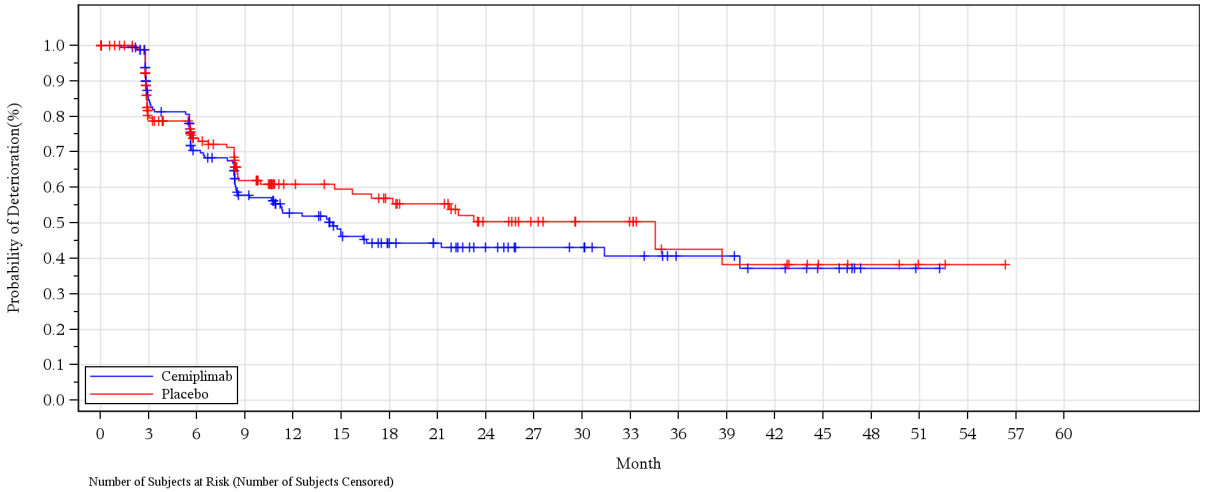
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	46 (25)	31 (29)	19 (31)	15 (34)	11 (34)	11 (34)	9 (36)	5 (39)	5 (39)	5 (39)	4 (39)	3 (40)	3 (40)	3 (40)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	85 (0)	48 (27)	37 (33)	26 (37)	21 (42)	15 (47)	13 (47)	12 (48)	8 (51)	7 (52)	6 (53)	5 (54)	4 (55)	3 (55)	3 (55)	2 (56)	2 (56)	0 (58)	0 (58)	0 (58)	0 (58)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Race: White



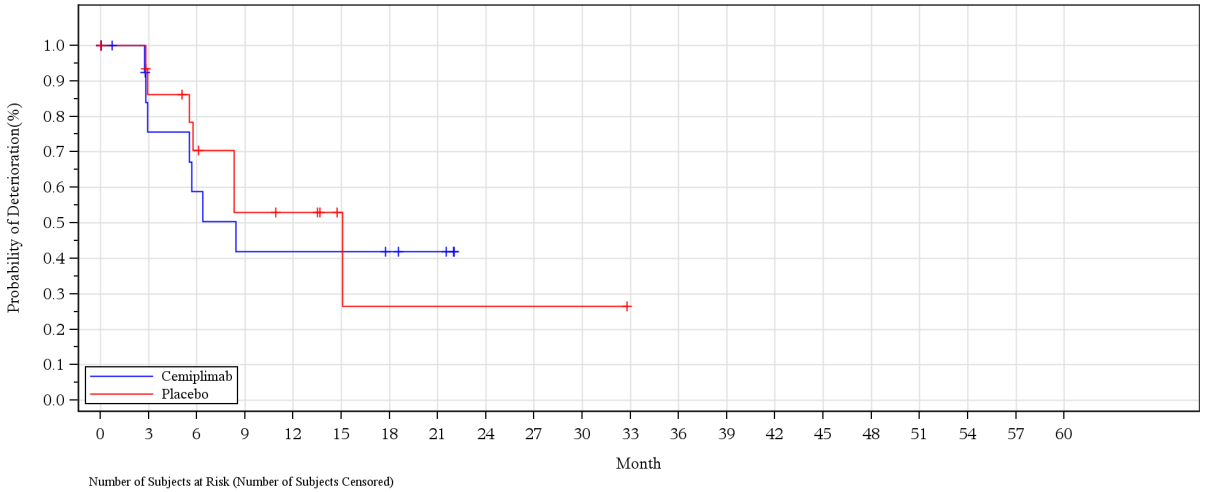
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	128 (37)	99 (45)	74 (53)	60 (61)	48 (66)	38 (74)	35 (77)	27 (84)	22 (89)	21 (90)	17 (93)	13 (97)	13 (97)	10 (99)	7 (102)	2 (107)	1 (108)	0 (109)	0 (109)	0 (109)
Placebo	189 (0)	109 (51)	85 (67)	63 (76)	48 (90)	45 (92)	40 (95)	36 (98)	26 (105)	21 (110)	17 (114)	16 (115)	10 (119)	9 (119)	9 (119)	5 (123)	4 (124)	2 (126)	1 (127)	0 (128)	0 (128)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (8)	7 (8)	5 (8)	5 (8)	5 (8)	4 (9)	3 (10)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)
Placebo	17 (0)	12 (3)	9 (4)	6 (5)	5 (6)	2 (9)	1 (9)	1 (9)	1 (9)	1 (9)	1 (9)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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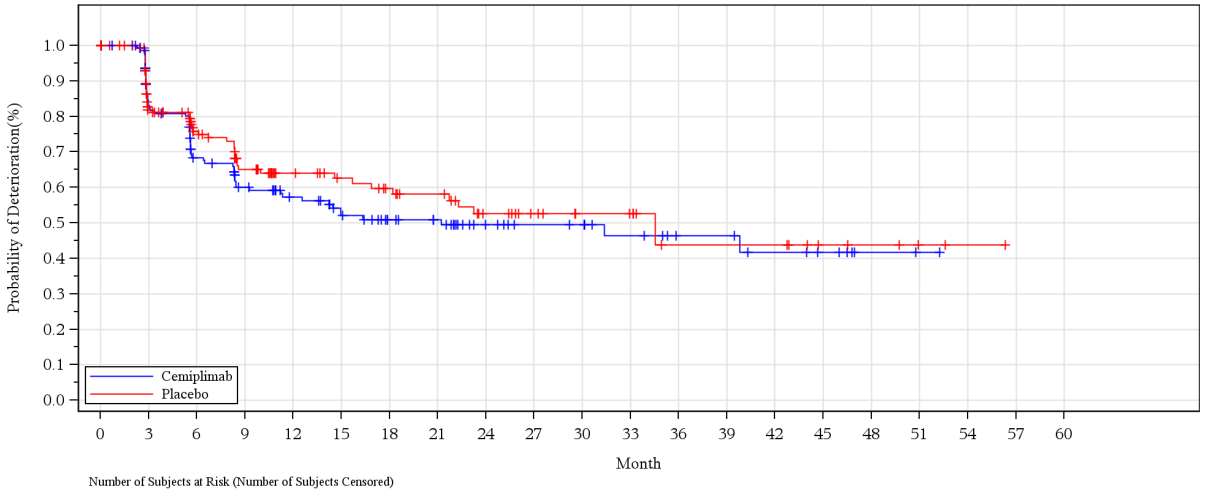
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	110 (33)	85 (39)	69 (45)	58 (53)	48 (58)	39 (66)	35 (70)	24 (80)	20 (84)	19 (85)	15 (88)	11 (92)	11 (92)	8 (94)	6 (96)	2 (100)	1 (101)	0 (102)	0 (102)	0 (102)
Placebo	177 (0)	105 (47)	82 (63)	63 (71)	49 (84)	43 (89)	38 (92)	34 (95)	25 (101)	20 (106)	16 (110)	15 (111)	9 (115)	9 (115)	9 (115)	5 (119)	4 (120)	2 (122)	1 (123)	0 (124)	0 (124)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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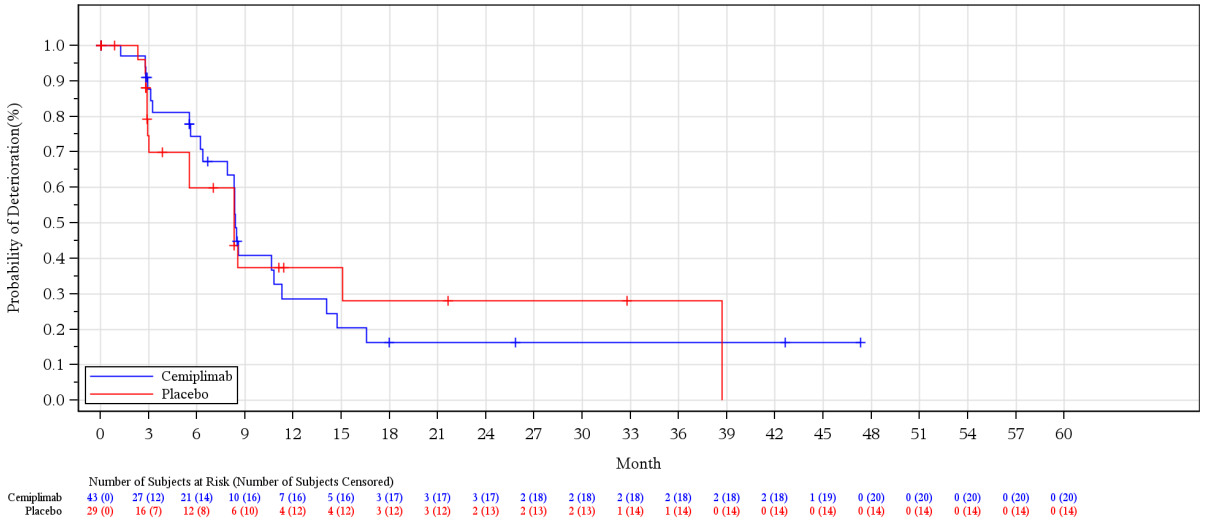
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	27 (12)	21 (14)	10 (16)	7 (16)	5 (16)	3 (17)	3 (17)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	29 (0)	16 (7)	12 (8)	6 (10)	4 (12)	4 (12)	3 (12)	3 (12)	2 (13)	2 (13)	2 (13)	1 (14)	1 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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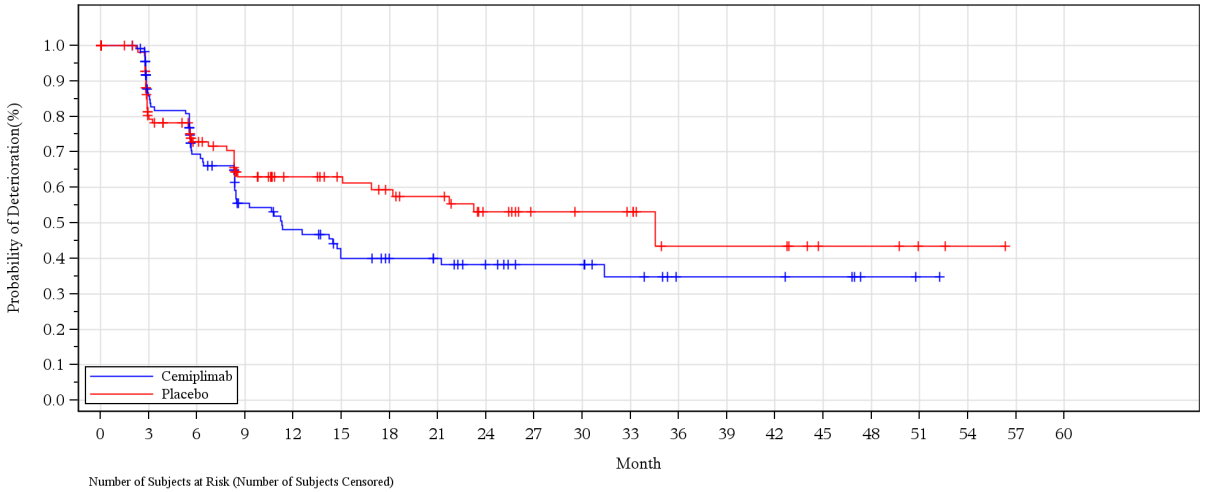
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



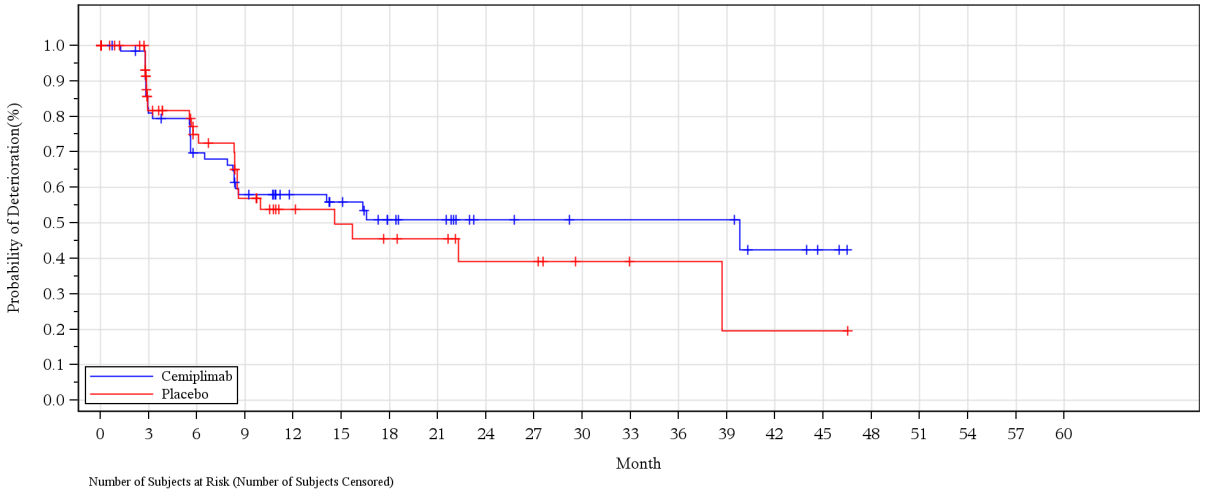
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	86 (32)	64 (38)	45 (45)	38 (46)	29 (49)	25 (53)	23 (55)	18 (59)	14 (63)	14 (63)	10 (66)	6 (70)	6 (70)	6 (70)	5 (71)	2 (74)	1 (75)	0 (76)	0 (76)	0 (76)
Placebo	131 (0)	80 (30)	63 (40)	48 (47)	39 (56)	35 (60)	31 (62)	28 (64)	21 (69)	16 (74)	15 (75)	14 (76)	8 (80)	8 (80)	8 (80)	4 (84)	4 (84)	2 (86)	1 (87)	0 (88)	0 (88)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



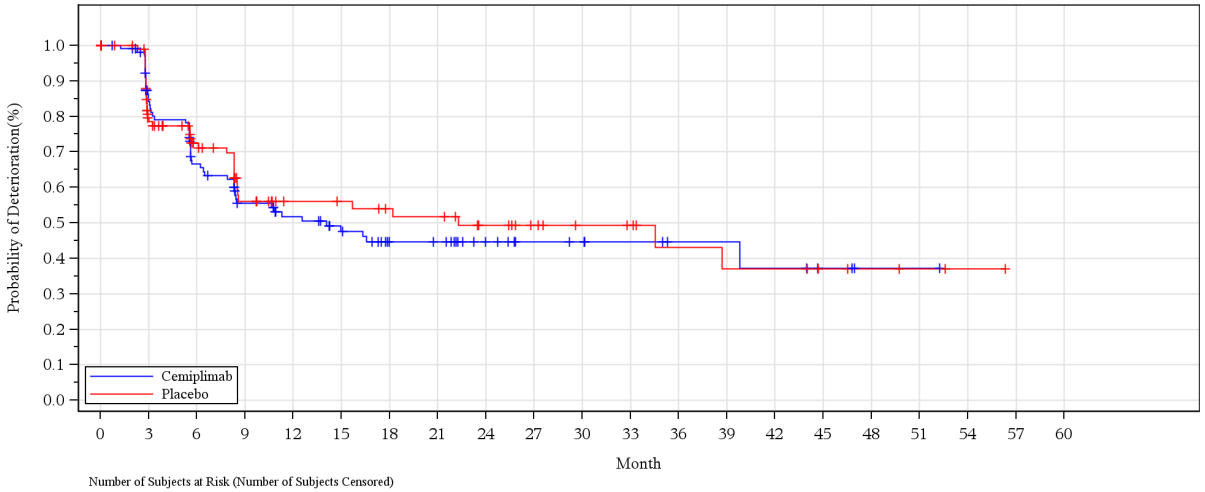
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	51 (13)	42 (15)	34 (16)	27 (23)	24 (25)	17 (30)	15 (32)	9 (38)	8 (39)	7 (40)	7 (40)	7 (40)	7 (40)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)
Placebo	75 (0)	41 (24)	31 (31)	21 (34)	14 (40)	12 (41)	10 (42)	9 (43)	6 (45)	6 (45)	3 (48)	2 (49)	2 (49)	1 (49)	1 (49)	1 (49)	0 (50)	0 (50)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



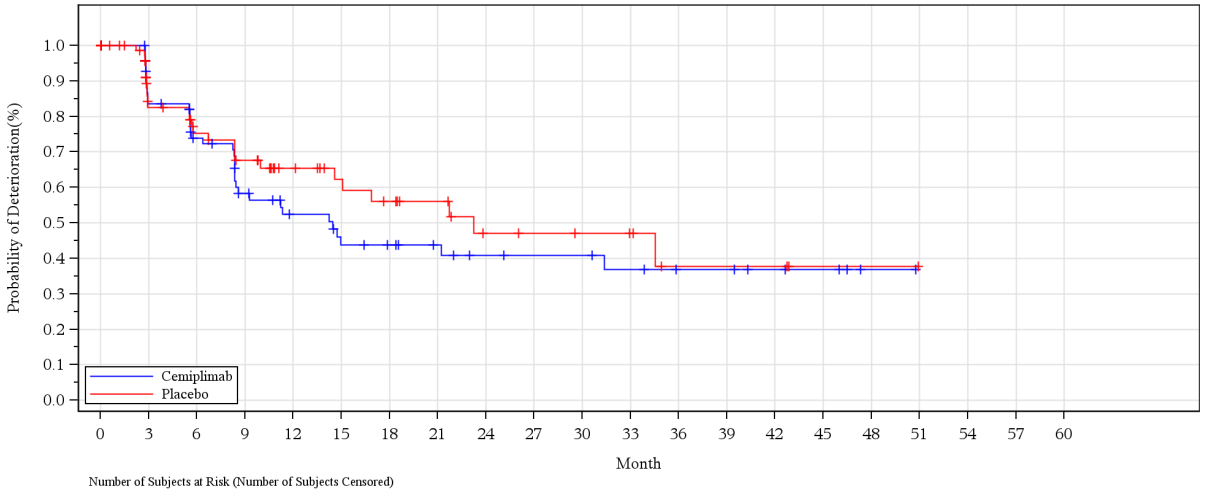
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	82 (27)	62 (30)	47 (35)	40 (39)	33 (43)	24 (50)	23 (51)	15 (59)	11 (63)	10 (64)	8 (66)	6 (68)	6 (68)	5 (68)	3 (70)	1 (72)	1 (72)	0 (73)	0 (73)	0 (73)
Placebo	117 (0)	73 (24)	54 (37)	35 (45)	28 (52)	27 (53)	24 (55)	23 (55)	18 (59)	14 (63)	11 (66)	10 (67)	7 (69)	6 (69)	6 (69)	4 (71)	3 (72)	2 (73)	1 (74)	0 (75)	0 (75)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



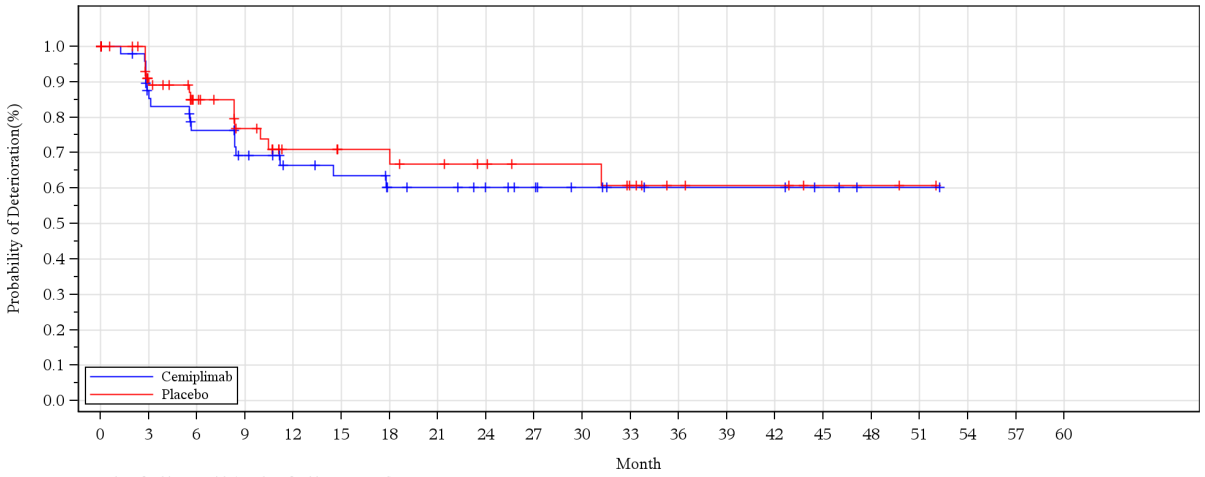
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	55 (18)	44 (23)	32 (26)	25 (30)	20 (31)	18 (33)	15 (36)	12 (38)	11 (39)	11 (39)	9 (40)	7 (42)	7 (42)	5 (44)	4 (45)	1 (48)	0 (49)	0 (49)	0 (49)	0 (49)
Placebo	89 (0)	48 (30)	40 (34)	34 (36)	25 (44)	20 (48)	17 (49)	14 (52)	9 (55)	8 (56)	7 (57)	6 (58)	3 (60)	3 (60)	3 (60)	1 (62)	1 (62)	0 (63)	0 (63)	0 (63)	0 (63)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



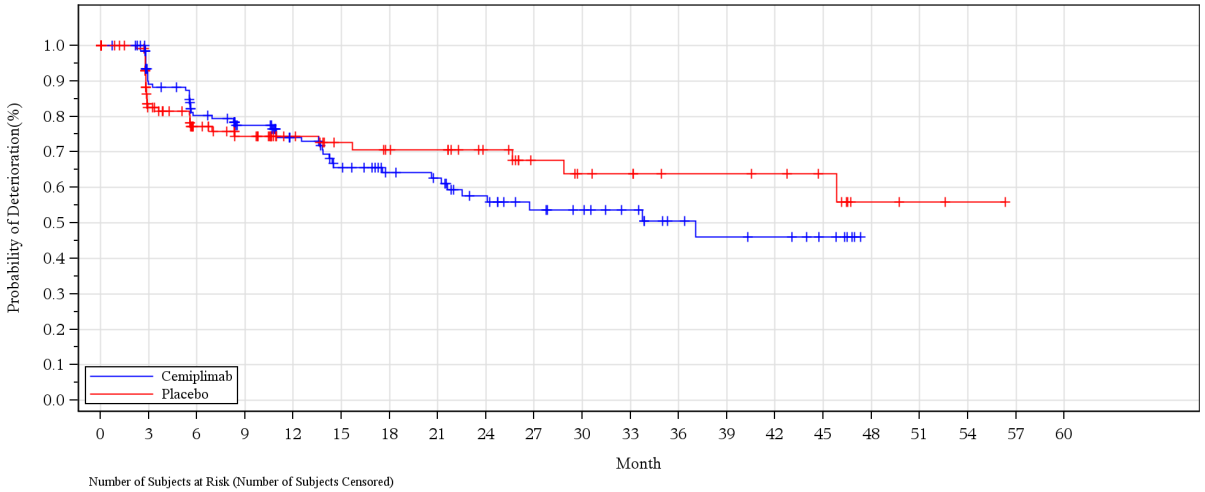
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	40 (10)	33 (12)	28 (14)	23 (18)	21 (19)	17 (22)	16 (23)	13 (26)	11 (28)	8 (31)	6 (33)	5 (34)	5 (34)	5 (34)	3 (36)	1 (38)	1 (38)	0 (39)	0 (39)	0 (39)
Placebo	65 (0)	47 (13)	35 (22)	27 (27)	19 (33)	17 (35)	17 (35)	15 (36)	13 (38)	11 (40)	11 (40)	8 (42)	5 (45)	4 (46)	4 (46)	2 (48)	2 (48)	1 (49)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



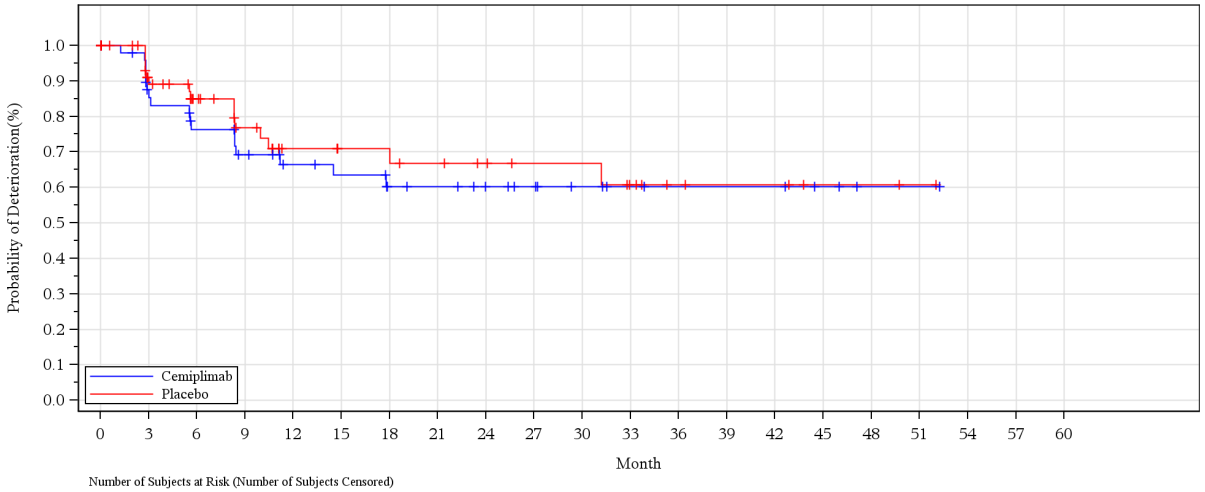
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	104 (36)	88 (42)	76 (51)	63 (61)	52 (65)	43 (73)	40 (75)	32 (80)	25 (85)	22 (88)	18 (92)	12 (97)	10 (98)	9 (99)	6 (102)	0 (108)	0 (108)	0 (108)	0 (108)	0 (108)
Placebo	141 (0)	83 (39)	63 (54)	53 (62)	41 (74)	35 (79)	32 (81)	31 (82)	25 (88)	18 (94)	15 (96)	14 (97)	11 (100)	11 (100)	10 (101)	8 (103)	3 (107)	2 (108)	1 (109)	0 (110)	0 (110)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



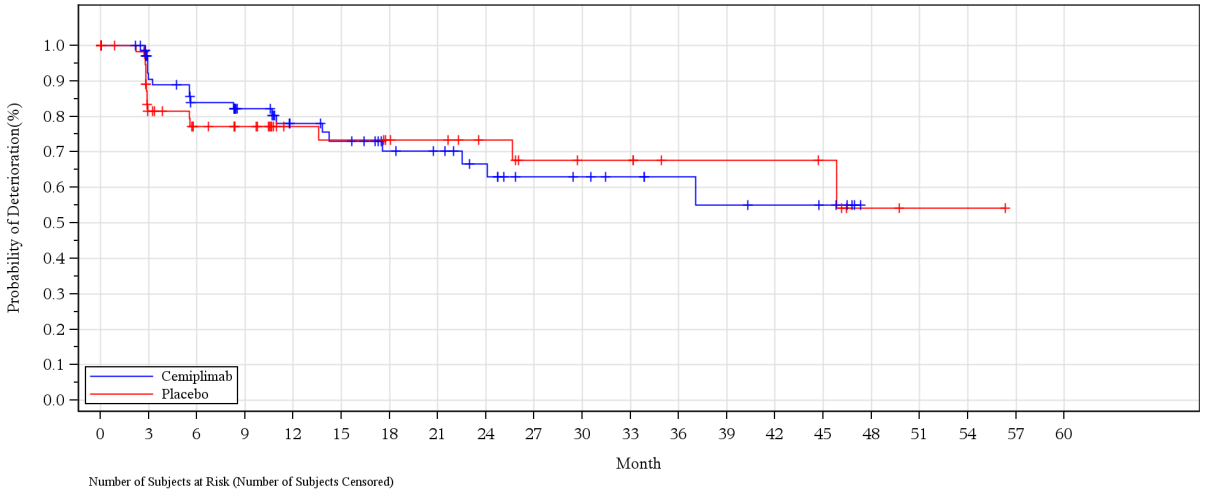
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	40 (10)	33 (12)	28 (14)	23 (18)	21 (19)	17 (22)	16 (23)	13 (26)	11 (28)	8 (31)	6 (33)	5 (34)	5 (34)	5 (34)	3 (36)	1 (38)	1 (38)	0 (39)	0 (39)	0 (39)
Placebo	65 (0)	47 (13)	35 (22)	27 (27)	19 (33)	17 (35)	17 (35)	15 (36)	13 (38)	11 (40)	11 (40)	8 (42)	5 (45)	4 (46)	4 (46)	2 (48)	2 (48)	1 (49)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



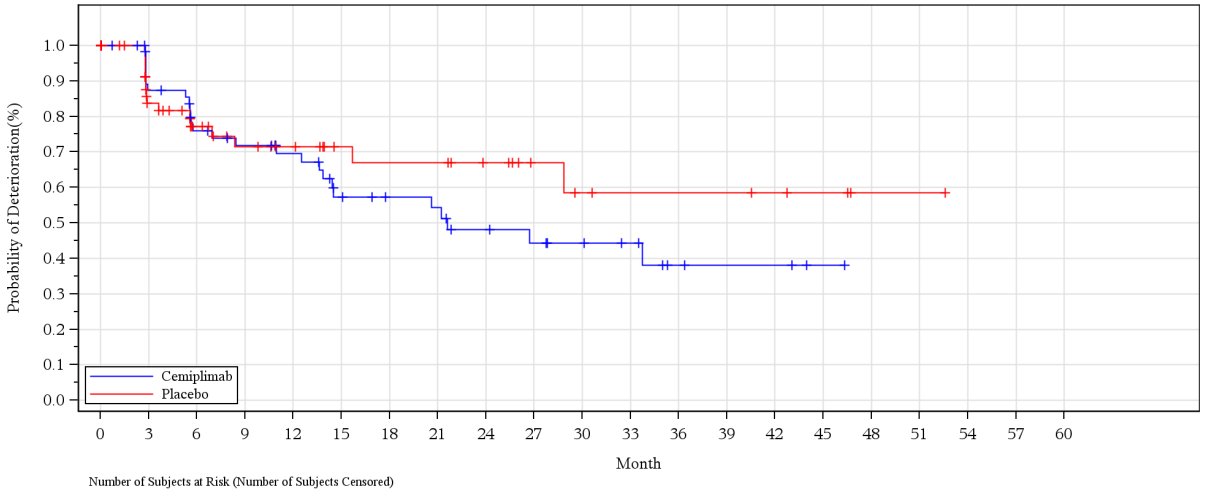
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	56 (18)	49 (21)	41 (28)	33 (34)	30 (35)	24 (40)	22 (42)	18 (45)	13 (49)	12 (50)	10 (52)	8 (54)	7 (54)	6 (55)	5 (56)	0 (61)	0 (61)	0 (61)	0 (61)	0 (61)
Placebo	69 (0)	41 (18)	33 (24)	29 (28)	20 (37)	19 (37)	17 (39)	16 (40)	13 (43)	10 (45)	9 (46)	9 (46)	6 (49)	6 (49)	6 (49)	5 (50)	2 (52)	1 (53)	1 (53)	0 (54)	0 (54)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



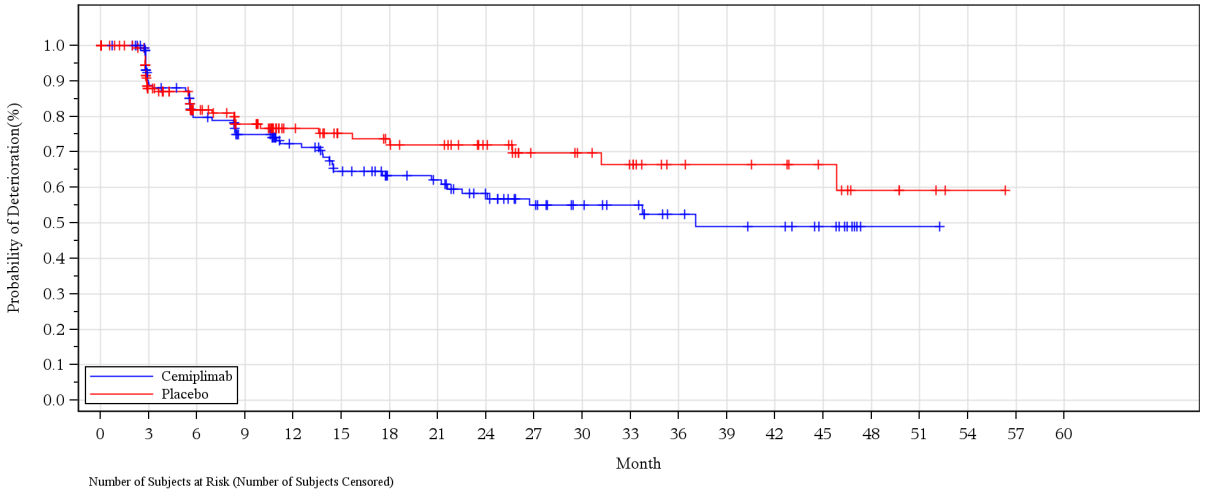
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	48 (18)	39 (21)	35 (23)	30 (27)	22 (30)	19 (33)	18 (33)	14 (35)	12 (36)	10 (38)	8 (40)	4 (43)	3 (44)	3 (44)	1 (46)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)
Placebo	72 (0)	42 (21)	30 (30)	24 (34)	21 (37)	16 (42)	15 (42)	15 (42)	12 (45)	8 (49)	6 (50)	5 (51)	5 (51)	5 (51)	4 (52)	3 (53)	1 (55)	1 (55)	0 (56)	0 (56)	0 (56)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Gender group: Male



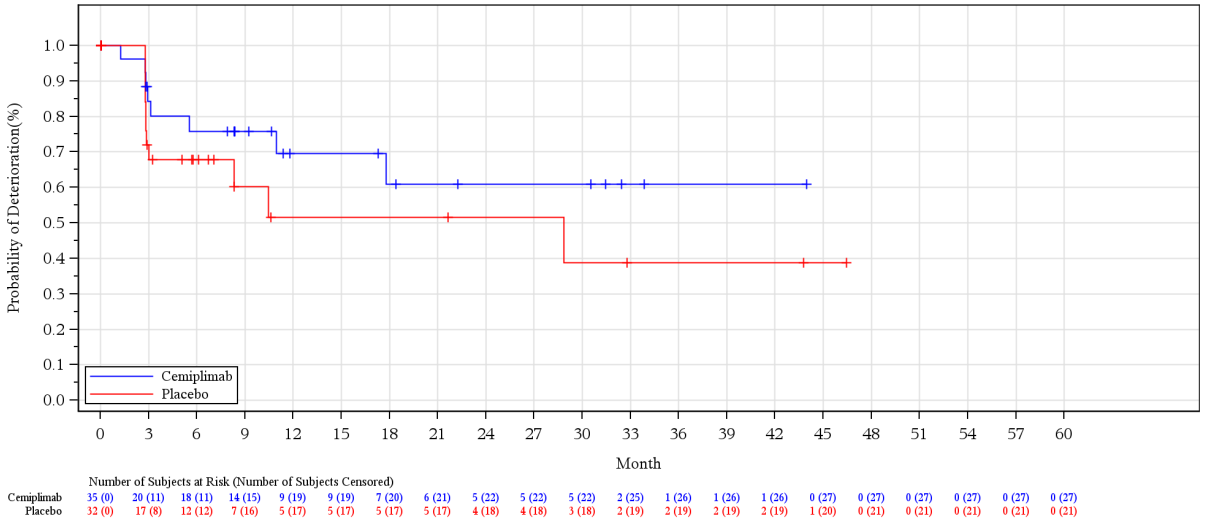
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	124 (35)	103 (43)	90 (50)	77 (60)	64 (65)	53 (75)	50 (77)	40 (84)	31 (91)	25 (97)	22 (100)	16 (105)	14 (106)	13 (107)	9 (111)	1 (119)	1 (119)	0 (120)	0 (120)	0 (120)
Placebo	174 (0)	113 (44)	86 (64)	73 (73)	55 (90)	47 (97)	44 (99)	41 (101)	34 (108)	25 (116)	23 (118)	20 (120)	14 (126)	13 (127)	12 (128)	9 (131)	5 (134)	3 (136)	1 (138)	0 (139)	0 (139)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	20 (11)	18 (11)	14 (15)	9 (19)	9 (19)	7 (20)	6 (21)	5 (22)	5 (22)	5 (22)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	32 (0)	17 (8)	12 (12)	7 (16)	5 (17)	5 (17)	5 (17)	5 (17)	4 (18)	4 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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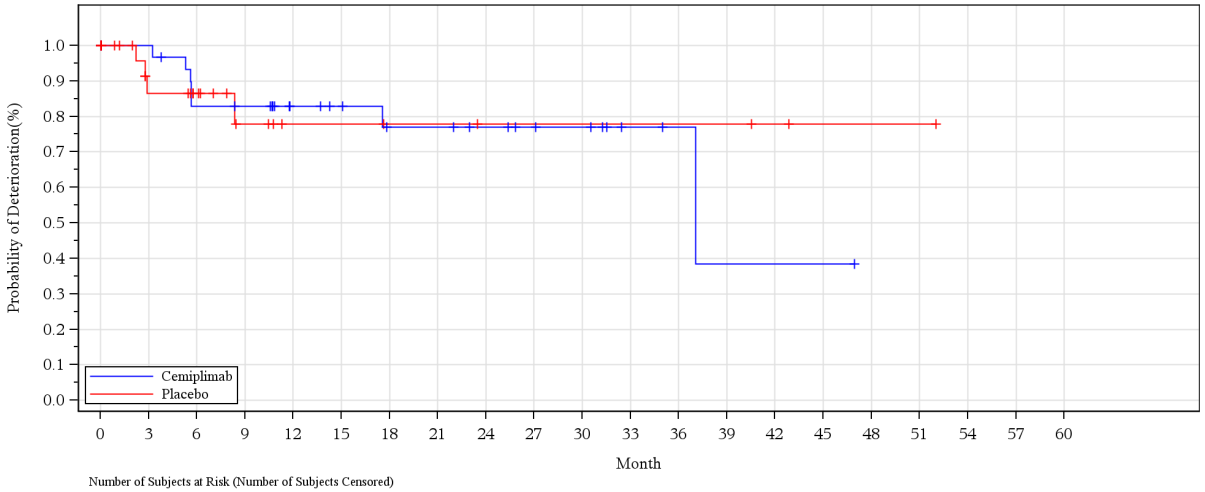
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (7)	24 (8)	23 (9)	17 (15)	15 (17)	12 (19)	12 (19)	10 (21)	8 (23)	7 (24)	3 (28)	2 (29)	1 (29)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)	0 (30)
Placebo	31 (0)	18 (10)	14 (14)	8 (19)	5 (22)	5 (22)	4 (23)	4 (23)	3 (24)	3 (24)	3 (24)	3 (24)	3 (24)	3 (24)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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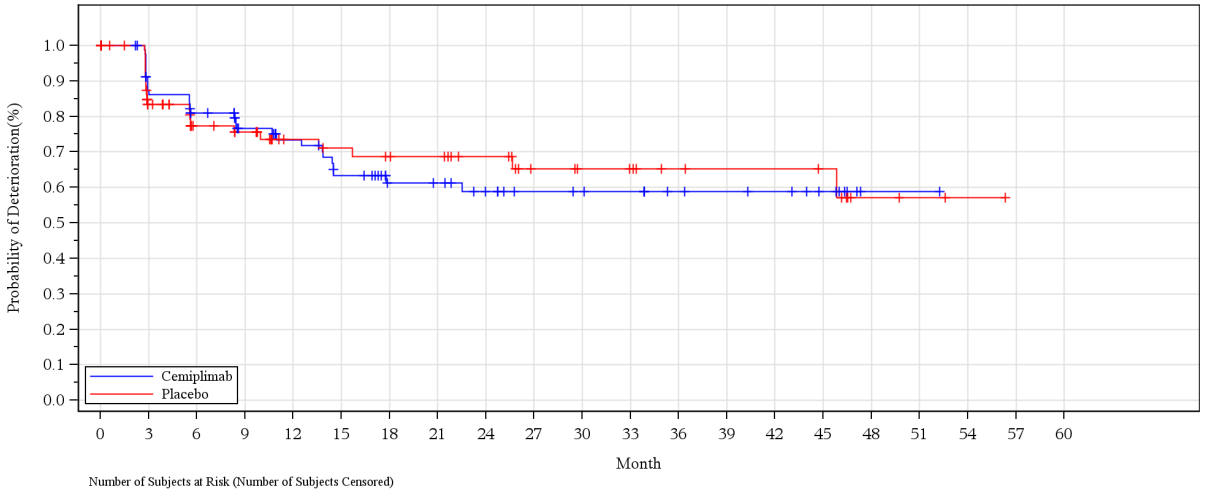
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	68 (12)	60 (15)	50 (22)	45 (25)	37 (27)	28 (35)	27 (36)	22 (40)	18 (44)	17 (45)	16 (46)	12 (50)	11 (51)	10 (52)	7 (55)	1 (61)	1 (61)	0 (62)	0 (62)	0 (62)
Placebo	90 (0)	60 (17)	45 (28)	41 (31)	31 (40)	29 (41)	27 (42)	26 (43)	22 (47)	16 (52)	14 (54)	13 (55)	10 (58)	9 (59)	9 (59)	8 (60)	3 (64)	2 (65)	1 (66)	0 (67)	0 (67)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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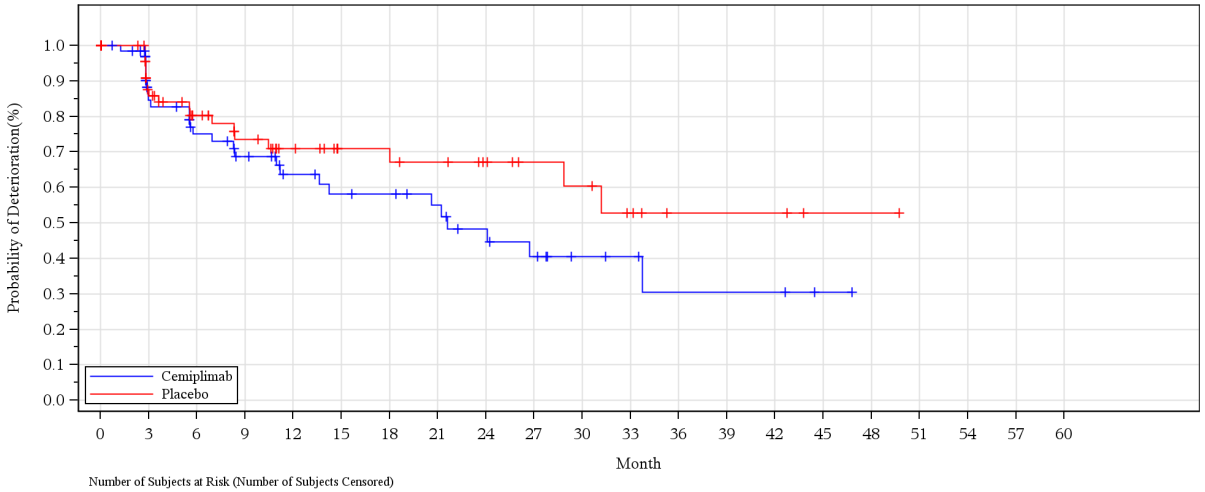
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



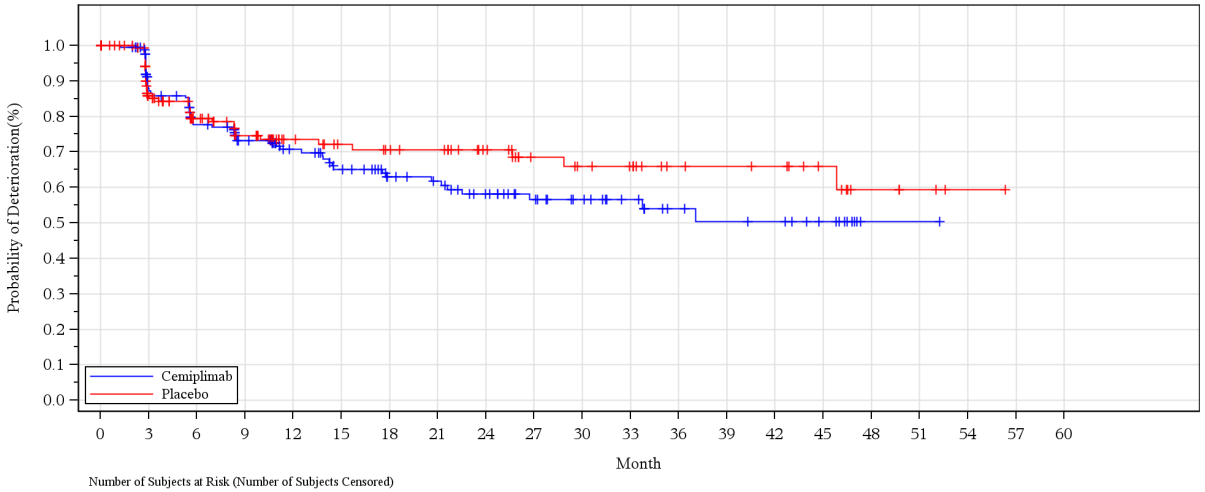
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	46 (27)	37 (31)	31 (34)	24 (39)	21 (40)	20 (41)	17 (43)	13 (45)	10 (46)	6 (50)	5 (51)	3 (52)	3 (52)	3 (52)	1 (54)	0 (55)	0 (55)	0 (55)	0 (55)	0 (55)
Placebo	85 (0)	52 (25)	39 (34)	31 (39)	24 (45)	18 (51)	18 (51)	16 (52)	13 (55)	10 (58)	9 (58)	6 (60)	3 (63)	3 (63)	3 (63)	1 (65)	1 (65)	0 (66)	0 (66)	0 (66)	0 (66)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	133 (37)	110 (45)	94 (55)	79 (67)	68 (72)	56 (82)	52 (85)	43 (91)	35 (98)	29 (104)	23 (110)	16 (116)	14 (117)	13 (118)	9 (122)	1 (130)	1 (130)	0 (131)	0 (131)	0 (131)
Placebo	189 (0)	117 (51)	89 (71)	73 (82)	55 (99)	49 (104)	46 (106)	44 (108)	36 (116)	27 (124)	24 (126)	22 (128)	16 (134)	15 (135)	14 (136)	10 (140)	5 (144)	3 (146)	1 (148)	0 (149)	0 (149)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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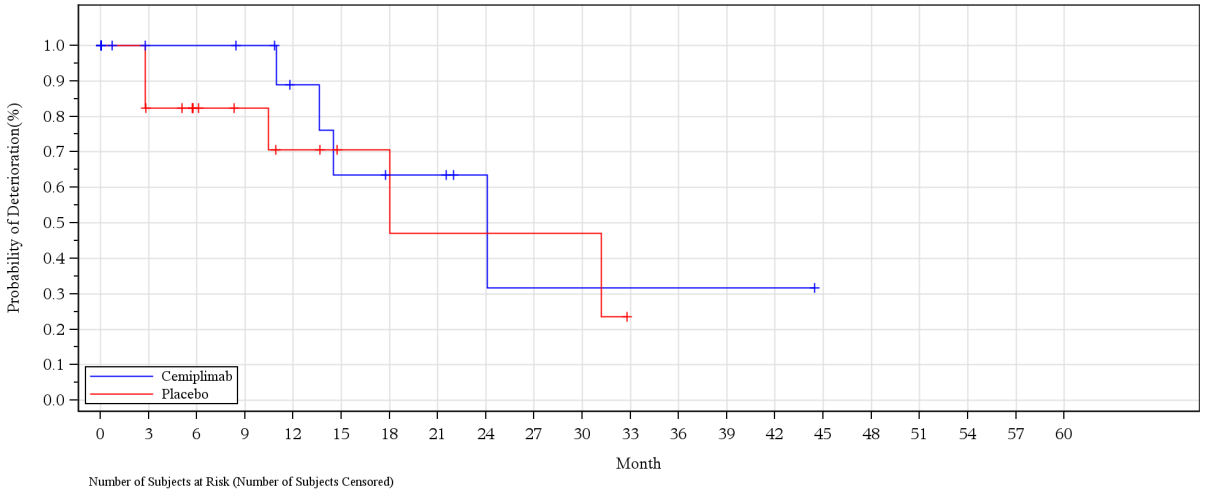
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Race: Non-white



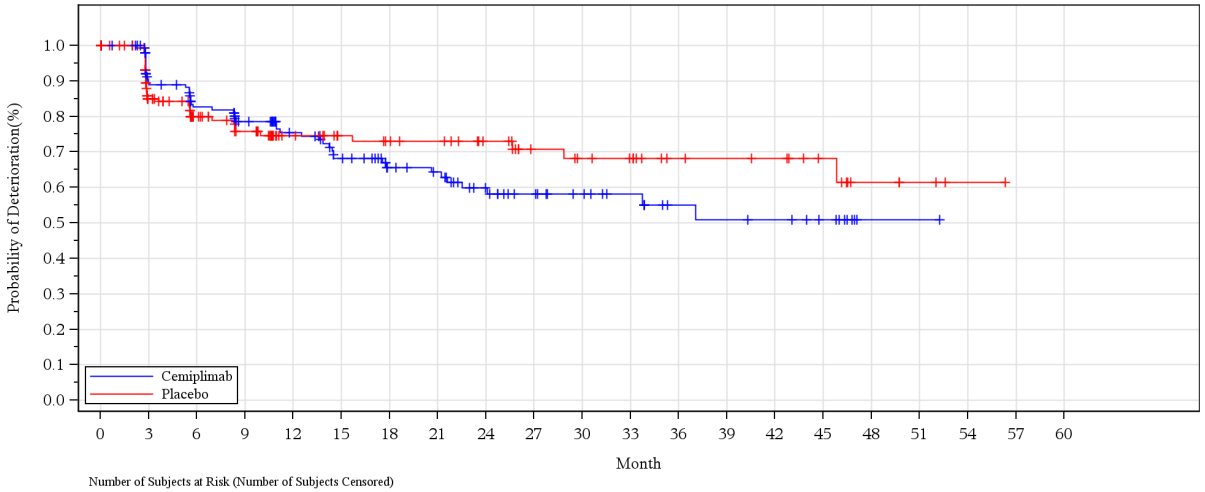
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (9)	11 (9)	10 (10)	7 (12)	5 (12)	4 (13)	4 (13)	2 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	17 (0)	13 (1)	9 (5)	7 (7)	5 (8)	3 (10)	3 (10)	2 (10)	2 (10)	2 (10)	2 (10)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	118 (34)	102 (41)	89 (49)	75 (60)	63 (65)	50 (76)	46 (79)	35 (87)	28 (93)	23 (98)	19 (102)	13 (107)	12 (107)	11 (108)	8 (111)	1 (118)	1 (118)	0 (119)	0 (119)	0 (119)
Placebo	177 (0)	110 (46)	83 (67)	70 (76)	53 (92)	46 (99)	43 (101)	41 (103)	35 (109)	27 (116)	24 (118)	22 (120)	16 (126)	15 (127)	14 (128)	10 (132)	5 (136)	3 (138)	1 (140)	0 (141)	0 (141)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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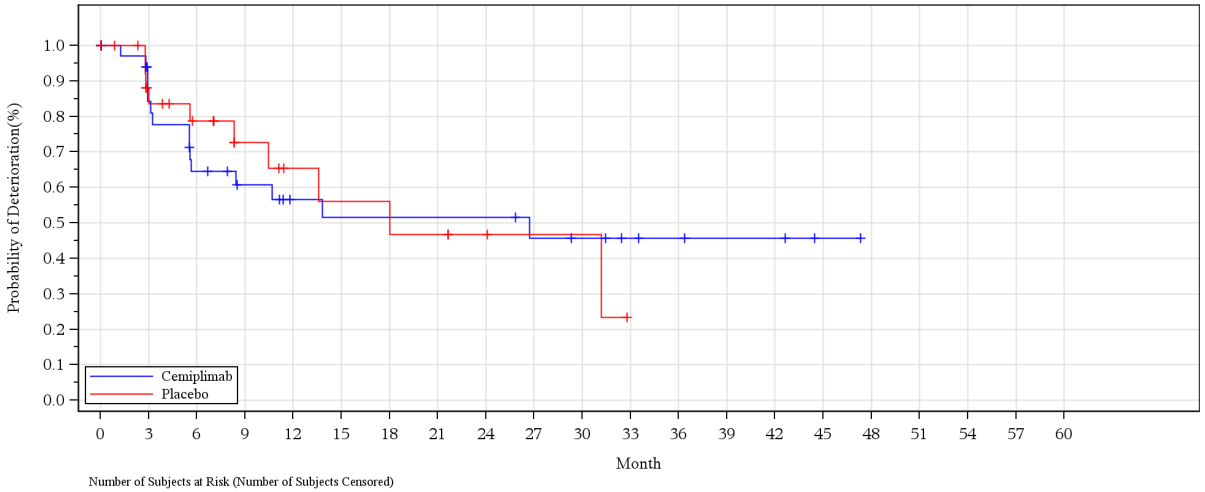
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	26 (12)	19 (13)	15 (16)	11 (19)	10 (19)	10 (19)	10 (19)	10 (19)	8 (20)	7 (21)	5 (23)	4 (24)	3 (25)	3 (25)	1 (27)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	29 (0)	20 (6)	15 (9)	10 (13)	7 (15)	6 (15)	6 (15)	5 (15)	3 (17)	2 (18)	2 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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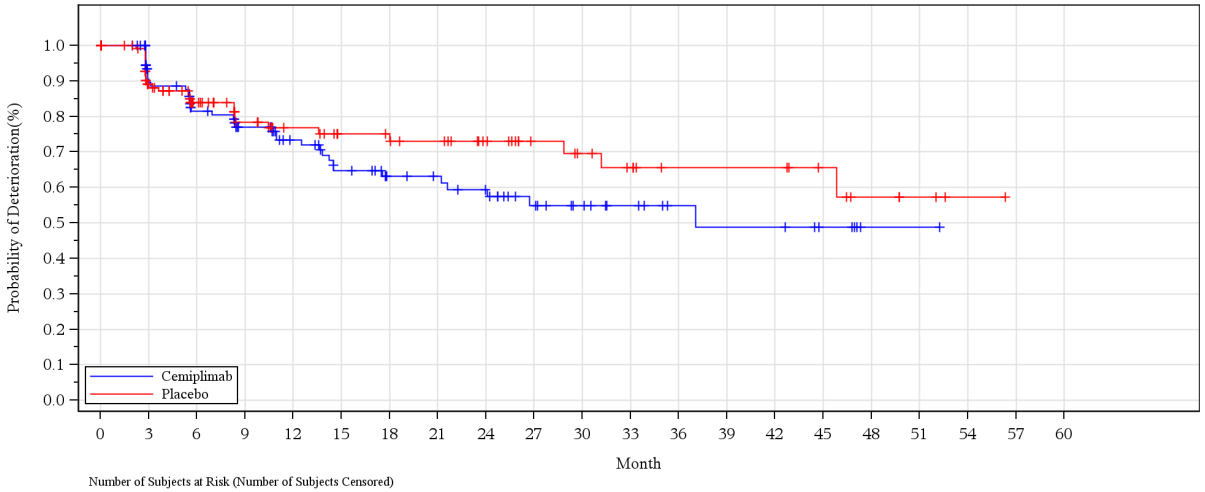
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	92 (31)	77 (37)	65 (45)	54 (53)	44 (57)	36 (64)	34 (66)	30 (68)	22 (74)	17 (79)	13 (83)	9 (87)	8 (87)	8 (87)	5 (90)	1 (94)	1 (94)	0 (95)	0 (95)	0 (95)
Placebo	131 (0)	92 (27)	69 (45)	54 (56)	44 (65)	38 (70)	37 (71)	34 (73)	28 (79)	21 (86)	18 (88)	15 (90)	11 (94)	11 (94)	11 (94)	8 (97)	5 (99)	3 (101)	1 (103)	0 (104)	0 (104)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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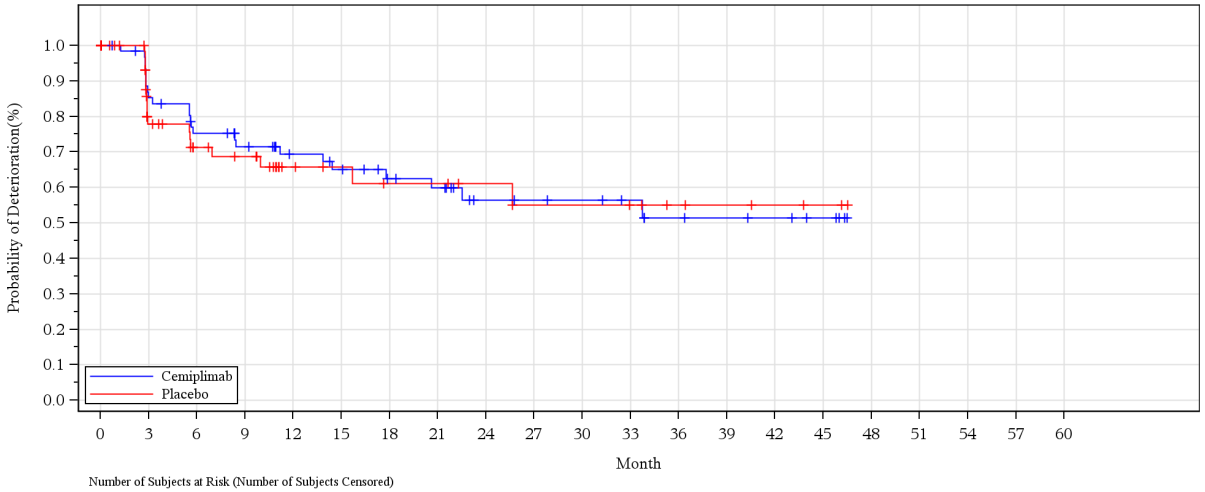
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	52 (15)	44 (17)	39 (20)	32 (26)	29 (27)	24 (31)	22 (32)	15 (38)	14 (39)	13 (40)	11 (42)	8 (44)	7 (45)	6 (46)	4 (48)	0 (52)	0 (52)	0 (52)	0 (52)	0 (52)
Placebo	75 (0)	38 (25)	29 (31)	26 (33)	16 (42)	14 (44)	12 (45)	12 (45)	10 (47)	8 (48)	8 (48)	7 (49)	5 (51)	4 (52)	3 (53)	2 (54)	0 (56)	0 (56)	0 (56)	0 (56)	0 (56)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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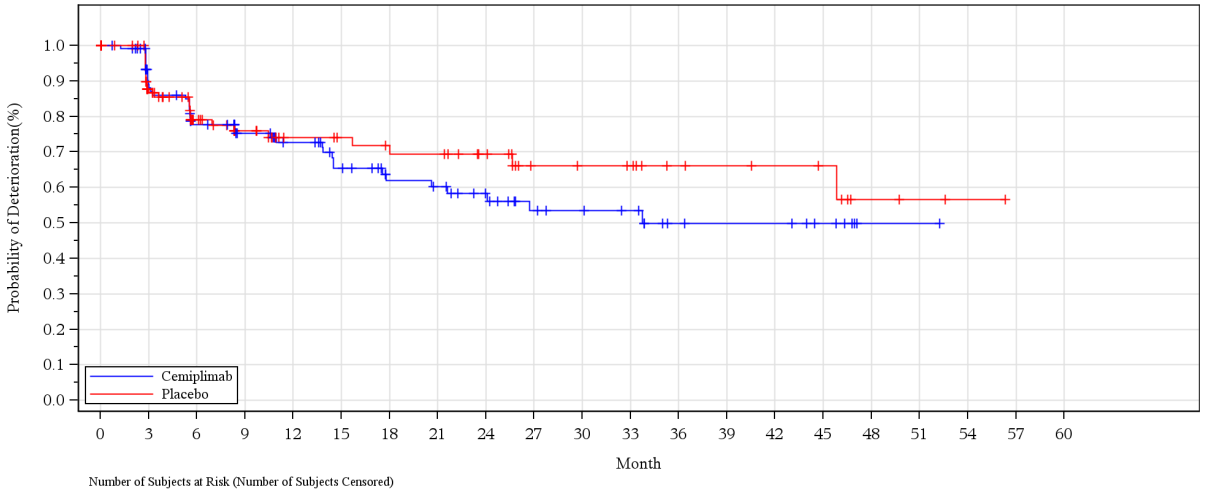
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



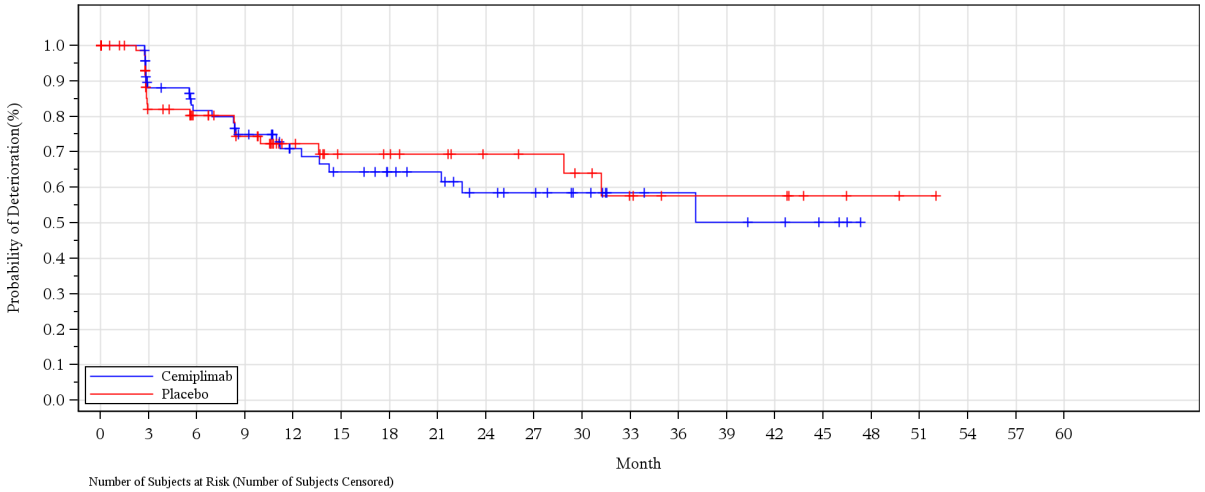
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	87 (27)	72 (31)	62 (39)	53 (46)	44 (50)	35 (57)	33 (58)	27 (63)	20 (68)	18 (70)	16 (72)	10 (77)	9 (78)	9 (78)	6 (81)	1 (86)	1 (86)	0 (87)	0 (87)	0 (87)
Placebo	117 (0)	79 (26)	54 (44)	43 (53)	34 (61)	32 (63)	30 (64)	29 (64)	24 (69)	16 (76)	15 (77)	14 (78)	10 (82)	9 (83)	8 (84)	7 (85)	3 (88)	2 (89)	1 (90)	0 (91)	0 (91)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



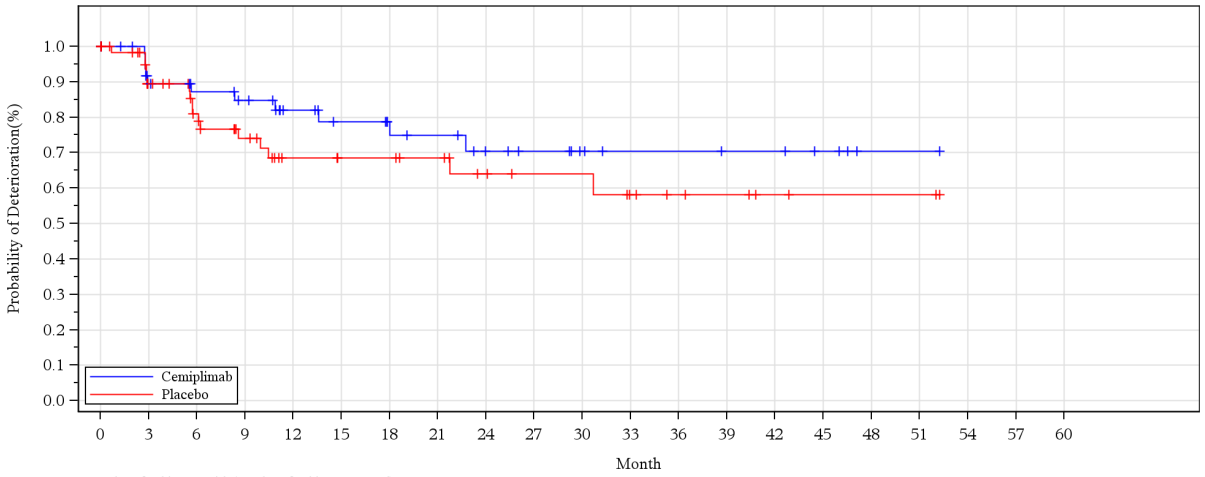
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	57 (19)	49 (23)	42 (26)	33 (33)	29 (34)	25 (38)	23 (40)	18 (43)	16 (45)	12 (49)	8 (53)	7 (54)	6 (54)	5 (55)	3 (57)	0 (60)	0 (60)	0 (60)	0 (60)	0 (60)
Placebo	89 (0)	51 (26)	44 (32)	37 (36)	26 (46)	20 (51)	19 (52)	17 (54)	14 (57)	13 (58)	11 (59)	8 (61)	6 (63)	6 (63)	6 (63)	3 (66)	2 (67)	1 (68)	0 (69)	0 (69)	0 (69)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (10)	37 (13)	34 (15)	27 (21)	23 (24)	20 (27)	18 (28)	14 (31)	12 (33)	9 (36)	7 (38)	7 (38)	6 (39)	6 (39)	4 (41)	1 (44)	1 (44)	0 (45)	0 (45)	0 (45)
Placebo	65 (0)	47 (12)	37 (18)	29 (23)	21 (29)	19 (31)	19 (31)	17 (33)	13 (36)	11 (38)	11 (38)	8 (40)	6 (42)	5 (43)	3 (45)	2 (46)	2 (46)	2 (46)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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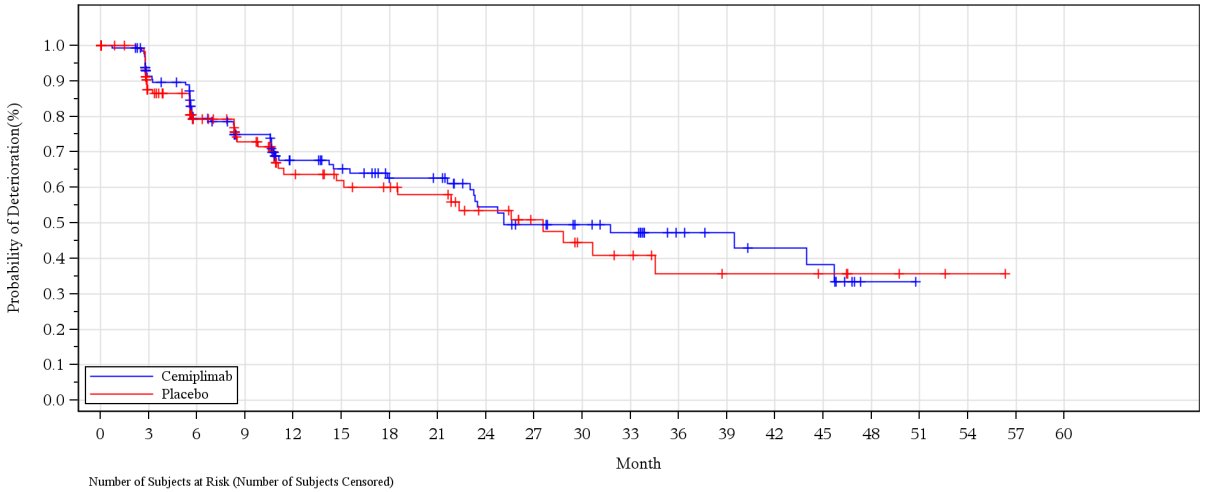
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	111 (31)	90 (38)	76 (47)	58 (58)	53 (61)	44 (68)	43 (69)	33 (74)	28 (76)	24 (80)	21 (82)	13 (90)	11 (92)	9 (93)	8 (93)	1 (99)	0 (100)	0 (100)	0 (100)	0 (100)
Placebo	141 (0)	92 (35)	69 (50)	54 (60)	39 (69)	34 (73)	31 (75)	28 (77)	21 (82)	16 (86)	12 (88)	10 (89)	7 (91)	6 (92)	6 (92)	5 (93)	3 (95)	2 (96)	1 (97)	0 (98)	0 (98)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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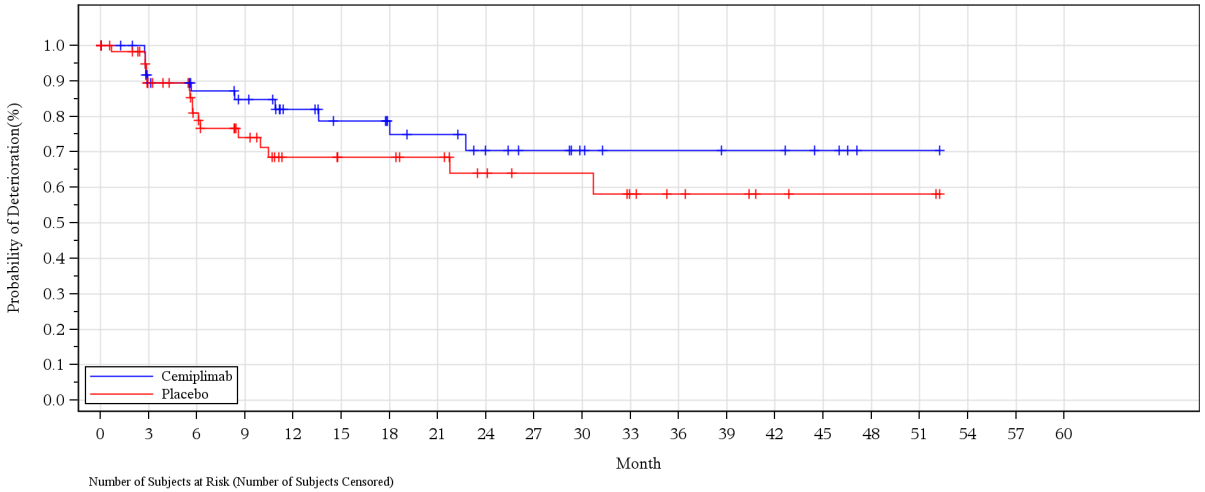
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (10)	37 (13)	34 (15)	27 (21)	23 (24)	20 (27)	18 (28)	14 (31)	12 (33)	9 (36)	7 (38)	7 (38)	6 (39)	6 (39)	4 (41)	1 (44)	1 (44)	0 (45)	0 (45)	0 (45)
Placebo	65 (0)	47 (12)	37 (18)	29 (23)	21 (29)	19 (31)	19 (31)	17 (33)	13 (36)	11 (38)	11 (38)	8 (40)	6 (42)	5 (43)	3 (45)	2 (46)	2 (46)	2 (46)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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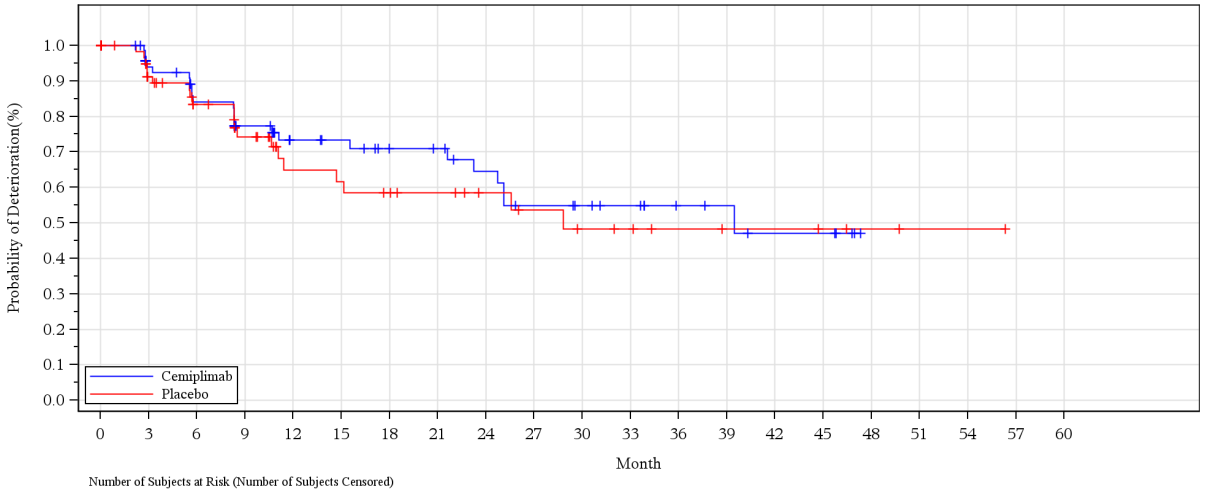
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	59 (17)	50 (20)	41 (25)	32 (32)	30 (34)	25 (38)	24 (39)	20 (41)	16 (42)	14 (44)	12 (46)	8 (50)	7 (51)	5 (52)	5 (52)	0 (57)	0 (57)	0 (57)	0 (57)	0 (57)
Placebo	69 (0)	49 (15)	39 (21)	30 (26)	20 (33)	19 (33)	17 (34)	15 (36)	12 (39)	10 (40)	8 (41)	7 (42)	5 (44)	4 (45)	4 (45)	3 (46)	2 (47)	1 (48)	1 (48)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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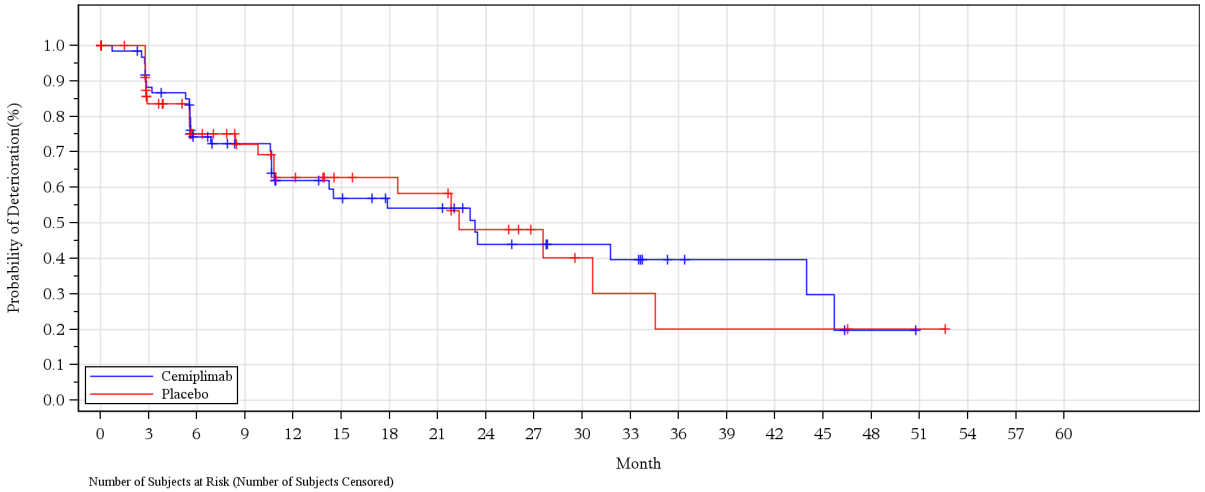
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



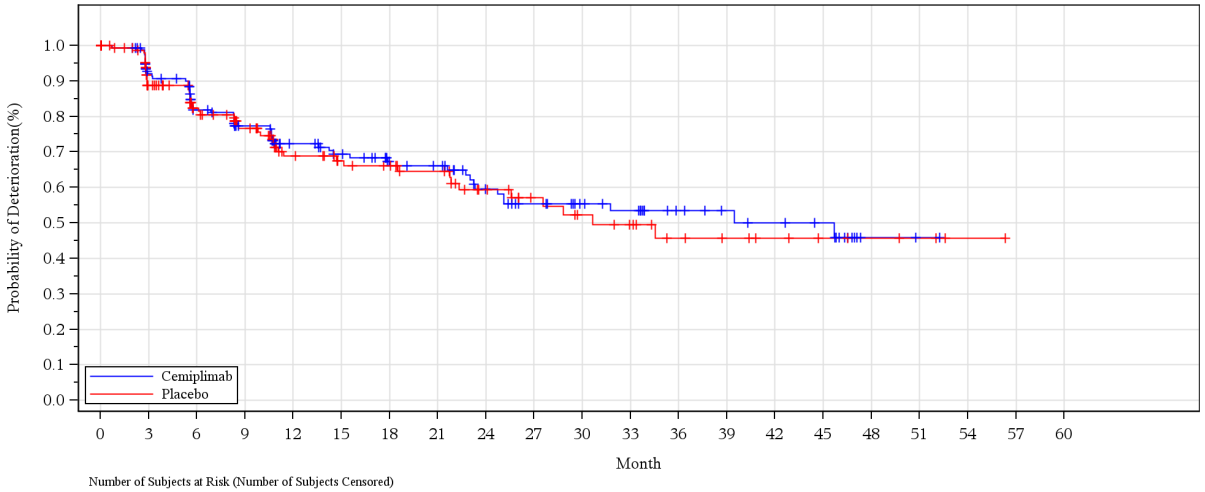
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	52 (14)	40 (18)	35 (22)	26 (26)	23 (27)	19 (30)	19 (30)	13 (33)	12 (34)	10 (36)	9 (36)	5 (40)	4 (41)	4 (41)	3 (41)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	72 (0)	43 (20)	30 (29)	24 (34)	19 (36)	15 (40)	14 (41)	13 (41)	9 (43)	6 (46)	4 (47)	3 (47)	2 (47)	2 (47)	2 (47)	2 (47)	1 (48)	1 (48)	0 (49)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Gender group: Male



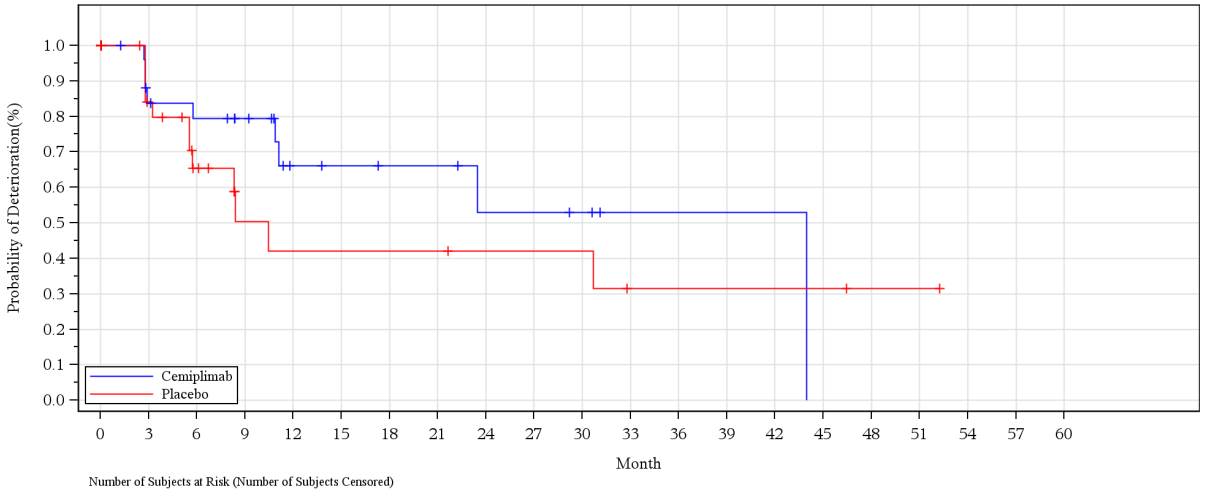
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	132 (30)	109 (39)	95 (47)	77 (59)	69 (64)	58 (73)	55 (75)	43 (82)	36 (86)	30 (92)	27 (94)	19 (102)	16 (105)	14 (106)	12 (108)	2 (117)	1 (118)	0 (119)	0 (119)	0 (119)
Placebo	174 (0)	119 (39)	94 (56)	77 (67)	55 (82)	48 (88)	45 (90)	40 (94)	30 (101)	23 (107)	19 (109)	16 (111)	11 (115)	9 (117)	7 (119)	5 (121)	4 (122)	3 (123)	1 (125)	0 (126)	0 (126)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Gender group: Female



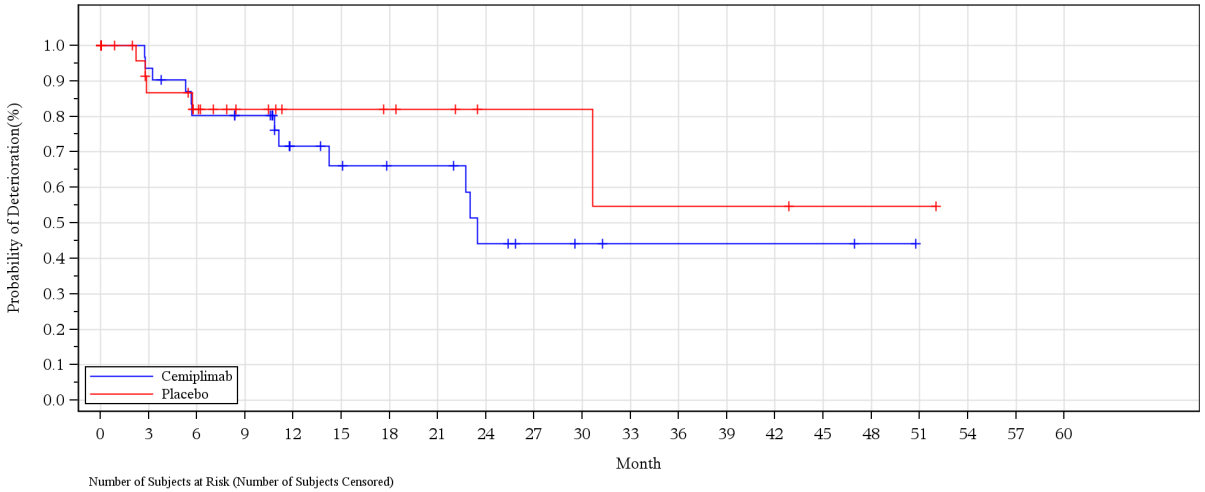
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	20 (11)	18 (12)	15 (15)	8 (20)	7 (21)	6 (22)	6 (22)	4 (23)	4 (23)	3 (24)	1 (26)	1 (26)	1 (26)	1 (26)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	32 (0)	20 (8)	12 (12)	6 (16)	5 (16)	5 (16)	5 (16)	5 (16)	4 (17)	4 (17)	4 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



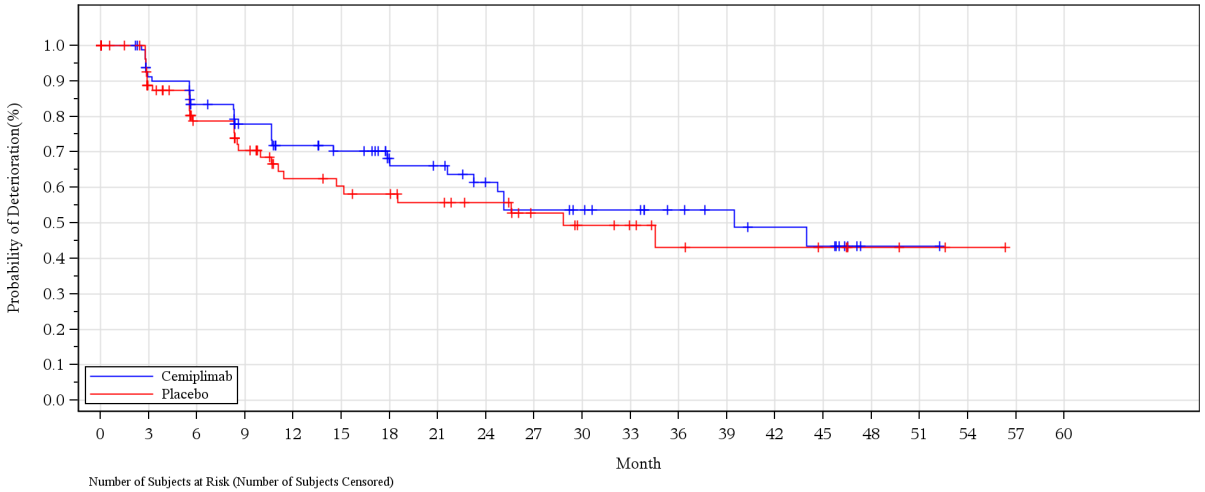
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (6)	24 (7)	22 (9)	14 (15)	12 (16)	10 (18)	10 (18)	6 (19)	4 (21)	3 (22)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	0 (25)	0 (25)	0 (25)	0 (25)
Placebo	31 (0)	19 (9)	15 (12)	10 (17)	7 (20)	7 (20)	6 (21)	5 (22)	3 (24)	3 (24)	3 (24)	2 (24)	2 (24)	2 (24)	2 (24)	1 (25)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	71 (12)	61 (16)	52 (21)	45 (24)	41 (27)	32 (35)	30 (36)	24 (40)	21 (40)	19 (42)	17 (44)	13 (48)	11 (50)	9 (51)	8 (51)	1 (58)	1 (58)	0 (59)	0 (59)	0 (59)
Placebo	90 (0)	66 (15)	50 (24)	41 (28)	30 (35)	28 (36)	26 (37)	23 (39)	20 (42)	15 (46)	12 (48)	10 (50)	7 (52)	6 (53)	6 (53)	5 (54)	3 (56)	2 (57)	1 (58)	0 (59)	0 (59)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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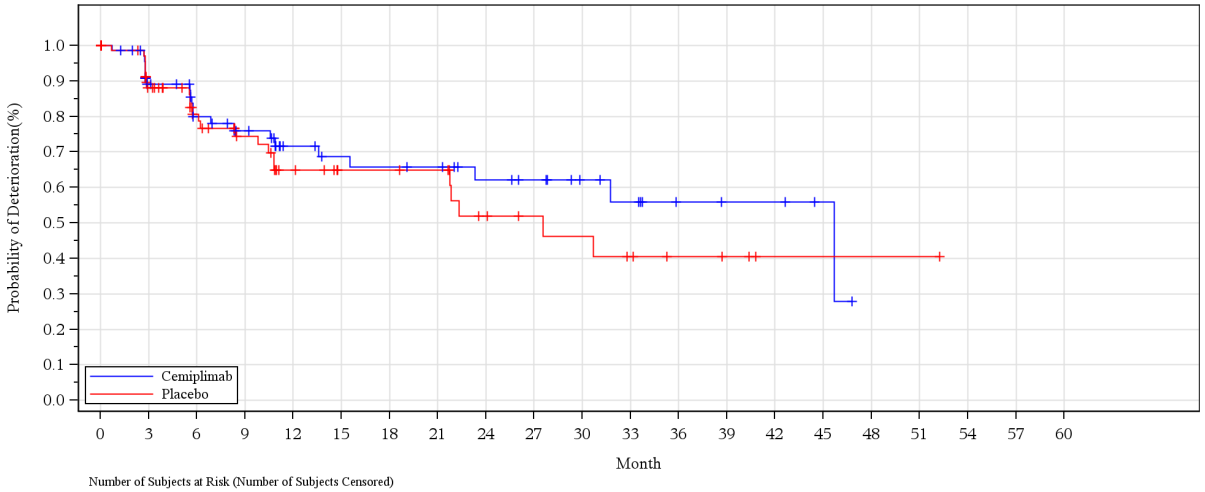
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



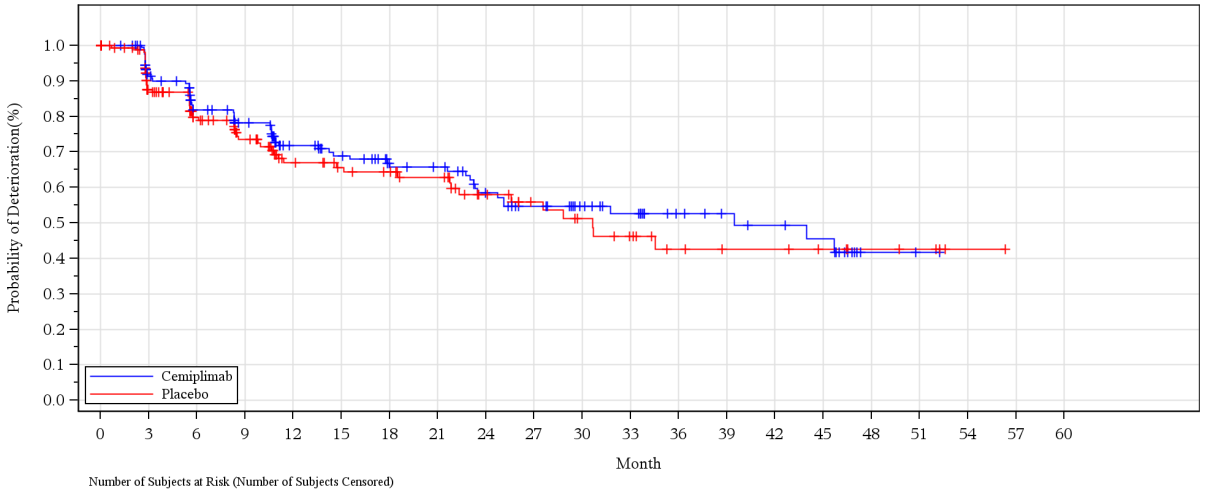
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	52 (23)	42 (28)	36 (32)	26 (40)	23 (42)	22 (42)	21 (43)	17 (46)	15 (48)	11 (52)	9 (53)	5 (57)	4 (58)	4 (58)	2 (60)	0 (61)	0 (61)	0 (61)	0 (61)	0 (61)
Placebo	85 (0)	54 (23)	41 (32)	32 (38)	23 (43)	18 (48)	18 (48)	17 (49)	11 (52)	9 (54)	8 (54)	6 (55)	4 (57)	3 (58)	1 (60)	1 (60)	1 (60)	1 (60)	0 (61)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Race: White



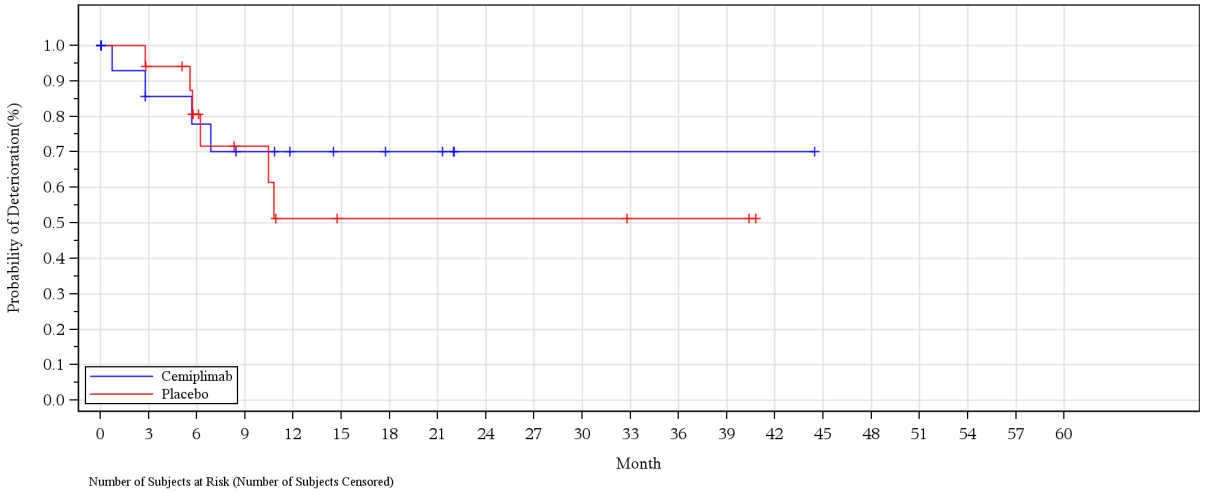
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	141 (34)	117 (44)	102 (54)	79 (69)	71 (74)	60 (83)	57 (85)	46 (90)	39 (94)	32 (101)	27 (105)	19 (113)	16 (116)	14 (117)	12 (118)	2 (127)	1 (128)	0 (129)	0 (129)	0 (129)
Placebo	189 (0)	124 (46)	96 (64)	76 (77)	56 (91)	50 (96)	47 (98)	42 (102)	31 (110)	24 (116)	20 (118)	16 (120)	11 (124)	9 (126)	9 (126)	7 (128)	5 (130)	4 (131)	1 (134)	0 (135)	0 (135)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (7)	10 (7)	8 (8)	6 (10)	5 (11)	4 (12)	4 (12)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	17 (0)	15 (1)	10 (4)	7 (6)	4 (7)	3 (8)	3 (8)	3 (8)	3 (8)	3 (8)	3 (8)	2 (9)	2 (9)	2 (9)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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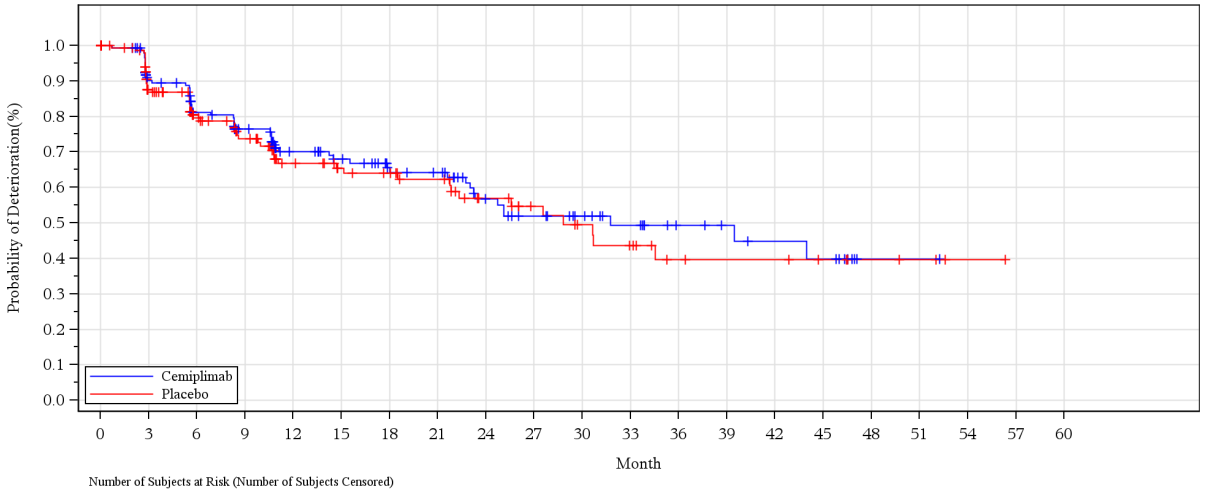
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



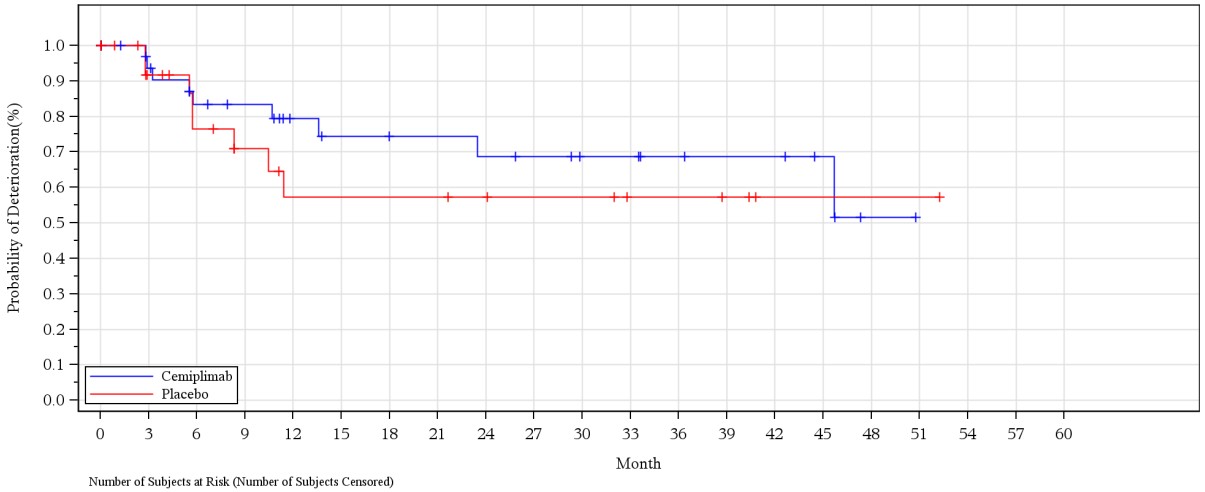
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	123 (29)	104 (36)	89 (45)	69 (58)	62 (63)	51 (72)	48 (74)	35 (82)	29 (85)	24 (90)	19 (94)	13 (100)	11 (102)	9 (103)	8 (103)	1 (110)	1 (110)	0 (111)	0 (111)	0 (111)
Placebo	177 (0)	119 (40)	91 (59)	72 (71)	52 (85)	45 (91)	42 (93)	37 (97)	27 (104)	21 (109)	17 (111)	14 (112)	9 (116)	8 (117)	8 (117)	6 (119)	4 (121)	3 (122)	1 (124)	0 (125)	0 (125)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (12)	23 (15)	21 (17)	16 (21)	14 (22)	13 (23)	13 (23)	12 (23)	11 (24)	9 (26)	9 (26)	7 (28)	6 (29)	6 (29)	4 (31)	1 (33)	0 (34)	0 (34)	0 (34)	0 (34)
Placebo	29 (0)	20 (7)	15 (9)	11 (12)	8 (13)	8 (13)	8 (13)	8 (13)	7 (14)	6 (15)	6 (15)	4 (17)	4 (17)	3 (18)	1 (20)	1 (20)	1 (20)	1 (20)	0 (21)	0 (21)	0 (21)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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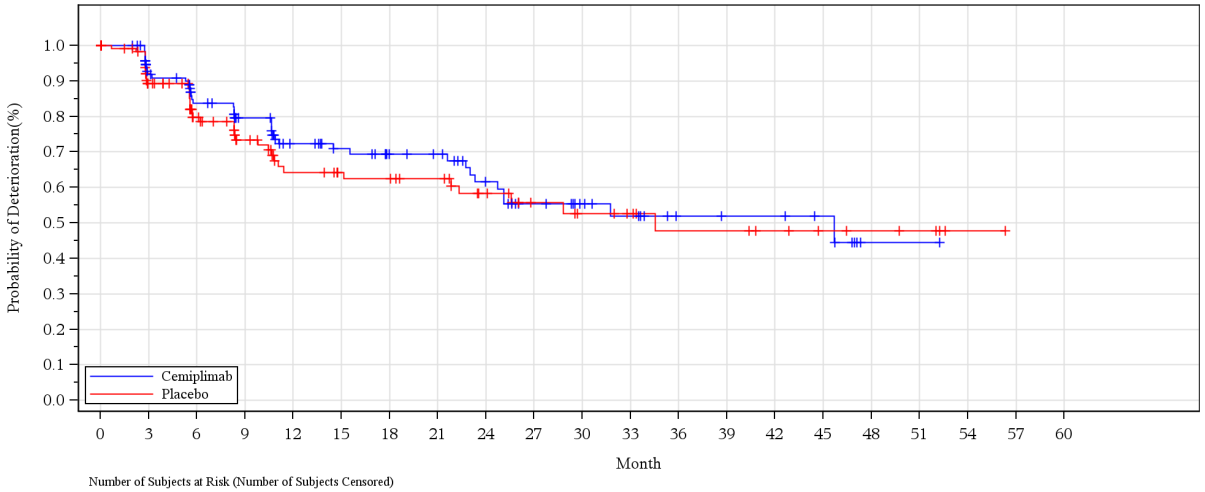
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	96 (28)	81 (35)	69 (43)	54 (52)	48 (57)	41 (63)	39 (65)	30 (70)	23 (74)	18 (79)	15 (81)	10 (86)	9 (87)	9 (87)	7 (89)	1 (94)	1 (94)	0 (95)	0 (95)	0 (95)
Placebo	131 (0)	93 (26)	69 (41)	53 (52)	40 (59)	36 (63)	35 (63)	32 (66)	25 (71)	18 (77)	15 (79)	13 (81)	10 (83)	10 (83)	8 (85)	6 (87)	5 (88)	4 (89)	1 (92)	0 (93)	0 (93)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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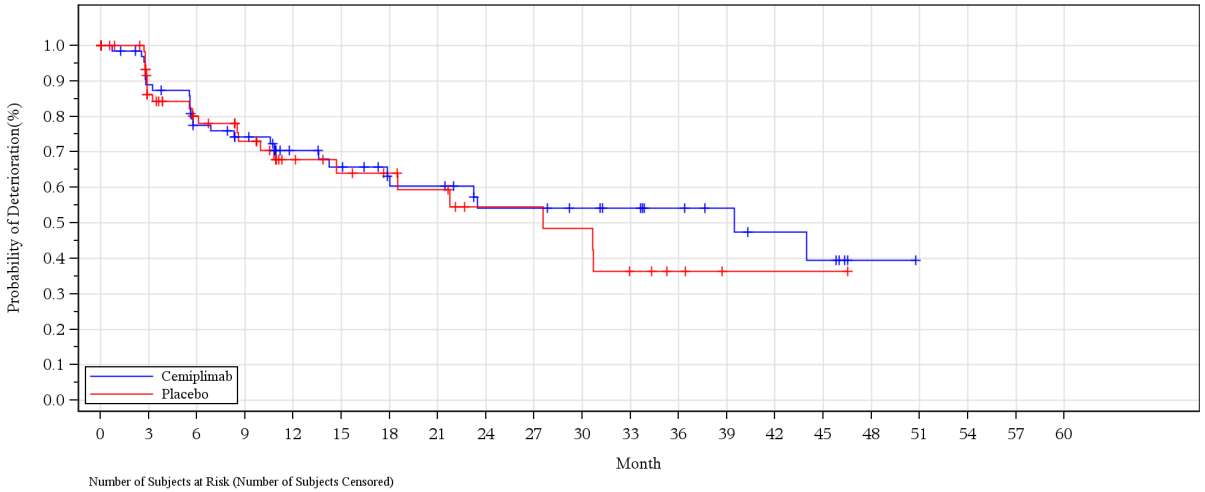
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	56 (13)	46 (16)	41 (19)	31 (27)	28 (28)	23 (32)	22 (32)	17 (35)	17 (35)	15 (37)	13 (39)	10 (42)	8 (44)	6 (45)	5 (45)	1 (49)	0 (50)	0 (50)	0 (50)	0 (50)
Placebo	75 (0)	46 (21)	37 (27)	30 (31)	20 (39)	17 (41)	15 (43)	13 (44)	9 (47)	9 (47)	8 (47)	5 (48)	3 (50)	1 (52)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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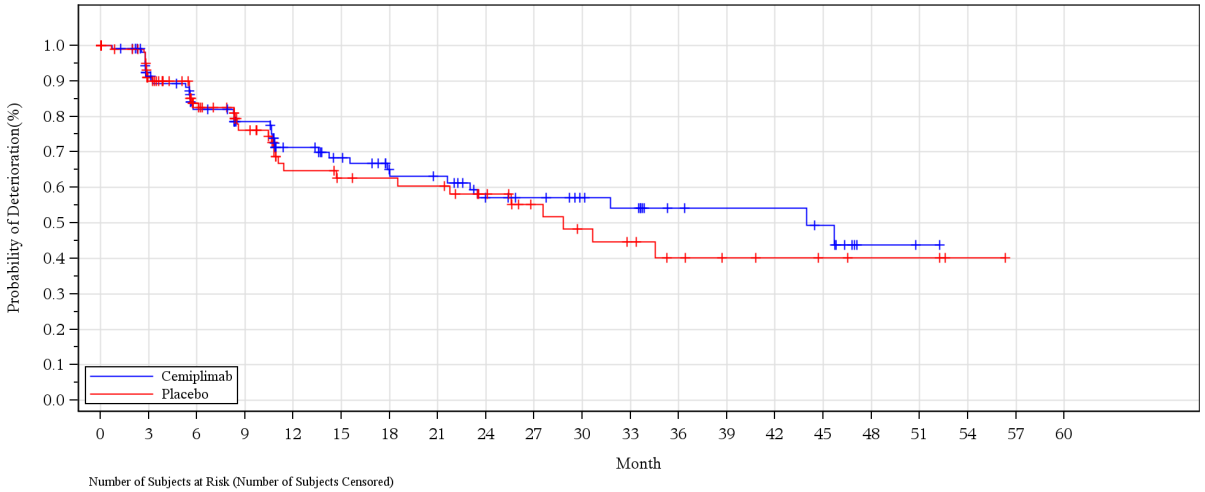
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



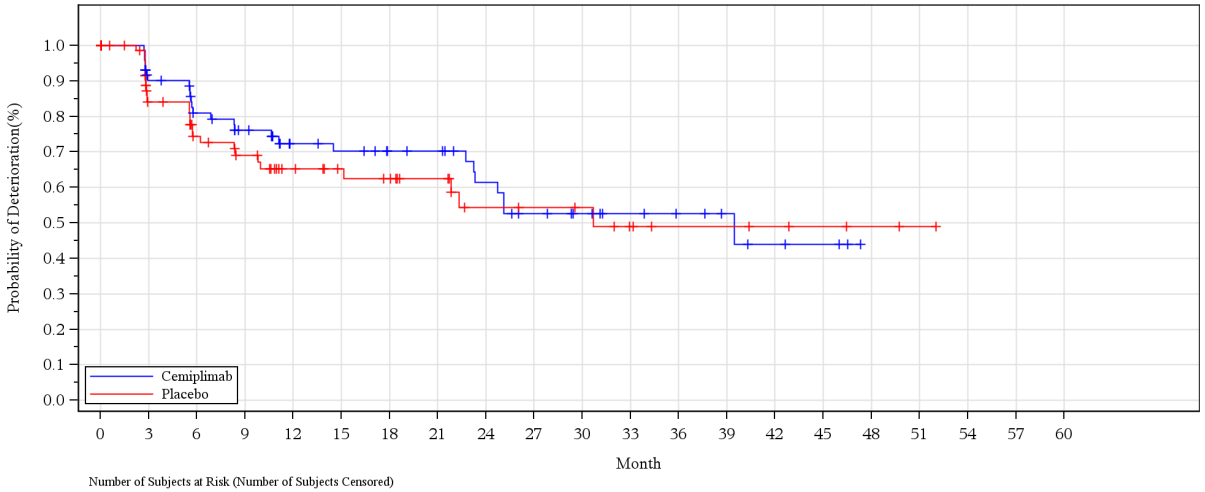
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	91 (25)	76 (31)	66 (38)	51 (47)	44 (52)	36 (58)	34 (59)	26 (64)	24 (66)	20 (70)	18 (71)	12 (77)	11 (78)	11 (78)	9 (79)	2 (85)	1 (86)	0 (87)	0 (87)	0 (87)
Placebo	117 (0)	85 (23)	63 (39)	46 (51)	32 (59)	29 (61)	28 (62)	27 (62)	22 (66)	16 (71)	13 (72)	11 (73)	8 (75)	6 (77)	5 (78)	4 (79)	3 (80)	3 (80)	1 (82)	0 (83)	0 (83)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



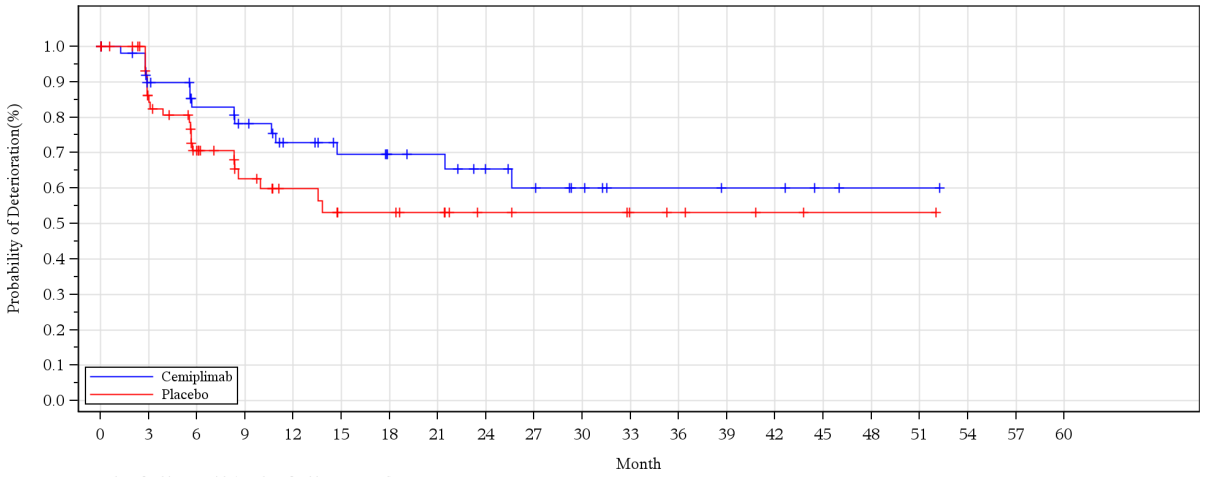
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	61 (16)	51 (20)	44 (24)	34 (32)	32 (33)	28 (37)	27 (38)	21 (41)	16 (43)	13 (46)	10 (49)	8 (51)	6 (53)	4 (54)	3 (55)	0 (58)	0 (58)	0 (58)	0 (58)	0 (58)
Placebo	89 (0)	54 (24)	43 (29)	37 (32)	28 (39)	24 (43)	22 (44)	18 (48)	12 (52)	11 (53)	10 (54)	7 (56)	5 (58)	5 (58)	4 (59)	3 (60)	2 (61)	1 (62)	0 (63)	0 (63)	0 (63)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



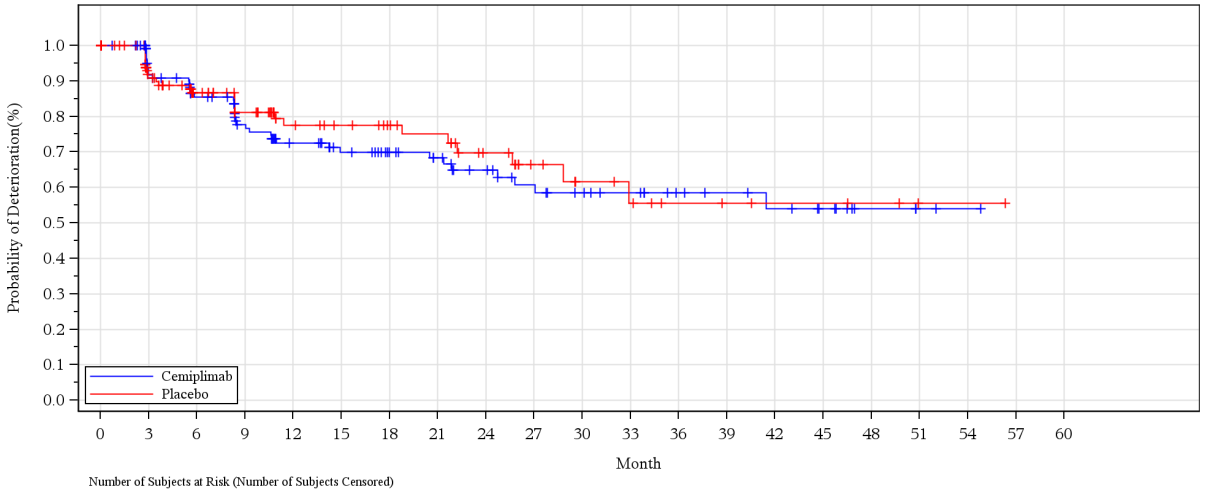
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	42 (9)	35 (13)	31 (15)	25 (19)	21 (22)	18 (25)	17 (26)	13 (29)	11 (30)	8 (33)	5 (36)	5 (36)	4 (37)	4 (37)	2 (39)	1 (40)	1 (40)	0 (41)	0 (41)	0 (41)
Placebo	65 (0)	47 (10)	33 (16)	23 (23)	18 (27)	14 (29)	14 (29)	12 (31)	8 (35)	7 (36)	7 (36)	5 (38)	4 (39)	3 (40)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



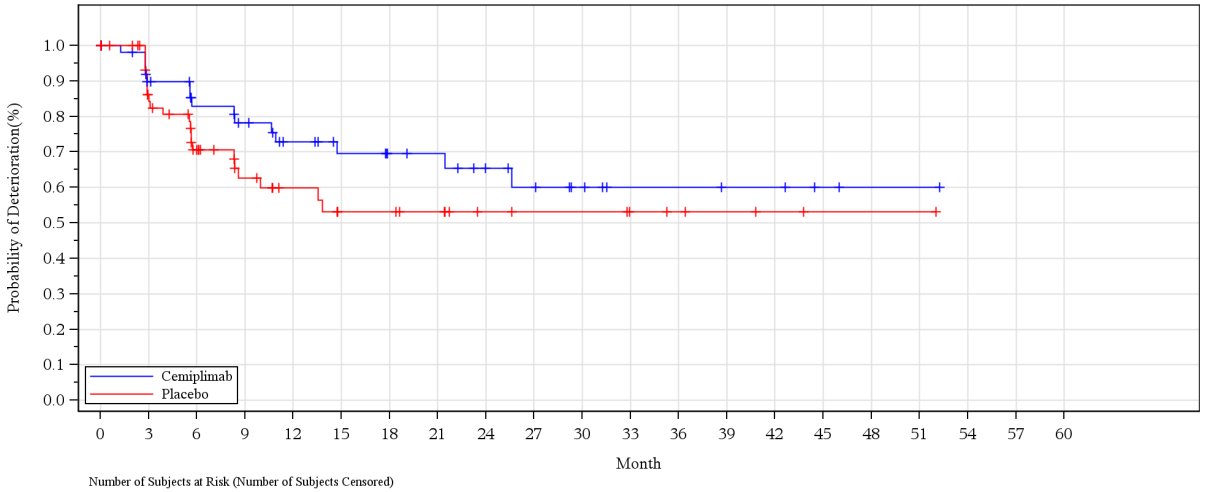
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	109 (34)	94 (42)	76 (52)	62 (61)	54 (67)	46 (75)	41 (79)	34 (84)	28 (88)	24 (91)	21 (94)	16 (99)	14 (101)	12 (102)	9 (105)	4 (110)	2 (112)	1 (113)	0 (114)	0 (114)
Placebo	141 (0)	92 (39)	71 (56)	56 (67)	41 (80)	37 (84)	33 (88)	30 (90)	22 (96)	15 (102)	11 (105)	9 (106)	6 (109)	5 (110)	4 (111)	4 (111)	3 (112)	1 (114)	1 (114)	0 (115)	0 (115)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



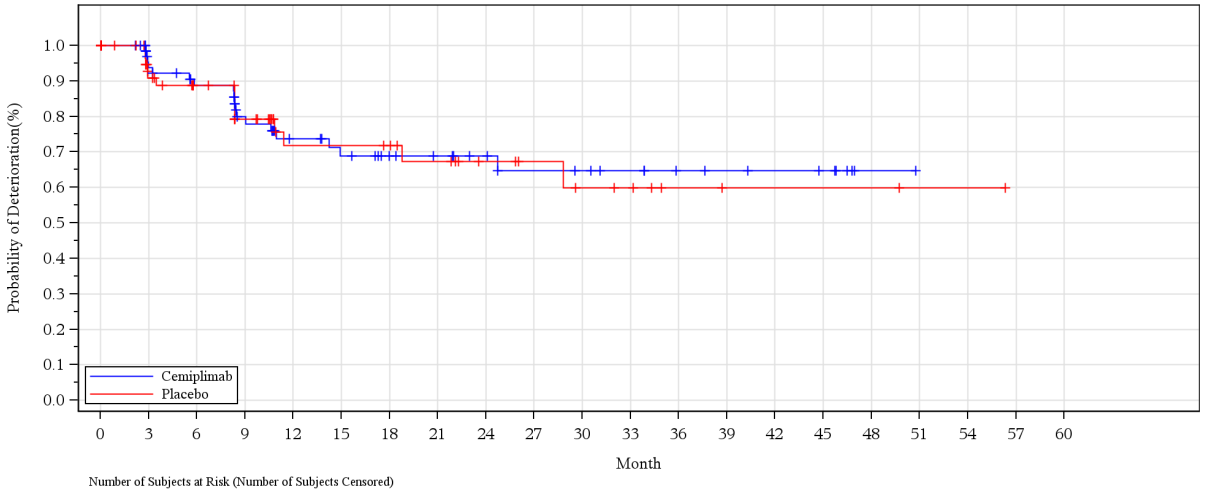
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	42 (9)	35 (13)	31 (15)	25 (19)	21 (22)	18 (25)	17 (26)	13 (29)	11 (30)	8 (33)	5 (36)	5 (36)	4 (37)	4 (37)	2 (39)	1 (40)	1 (40)	0 (41)	0 (41)	0 (41)
Placebo	65 (0)	47 (10)	33 (16)	23 (23)	18 (27)	14 (29)	14 (29)	12 (31)	8 (35)	7 (36)	7 (36)	5 (38)	4 (39)	3 (40)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



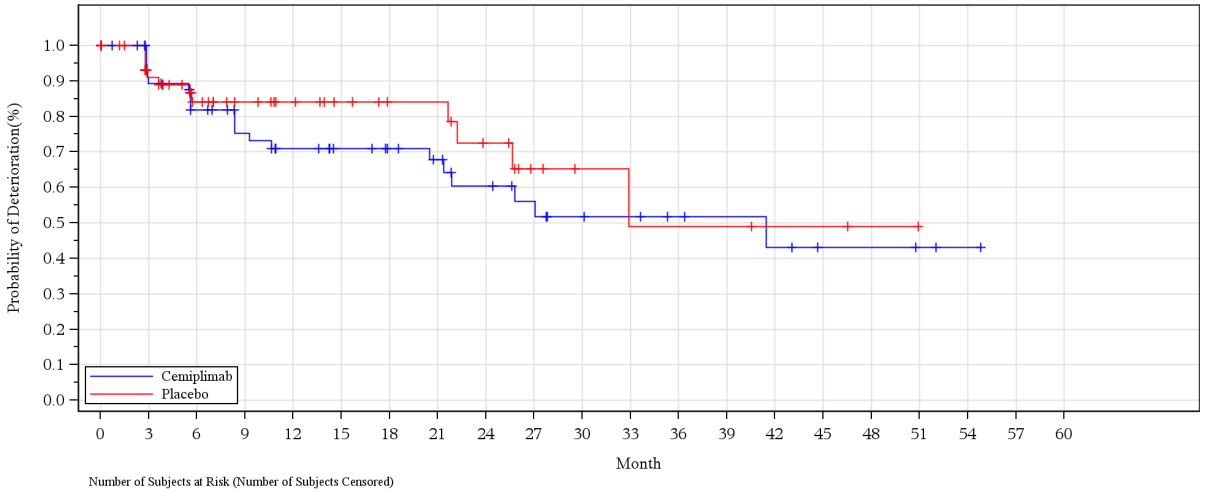
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	59 (17)	52 (21)	41 (27)	32 (33)	28 (35)	23 (40)	21 (42)	18 (45)	15 (47)	14 (48)	12 (50)	9 (53)	8 (54)	7 (55)	6 (56)	1 (61)	0 (62)	0 (62)	0 (62)
Placebo	69 (0)	47 (17)	39 (24)	30 (29)	19 (38)	19 (38)	18 (39)	15 (41)	11 (45)	9 (47)	7 (48)	6 (49)	3 (52)	2 (53)	2 (53)	2 (53)	2 (53)	1 (54)	1 (54)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



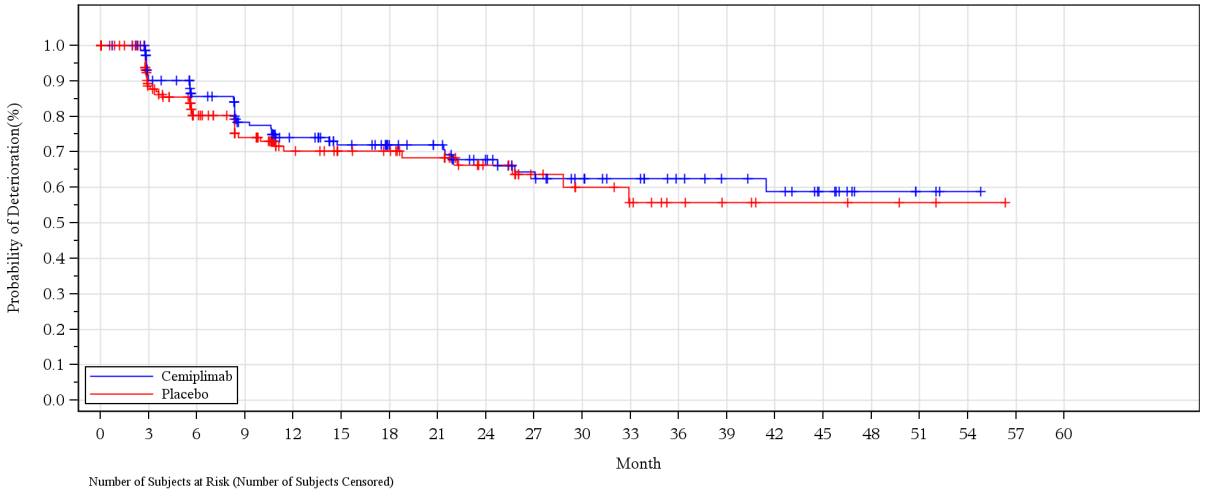
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	50 (17)	42 (21)	35 (25)	30 (28)	26 (32)	23 (35)	20 (37)	16 (39)	13 (41)	10 (43)	9 (44)	7 (46)	6 (47)	5 (47)	3 (49)	3 (49)	2 (50)	1 (51)	0 (52)	0 (52)
Placebo	72 (0)	45 (22)	32 (32)	26 (38)	22 (42)	18 (46)	15 (49)	15 (49)	11 (51)	6 (55)	4 (57)	3 (57)	3 (57)	3 (57)	2 (58)	2 (58)	1 (59)	0 (60)	0 (60)	0 (60)	0 (60)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Gender group: Male



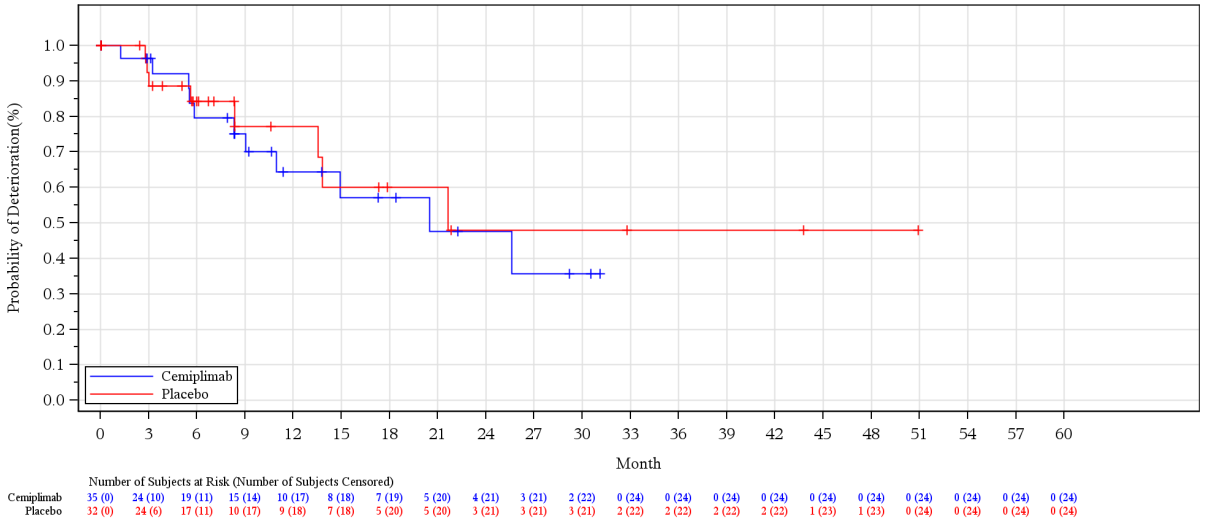
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	127 (33)	110 (44)	92 (53)	77 (63)	67 (71)	57 (81)	53 (85)	43 (92)	36 (97)	30 (102)	26 (106)	21 (111)	18 (114)	16 (115)	11 (120)	5 (126)	3 (128)	1 (130)	0 (131)	0 (131)
Placebo	174 (0)	115 (43)	87 (61)	69 (73)	50 (89)	44 (95)	42 (97)	37 (101)	27 (110)	19 (117)	15 (120)	12 (122)	8 (126)	6 (128)	4 (130)	4 (130)	3 (131)	2 (132)	1 (133)	0 (134)	0 (134)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Gender group: Female



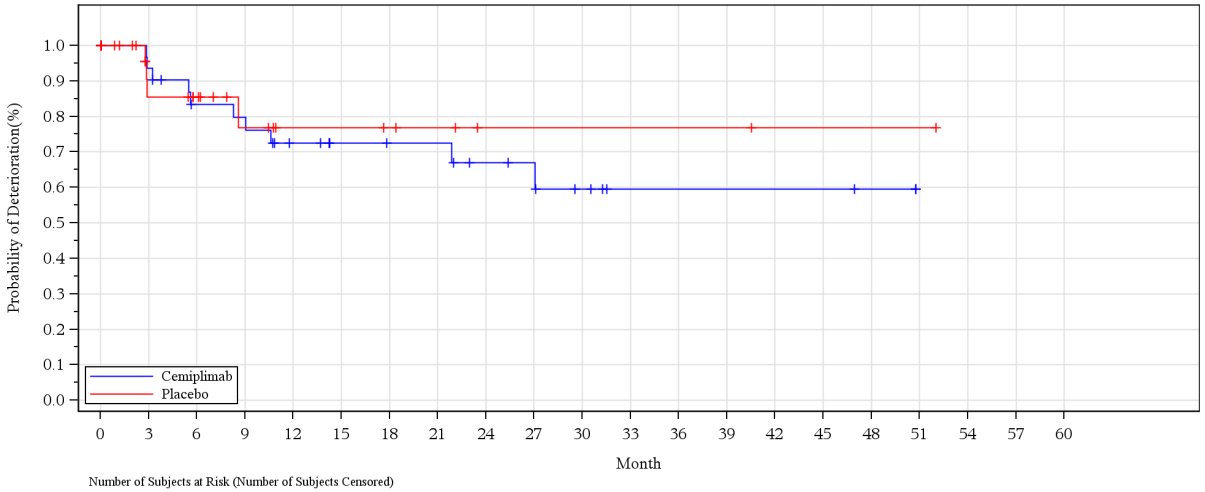
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	24 (10)	19 (11)	15 (14)	10 (17)	8 (18)	7 (19)	5 (20)	4 (21)	3 (21)	2 (22)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)
Placebo	32 (0)	24 (6)	17 (11)	10 (17)	9 (18)	7 (18)	5 (20)	5 (20)	3 (21)	3 (21)	3 (21)	2 (22)	2 (22)	2 (22)	2 (22)	1 (23)	1 (23)	0 (24)	0 (24)	0 (24)	0 (24)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (6)	23 (9)	22 (9)	17 (12)	14 (15)	13 (16)	13 (16)	10 (18)	9 (19)	6 (21)	3 (24)	3 (24)	3 (24)	3 (24)	3 (24)	2 (25)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	31 (0)	17 (11)	14 (14)	9 (18)	6 (21)	6 (21)	5 (22)	4 (23)	2 (25)	2 (25)	2 (25)	2 (25)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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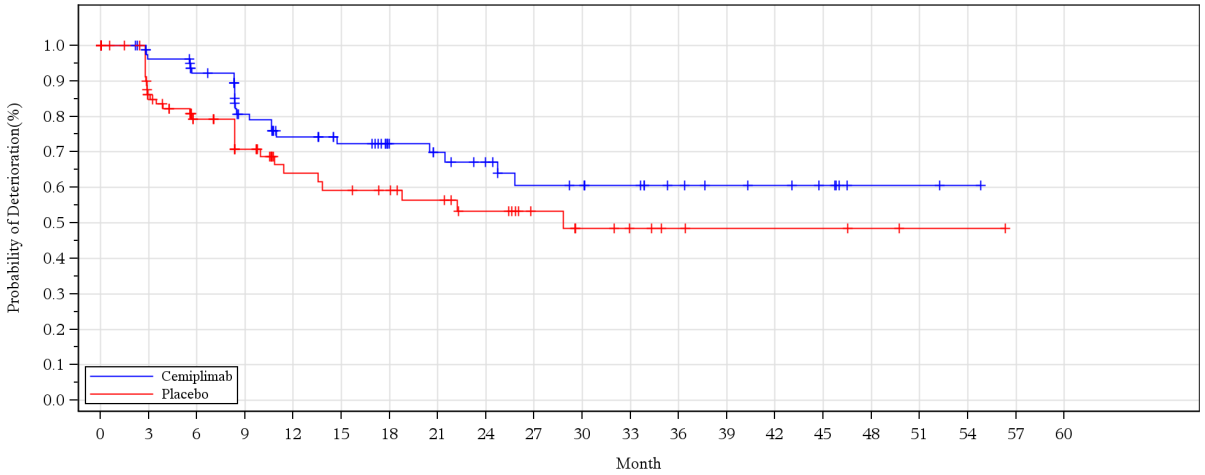
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	75 (12)	68 (16)	52 (24)	43 (29)	38 (33)	29 (42)	26 (44)	22 (47)	18 (49)	17 (50)	15 (52)	11 (56)	9 (58)	8 (59)	6 (61)	2 (65)	2 (65)	1 (66)	0 (67)	0 (67)
Placebo	90 (0)	65 (14)	49 (25)	38 (31)	27 (39)	25 (39)	23 (41)	20 (43)	16 (46)	11 (51)	8 (53)	6 (55)	4 (57)	3 (58)	3 (58)	3 (58)	2 (59)	1 (60)	1 (60)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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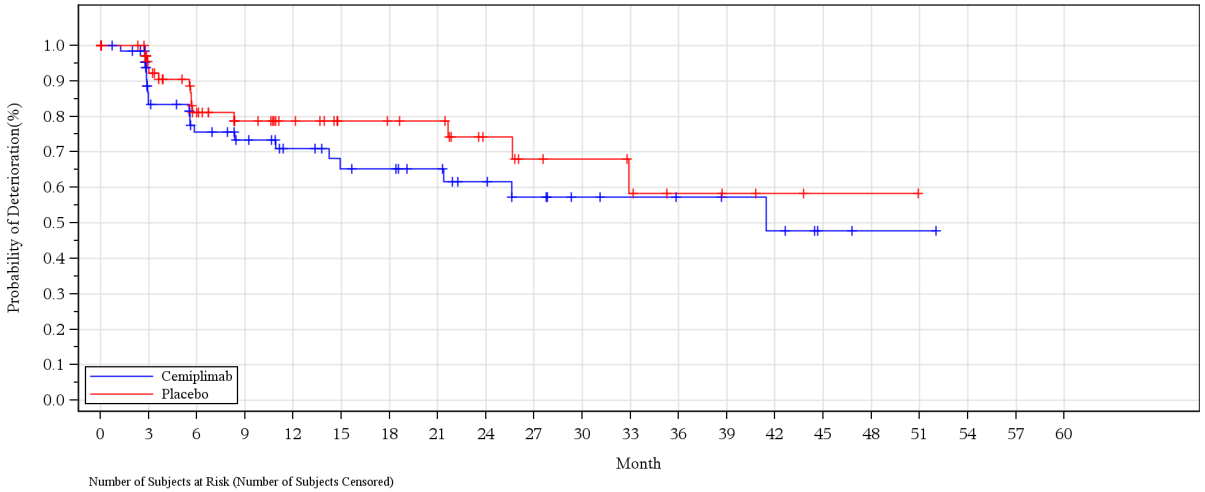
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	47 (25)	38 (30)	33 (34)	27 (39)	23 (41)	22 (42)	19 (45)	15 (48)	12 (50)	9 (53)	8 (54)	7 (55)	6 (56)	5 (56)	2 (59)	1 (60)	1 (60)	0 (61)	0 (61)	0 (61)
Placebo	85 (0)	57 (24)	41 (33)	32 (41)	26 (47)	20 (53)	19 (54)	18 (55)	12 (60)	9 (62)	8 (63)	6 (64)	4 (66)	3 (67)	2 (68)	1 (69)	1 (69)	0 (70)	0 (70)	0 (70)	0 (70)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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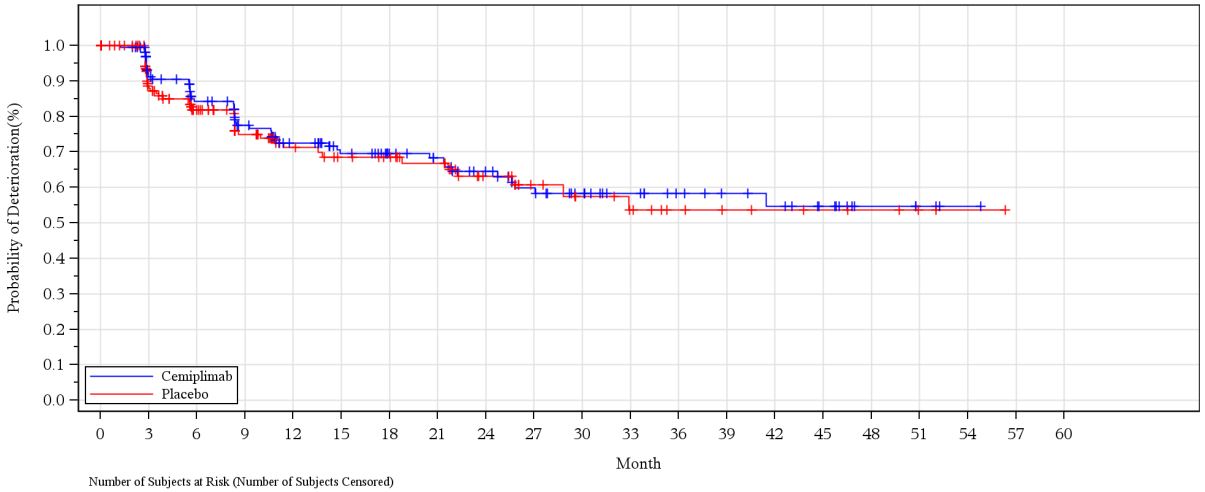
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Race: White



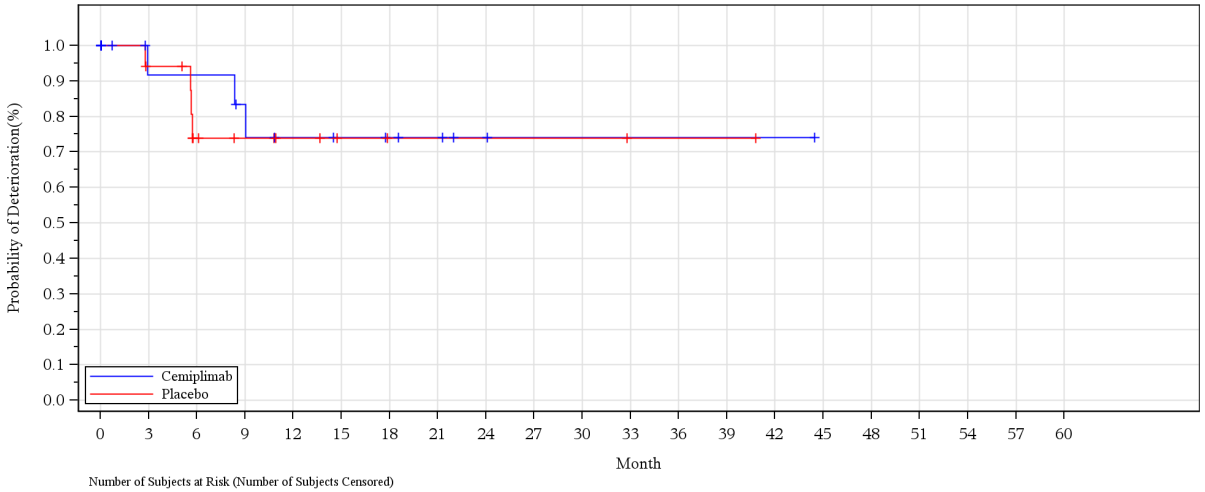
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	140 (35)	118 (47)	98 (58)	80 (70)	69 (78)	59 (88)	54 (92)	45 (98)	38 (102)	31 (108)	25 (114)	20 (119)	17 (122)	15 (123)	11 (127)	5 (133)	3 (135)	1 (137)	0 (138)	0 (138)
Placebo	189 (0)	124 (48)	95 (68)	72 (84)	54 (99)	48 (103)	45 (106)	40 (110)	28 (120)	20 (127)	16 (130)	13 (132)	9 (136)	7 (138)	6 (139)	5 (140)	4 (141)	2 (143)	1 (144)	0 (145)	0 (145)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Race: Non-white



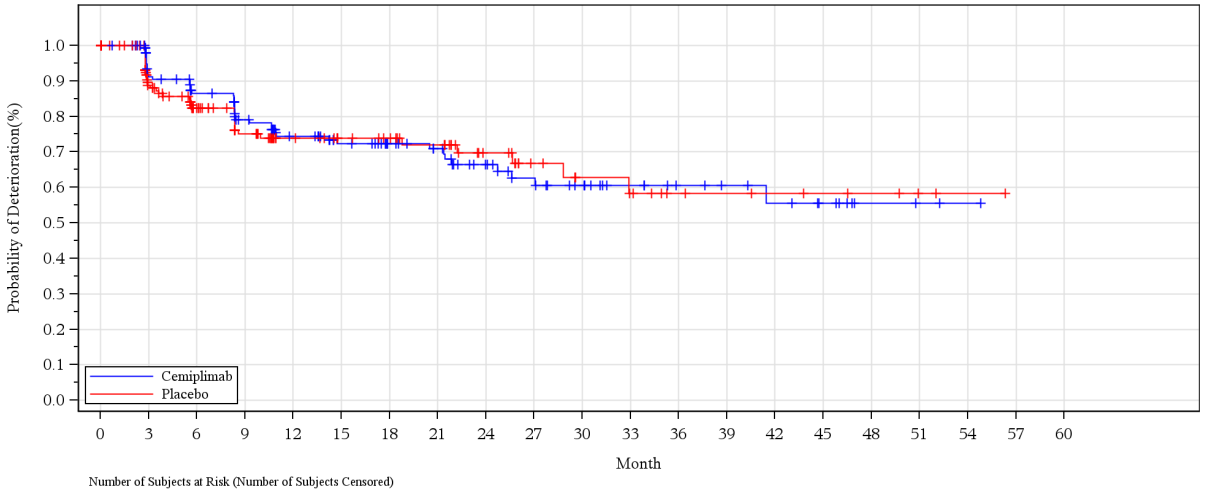
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (8)	11 (8)	9 (9)	7 (10)	6 (11)	5 (12)	4 (13)	2 (15)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	17 (0)	15 (1)	9 (4)	7 (6)	5 (8)	3 (10)	2 (11)	2 (11)	2 (11)	2 (11)	2 (11)	1 (12)	1 (12)	1 (12)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



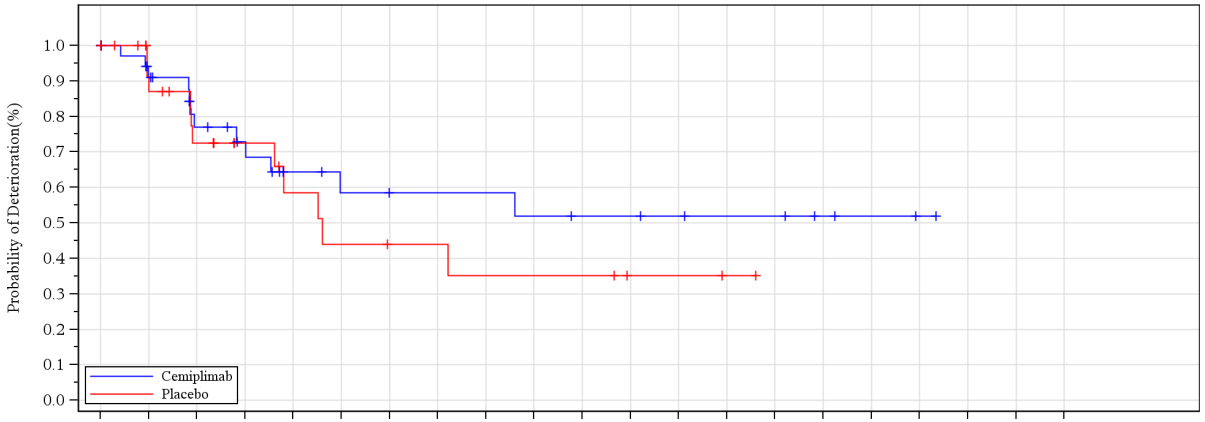
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	122 (32)	108 (40)	90 (49)	75 (59)	65 (67)	55 (77)	49 (82)	38 (90)	31 (95)	25 (100)	19 (106)	15 (110)	13 (112)	11 (113)	8 (116)	3 (121)	2 (122)	1 (123)	0 (124)	0 (124)
Placebo	177 (0)	118 (43)	89 (64)	68 (78)	51 (94)	45 (100)	42 (103)	37 (107)	26 (117)	18 (124)	14 (127)	12 (128)	8 (132)	7 (133)	6 (134)	5 (135)	4 (136)	2 (138)	1 (139)	0 (140)	0 (140)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



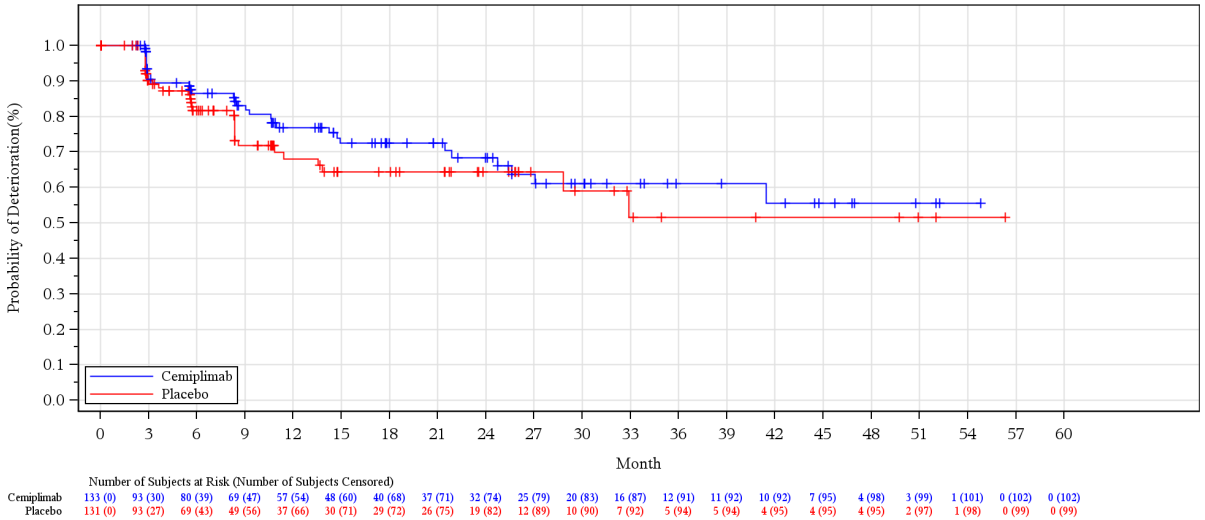
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (11)	21 (15)	17 (18)	12 (21)	10 (22)	9 (23)	9 (23)	9 (23)	8 (23)	7 (24)	7 (24)	6 (25)	5 (26)	5 (26)	3 (28)	2 (29)	1 (30)	0 (31)	0 (31)	0 (31)
Placebo	29 (0)	21 (6)	15 (8)	11 (12)	8 (13)	6 (13)	5 (14)	5 (14)	4 (14)	4 (14)	4 (14)	2 (16)	2 (16)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	93 (30)	80 (39)	69 (47)	57 (54)	48 (60)	40 (68)	37 (71)	32 (74)	25 (79)	20 (83)	16 (87)	12 (91)	11 (92)	10 (92)	7 (95)	4 (98)	3 (99)	1 (101)	0 (102)	0 (102)
Placebo	131 (0)	93 (27)	69 (43)	49 (56)	37 (66)	30 (71)	29 (72)	26 (75)	19 (82)	12 (89)	10 (90)	7 (92)	5 (94)	5 (94)	4 (95)	4 (95)	4 (95)	2 (97)	1 (98)	0 (99)	0 (99)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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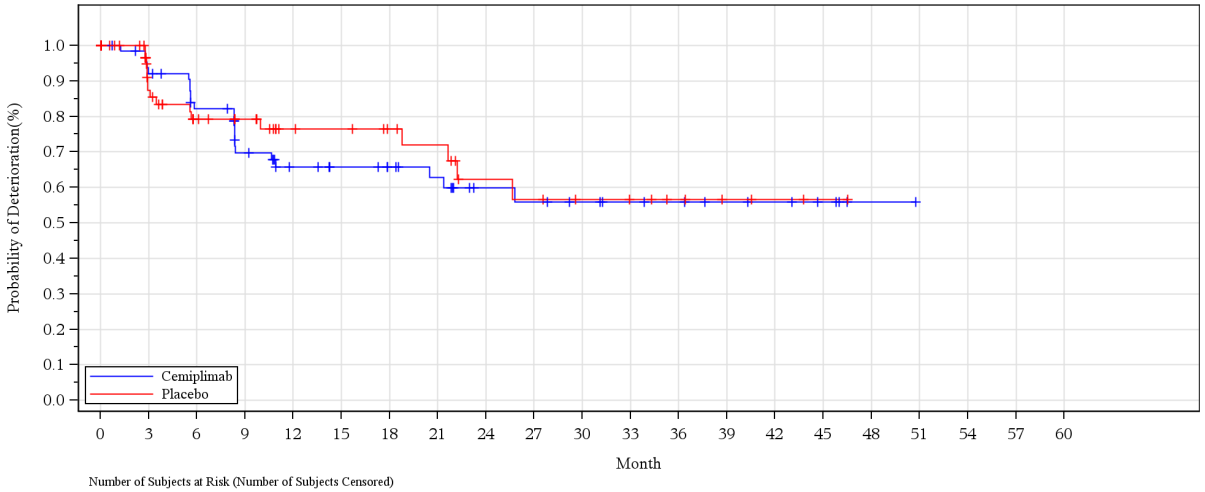
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	58 (13)	49 (16)	38 (20)	30 (26)	27 (29)	24 (32)	21 (34)	15 (39)	14 (39)	12 (41)	10 (43)	9 (44)	7 (46)	6 (47)	4 (49)	1 (52)	0 (53)	0 (53)	0 (53)	0 (53)
Placebo	75 (0)	46 (22)	35 (29)	30 (34)	22 (41)	21 (42)	18 (45)	16 (46)	11 (49)	10 (49)	8 (51)	7 (52)	5 (54)	3 (56)	2 (57)	1 (58)	0 (59)	0 (59)	0 (59)	0 (59)	0 (59)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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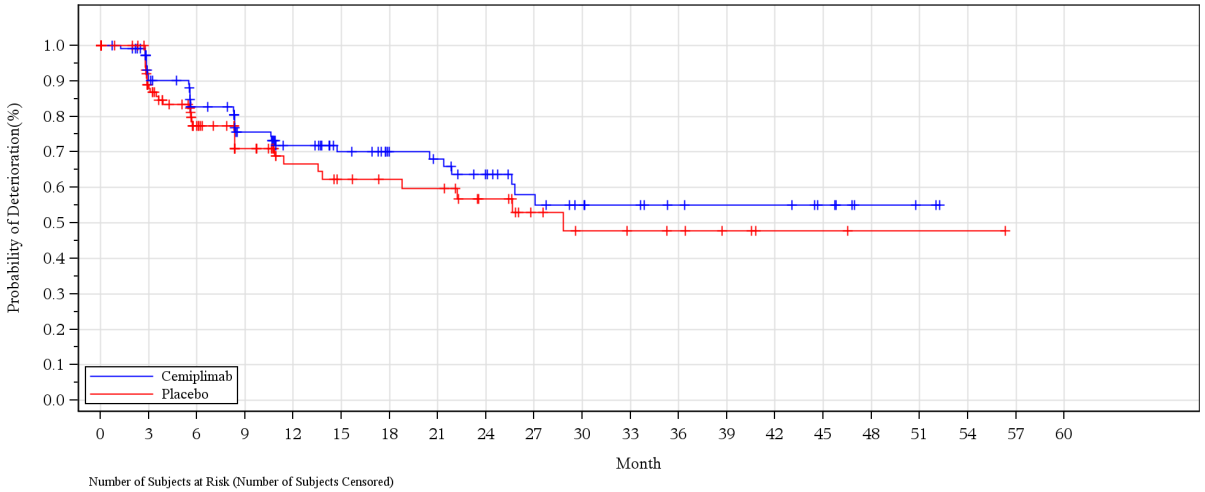
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	89 (26)	75 (33)	61 (41)	50 (49)	42 (56)	34 (64)	32 (65)	26 (69)	20 (73)	16 (76)	14 (78)	11 (81)	10 (82)	10 (82)	7 (85)	3 (89)	2 (90)	0 (92)	0 (92)	0 (92)
Placebo	117 (0)	84 (22)	58 (38)	41 (51)	30 (60)	26 (62)	24 (64)	23 (64)	17 (69)	11 (74)	8 (76)	7 (77)	6 (78)	4 (80)	2 (82)	2 (82)	1 (83)	1 (83)	1 (83)	0 (84)	0 (84)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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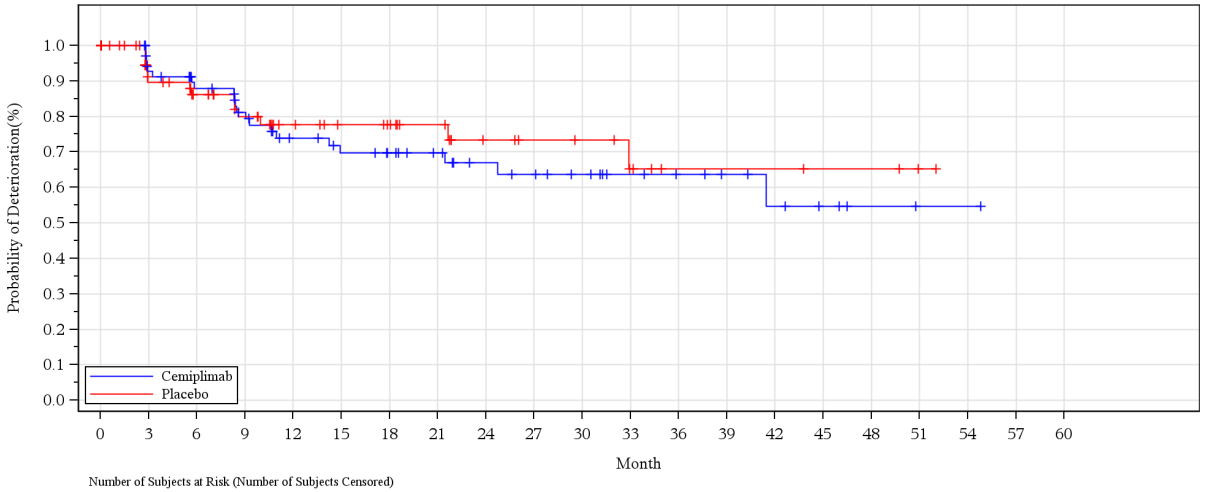
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



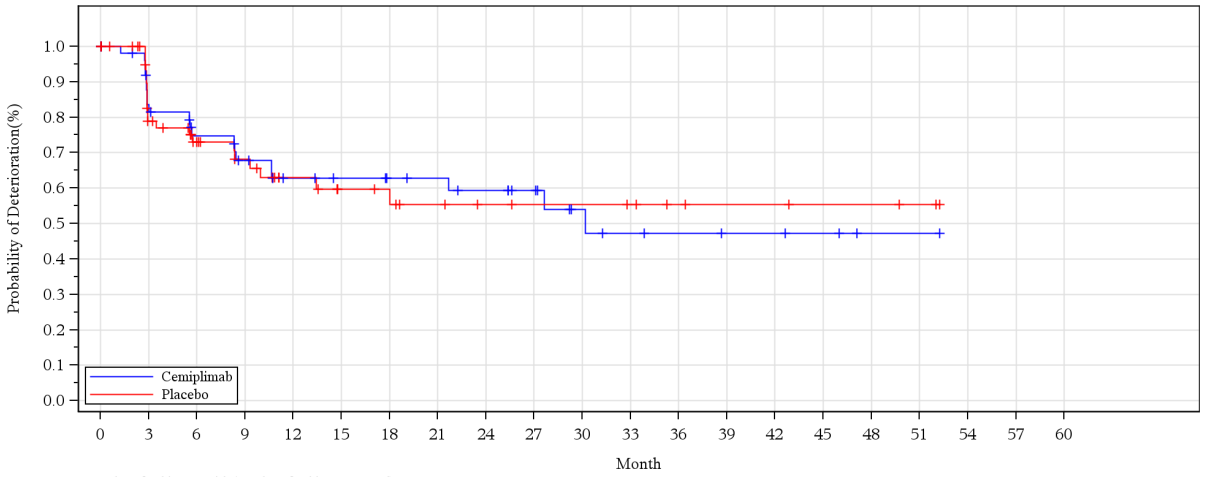
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	62 (17)	54 (22)	46 (26)	37 (31)	33 (33)	30 (36)	26 (40)	21 (44)	19 (45)	16 (48)	12 (52)	10 (54)	8 (56)	6 (57)	4 (59)	2 (61)	1 (62)	1 (62)	0 (63)	0 (63)
Placebo	89 (0)	55 (27)	46 (34)	38 (39)	29 (47)	25 (51)	23 (53)	19 (57)	13 (62)	11 (64)	10 (65)	7 (67)	4 (70)	4 (70)	4 (70)	3 (71)	3 (71)	1 (73)	0 (74)	0 (74)	0 (74)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



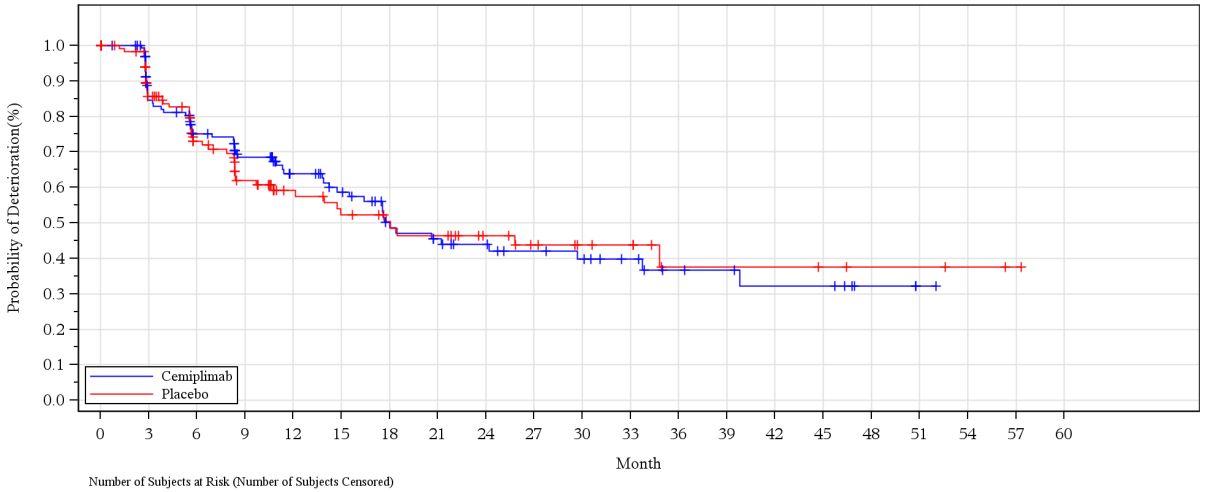
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	40 (8)	33 (11)	28 (13)	23 (16)	21 (18)	19 (20)	18 (21)	16 (22)	13 (25)	8 (29)	6 (30)	5 (31)	4 (32)	4 (32)	3 (33)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)
Placebo	65 (0)	43 (10)	33 (17)	27 (21)	19 (27)	15 (30)	14 (31)	11 (33)	9 (35)	8 (36)	8 (36)	7 (37)	5 (39)	4 (40)	4 (40)	3 (41)	3 (41)	2 (42)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



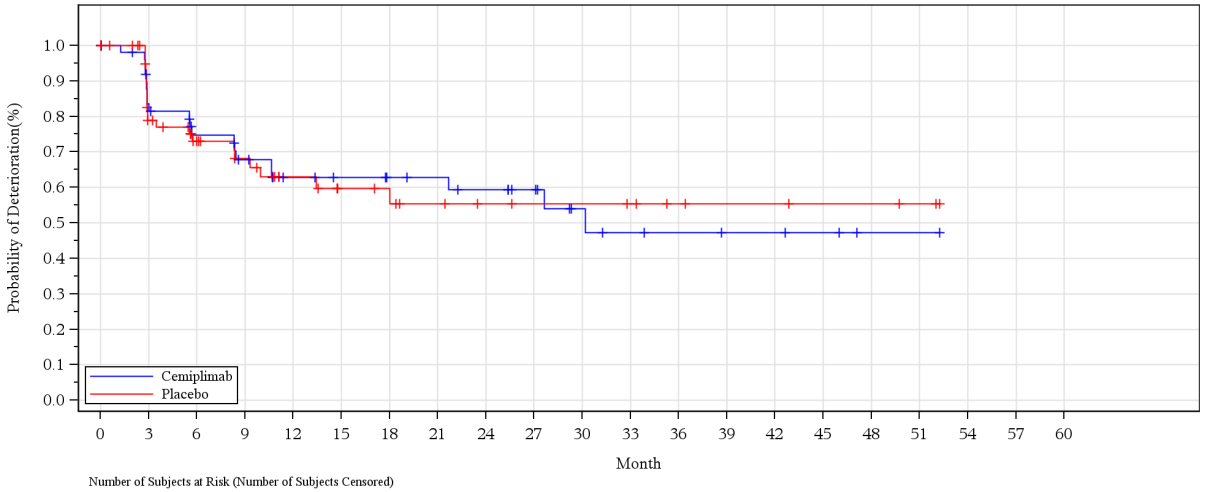
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	101 (33)	83 (40)	68 (48)	53 (59)	45 (63)	33 (69)	28 (71)	24 (74)	20 (77)	18 (78)	14 (82)	10 (85)	9 (86)	7 (87)	7 (87)	3 (91)	1 (93)	0 (94)	0 (94)	0 (94)
Placebo	141 (0)	89 (36)	63 (50)	47 (57)	35 (67)	30 (68)	26 (71)	24 (71)	18 (77)	14 (80)	11 (83)	10 (84)	5 (88)	5 (88)	5 (88)	4 (89)	3 (90)	3 (90)	2 (91)	1 (92)	0 (93)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	40 (8)	33 (11)	28 (13)	23 (16)	21 (18)	19 (20)	18 (21)	16 (22)	13 (25)	8 (29)	6 (30)	5 (31)	4 (32)	4 (32)	3 (33)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)
Placebo	65 (0)	43 (10)	33 (17)	27 (21)	19 (27)	15 (30)	14 (31)	11 (33)	9 (35)	8 (36)	8 (36)	7 (37)	5 (39)	4 (40)	4 (40)	3 (41)	3 (41)	2 (42)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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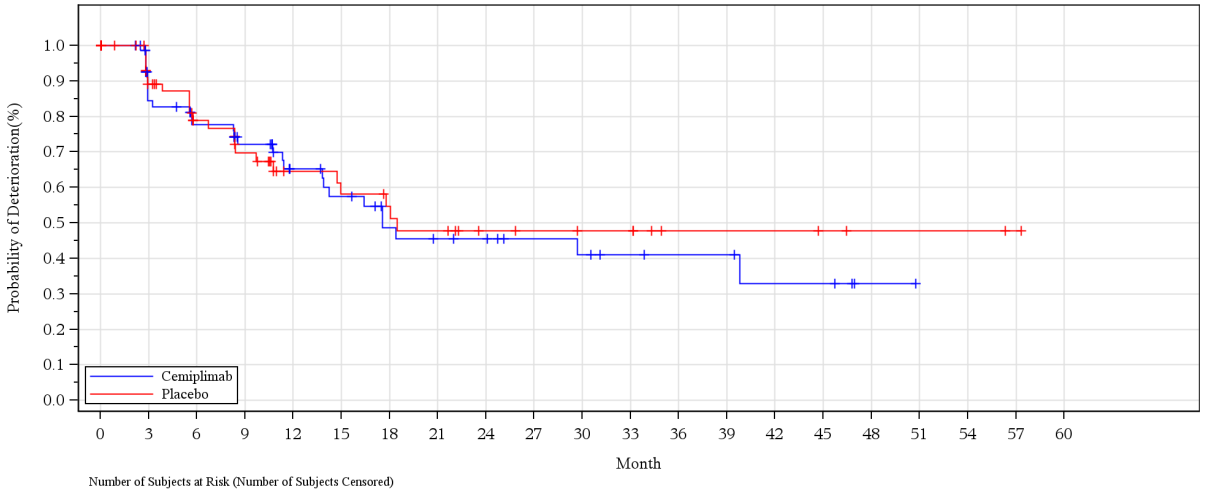
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	52 (18)	45 (21)	36 (27)	26 (34)	22 (35)	16 (38)	14 (39)	13 (40)	10 (43)	9 (43)	7 (45)	6 (46)	6 (46)	4 (47)	4 (47)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	69 (0)	47 (16)	35 (23)	29 (25)	20 (32)	18 (32)	16 (33)	14 (33)	10 (37)	9 (38)	8 (39)	8 (39)	4 (43)	4 (43)	4 (43)	3 (44)	2 (45)	2 (45)	2 (45)	1 (46)	0 (47)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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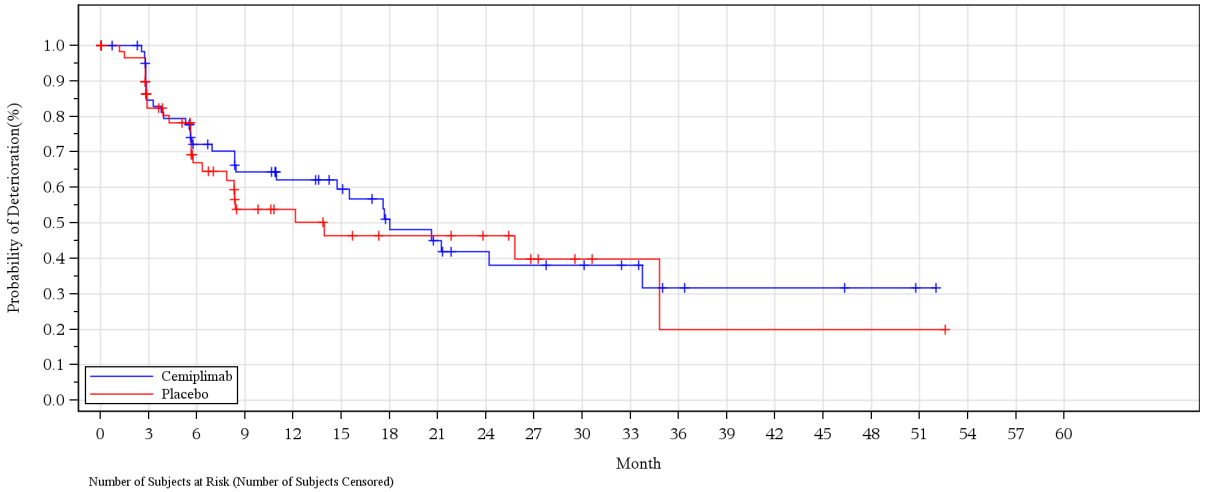
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	49 (15)	38 (19)	32 (21)	27 (25)	23 (28)	17 (31)	14 (32)	11 (34)	10 (34)	9 (35)	7 (37)	4 (39)	3 (40)	3 (40)	3 (40)	2 (41)	1 (42)	0 (43)	0 (43)	0 (43)
Placebo	72 (0)	42 (20)	28 (27)	18 (32)	15 (35)	12 (36)	10 (38)	10 (38)	8 (40)	5 (42)	3 (44)	2 (45)	1 (45)	1 (45)	1 (45)	1 (45)	1 (45)	1 (45)	0 (46)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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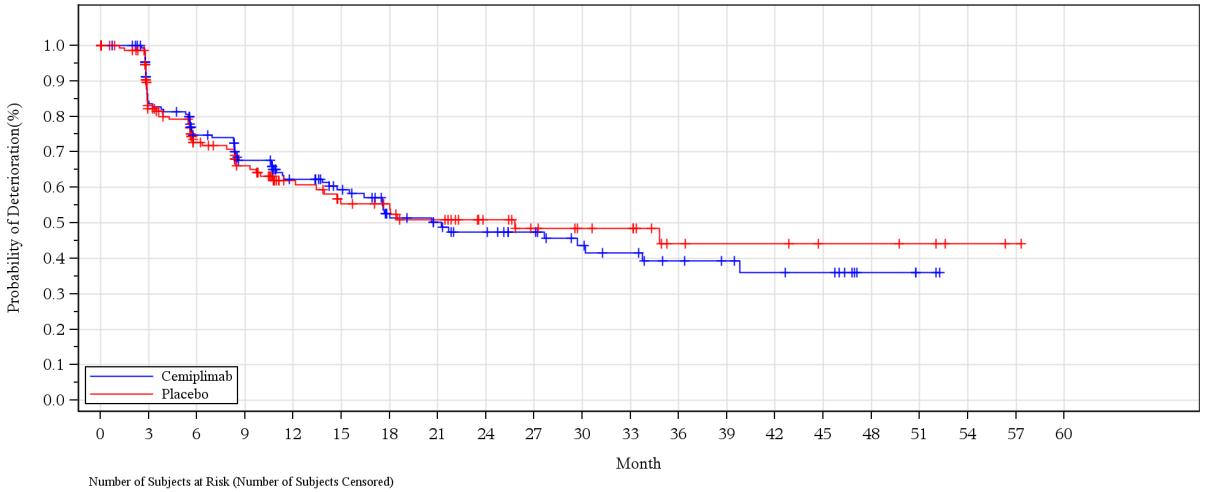
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



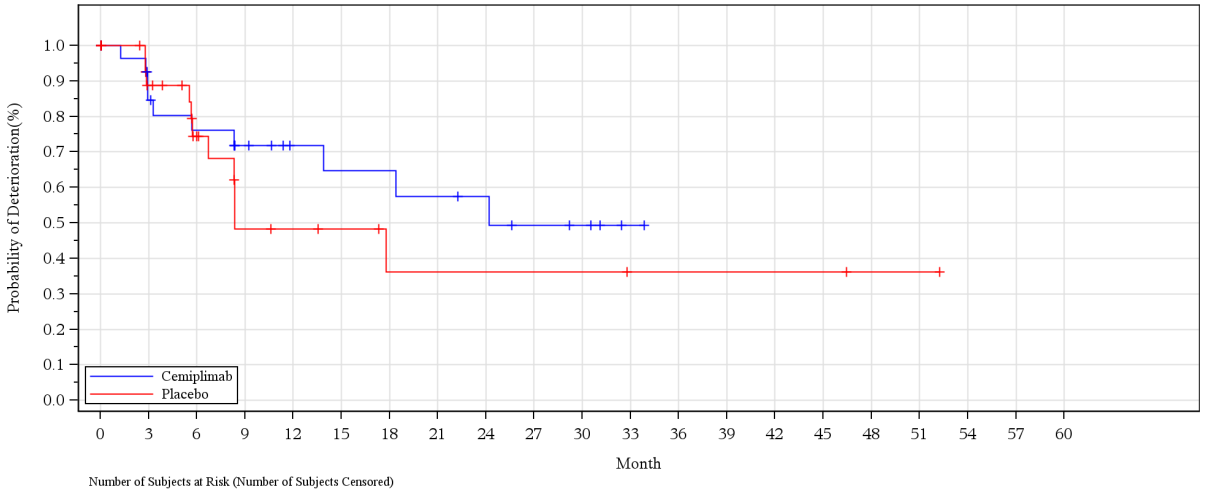
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	120 (31)	98 (40)	82 (47)	66 (57)	57 (63)	43 (71)	38 (74)	33 (77)	28 (82)	22 (86)	19 (88)	15 (91)	13 (93)	11 (94)	10 (95)	4 (101)	2 (103)	0 (105)	0 (105)	0 (105)
Placebo	174 (0)	110 (39)	82 (55)	67 (63)	48 (78)	40 (81)	37 (84)	32 (86)	24 (94)	19 (98)	16 (101)	15 (102)	8 (108)	7 (109)	7 (109)	5 (111)	5 (111)	4 (112)	2 (114)	1 (115)	0 (116)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



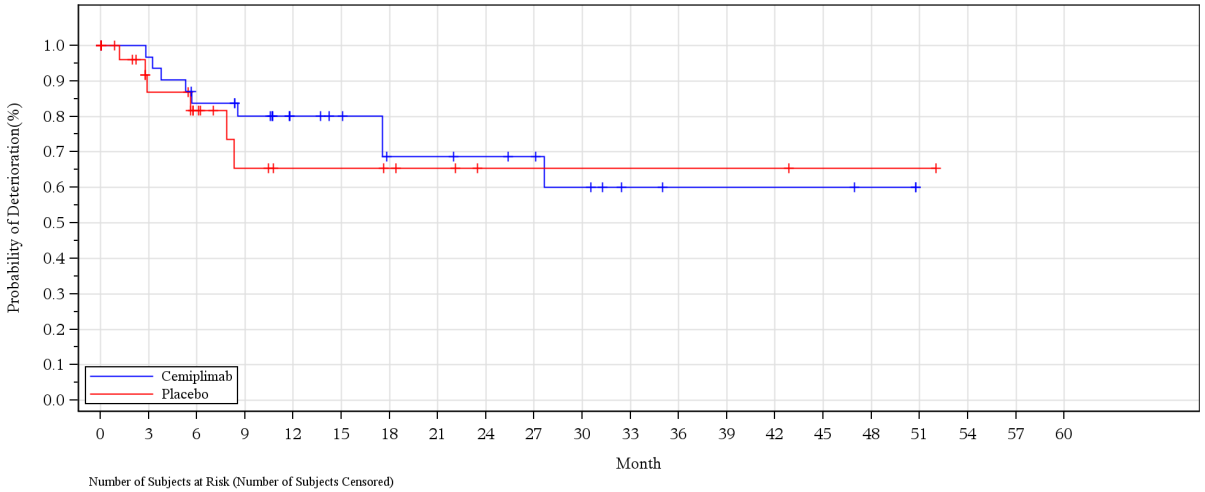
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	21 (10)	18 (11)	14 (14)	10 (18)	9 (18)	9 (18)	8 (18)	7 (19)	5 (20)	4 (21)	1 (24)	0 (25)	0 (25)	0 (25)	0 (25)	0 (25)	0 (25)	0 (25)	0 (25)
Placebo	32 (0)	22 (7)	14 (12)	7 (15)	6 (16)	5 (17)	3 (18)	3 (18)	3 (18)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	1 (20)	0 (21)	0 (21)	0 (21)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (6)	25 (7)	22 (9)	17 (14)	15 (16)	11 (18)	11 (18)	10 (19)	9 (20)	7 (21)	4 (24)	3 (25)	3 (25)	3 (25)	3 (25)	2 (26)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	31 (0)	18 (10)	13 (14)	8 (17)	6 (19)	6 (19)	5 (20)	4 (21)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)	0 (25)	0 (25)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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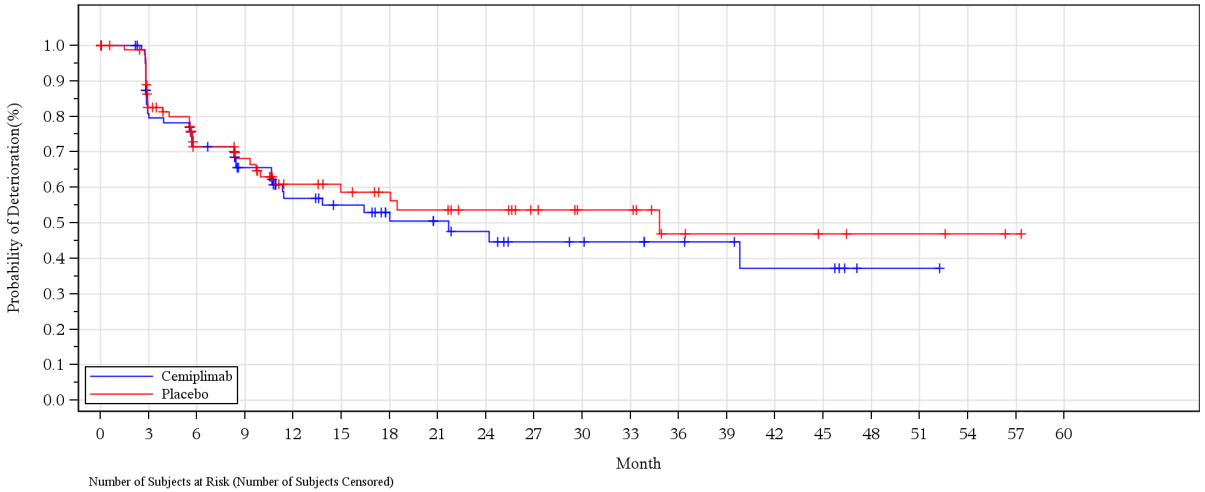
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



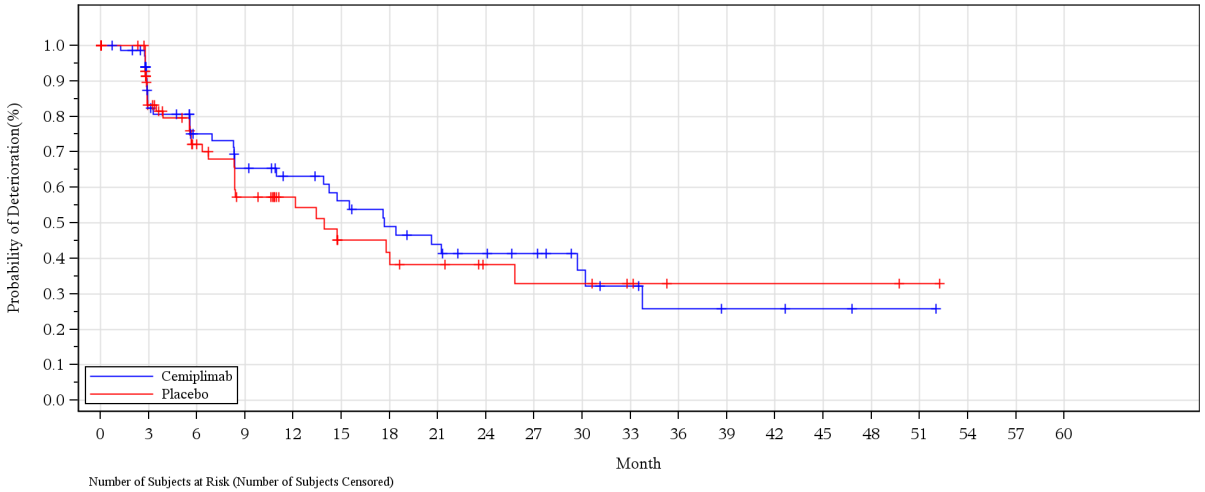
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	62 (13)	52 (16)	41 (23)	31 (28)	27 (31)	21 (36)	18 (38)	16 (39)	12 (42)	11 (43)	10 (44)	8 (46)	7 (47)	5 (48)	5 (48)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)
Placebo	90 (0)	64 (12)	47 (21)	40 (26)	29 (33)	26 (35)	23 (38)	21 (38)	18 (41)	14 (45)	11 (48)	11 (48)	6 (52)	5 (53)	5 (53)	4 (54)	3 (55)	3 (55)	2 (56)	1 (57)	0 (58)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	49 (22)	39 (28)	33 (29)	28 (33)	24 (34)	20 (35)	17 (36)	14 (38)	12 (40)	8 (43)	6 (44)	4 (45)	3 (46)	3 (46)	2 (47)	1 (48)	1 (48)	0 (49)	0 (49)	0 (49)
Placebo	85 (0)	50 (24)	36 (32)	26 (35)	19 (42)	13 (44)	12 (44)	10 (45)	7 (48)	6 (48)	6 (48)	4 (50)	2 (52)	2 (52)	2 (52)	2 (52)	2 (52)	1 (53)	0 (54)	0 (54)	0 (54)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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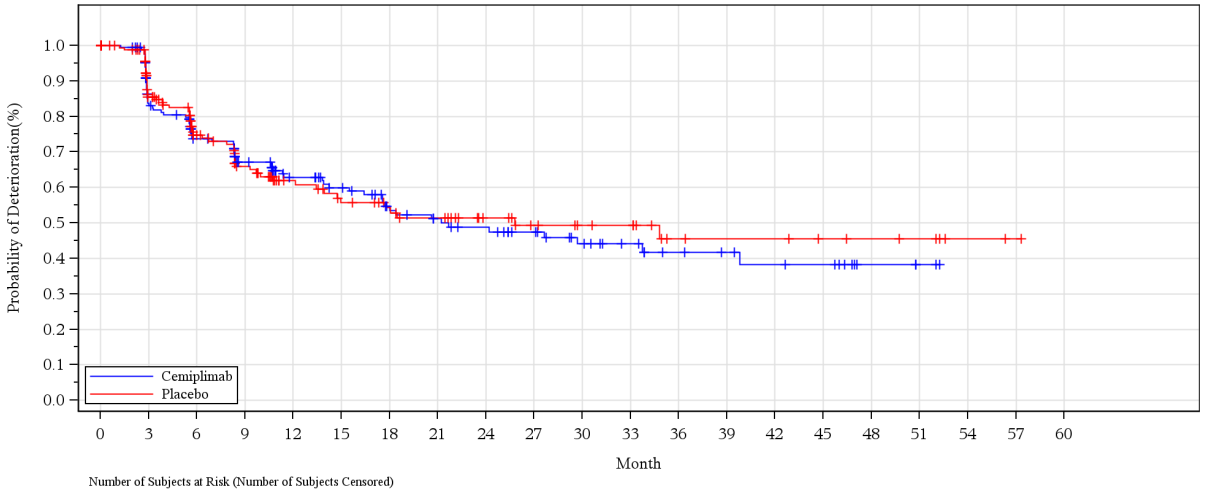
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	130 (33)	105 (43)	86 (53)	68 (66)	60 (71)	48 (78)	42 (81)	38 (83)	32 (88)	25 (93)	20 (98)	15 (102)	13 (104)	11 (105)	10 (106)	4 (112)	2 (114)	0 (116)	0 (116)	0 (116)
Placebo	189 (0)	122 (45)	90 (63)	70 (73)	51 (88)	43 (91)	38 (95)	34 (97)	26 (105)	21 (109)	18 (112)	17 (113)	10 (119)	9 (120)	9 (120)	7 (122)	6 (123)	5 (124)	2 (127)	1 (128)	0 (129)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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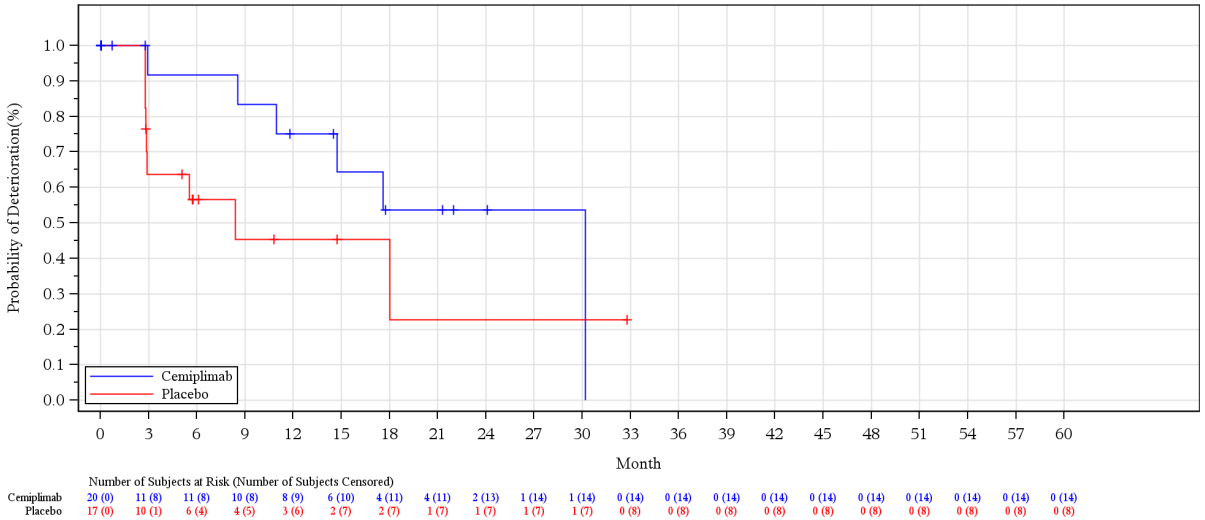
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (8)	11 (8)	10 (8)	8 (9)	6 (10)	4 (11)	4 (11)	2 (13)	1 (14)	1 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)
Placebo	17 (0)	10 (1)	6 (4)	4 (5)	3 (6)	2 (7)	2 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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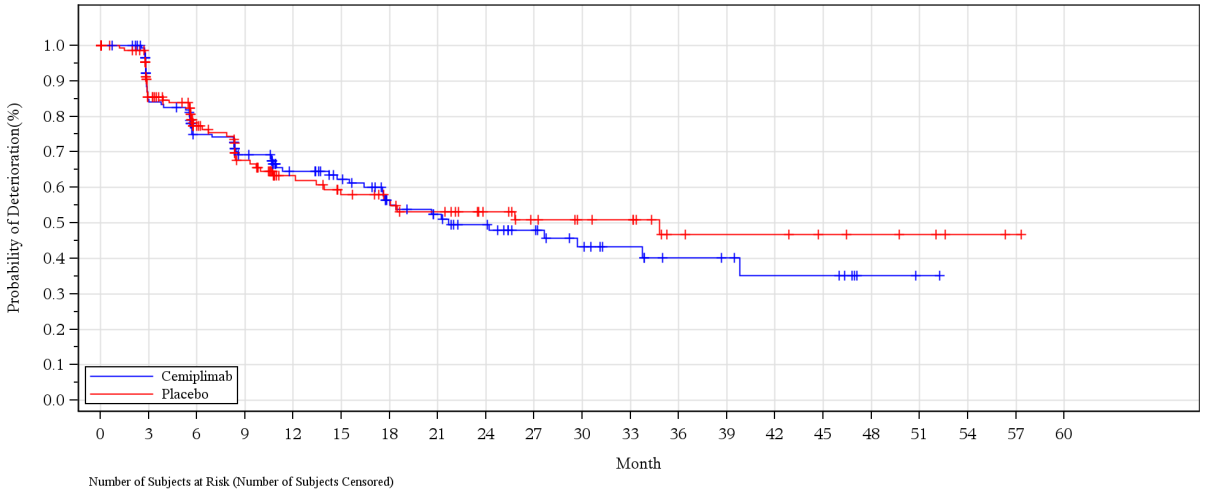
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	115 (30)	95 (37)	80 (45)	64 (56)	56 (62)	43 (70)	37 (73)	31 (77)	24 (83)	18 (87)	14 (91)	10 (94)	9 (95)	7 (96)	7 (96)	2 (101)	1 (102)	0 (103)	0 (103)	0 (103)
Placebo	177 (0)	117 (39)	86 (60)	66 (70)	48 (84)	41 (87)	36 (91)	32 (93)	25 (100)	20 (104)	17 (107)	16 (108)	9 (114)	8 (115)	8 (115)	6 (117)	5 (118)	4 (119)	2 (121)	1 (122)	0 (123)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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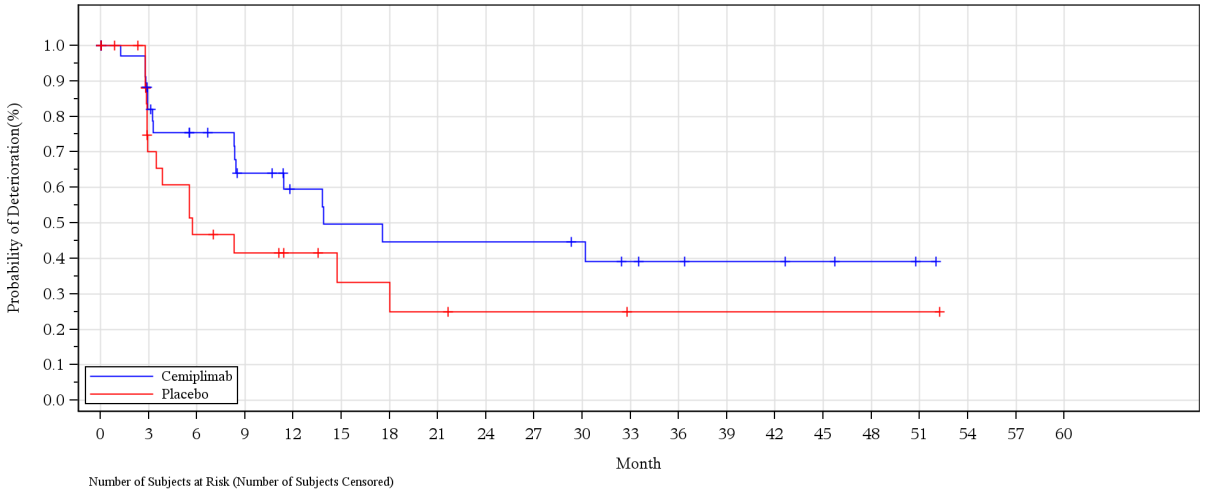
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	26 (11)	21 (14)	16 (16)	12 (19)	10 (19)	9 (19)	9 (19)	9 (19)	9 (19)	8 (20)	6 (21)	5 (22)	4 (23)	4 (23)	3 (24)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	29 (0)	15 (7)	10 (7)	8 (8)	6 (10)	4 (11)	4 (11)	3 (11)	2 (12)	2 (12)	2 (12)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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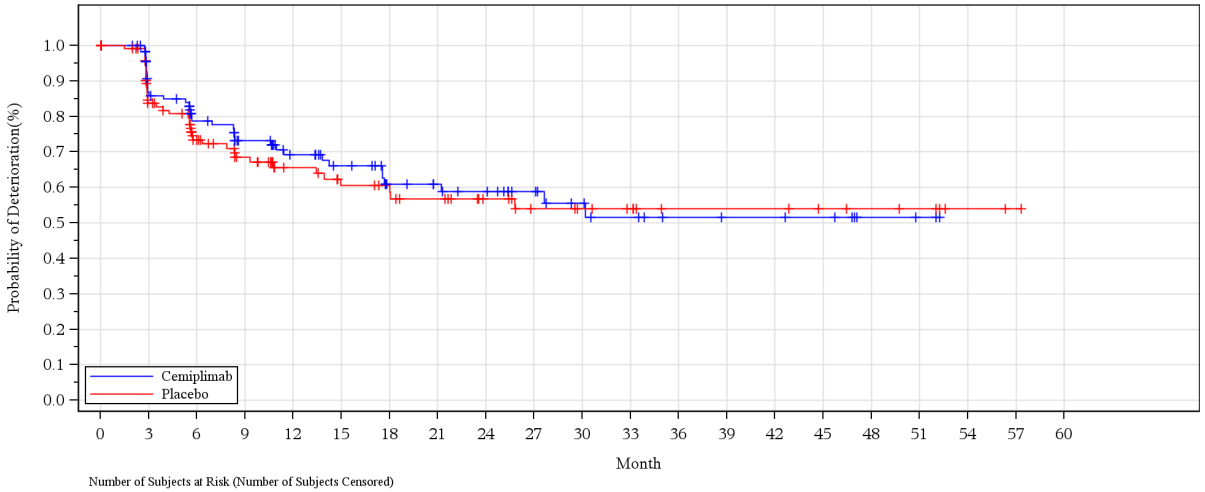
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	90 (29)	73 (38)	61 (45)	49 (54)	42 (59)	32 (66)	29 (69)	26 (71)	20 (77)	15 (81)	12 (83)	9 (86)	8 (87)	8 (87)	7 (88)	3 (92)	2 (93)	0 (95)	0 (95)	0 (95)
Placebo	131 (0)	88 (25)	65 (38)	52 (47)	40 (57)	34 (60)	32 (62)	28 (64)	22 (70)	17 (74)	15 (76)	13 (78)	9 (82)	9 (82)	9 (82)	7 (84)	6 (85)	5 (86)	2 (89)	1 (90)	0 (91)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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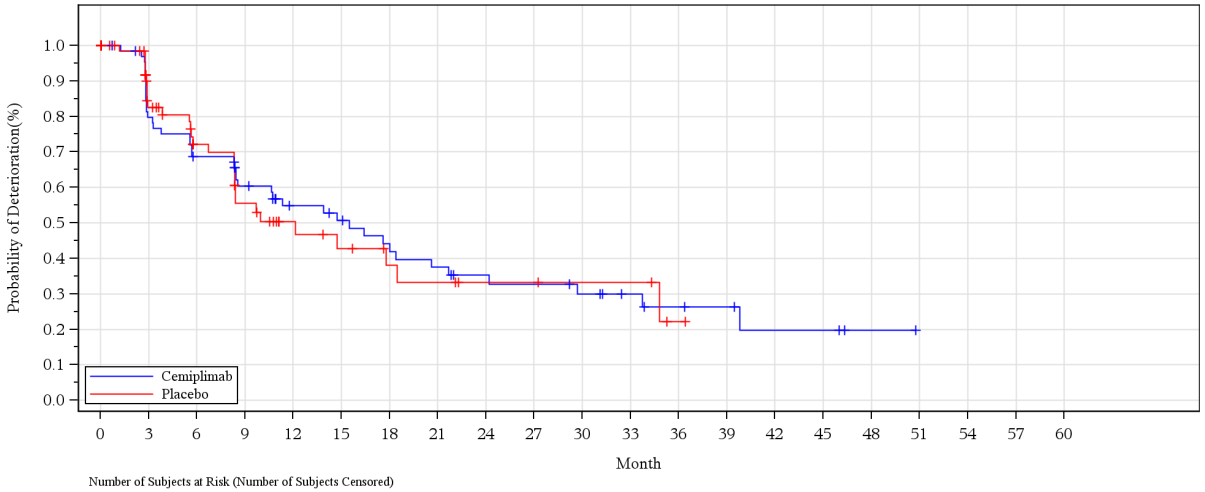
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	51 (12)	43 (13)	35 (16)	27 (21)	24 (22)	20 (23)	17 (23)	14 (25)	13 (25)	11 (26)	8 (29)	6 (30)	5 (31)	3 (32)	3 (32)	1 (34)	0 (35)	0 (35)	0 (35)	0 (35)
Placebo	75 (0)	44 (21)	31 (29)	22 (31)	14 (37)	11 (38)	8 (40)	7 (40)	5 (42)	5 (42)	4 (43)	4 (43)	1 (45)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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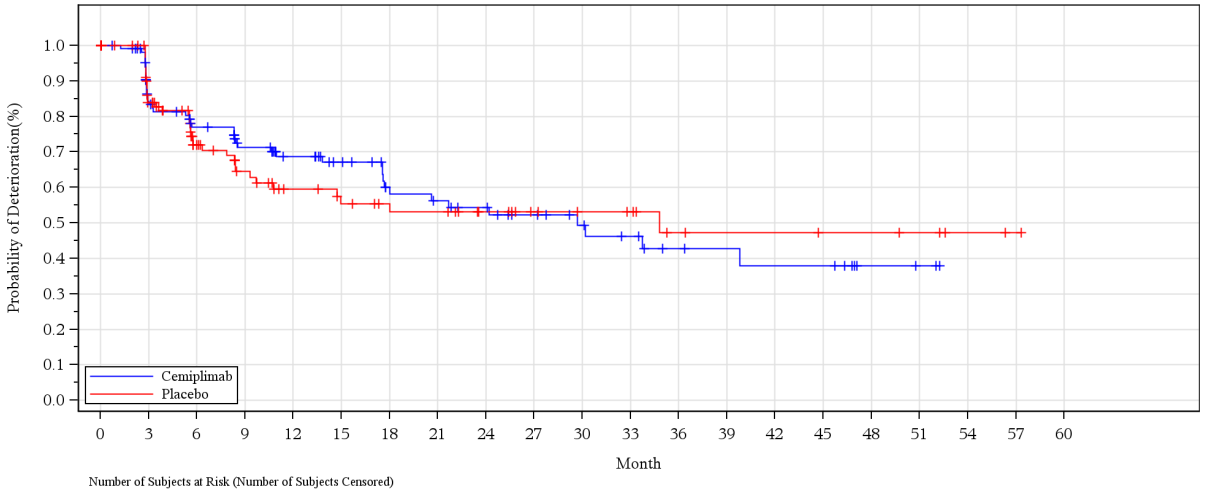
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	83 (26)	71 (31)	59 (38)	49 (46)	42 (52)	32 (58)	29 (59)	26 (61)	21 (65)	17 (68)	14 (70)	10 (73)	9 (74)	8 (74)	8 (74)	3 (79)	2 (80)	0 (82)	0 (82)	0 (82)
Placebo	117 (0)	80 (21)	54 (37)	40 (46)	31 (52)	27 (54)	24 (57)	23 (57)	18 (62)	14 (66)	12 (68)	11 (69)	7 (72)	6 (73)	6 (73)	5 (74)	5 (74)	4 (75)	2 (77)	1 (78)	0 (79)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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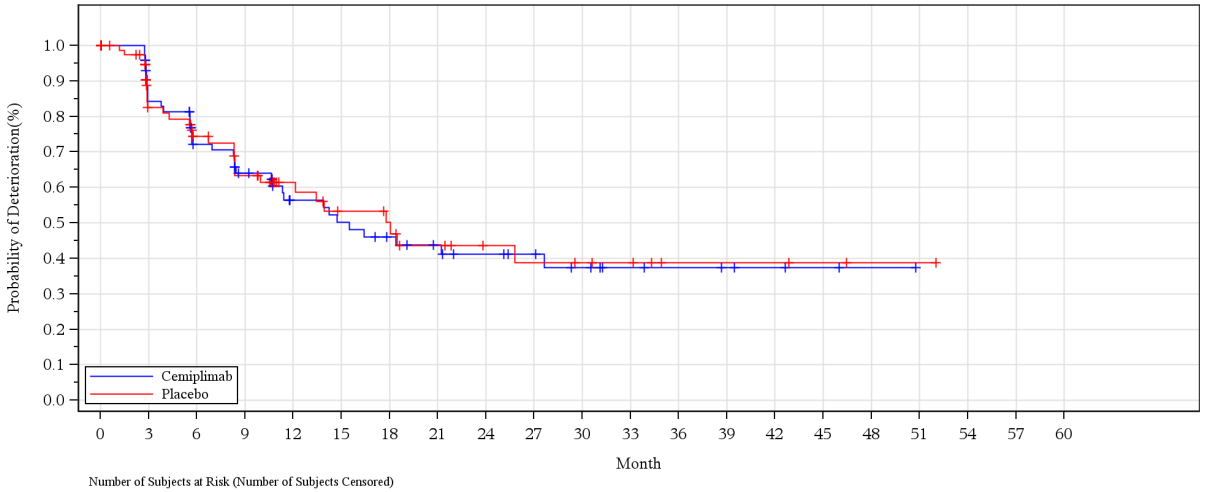
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



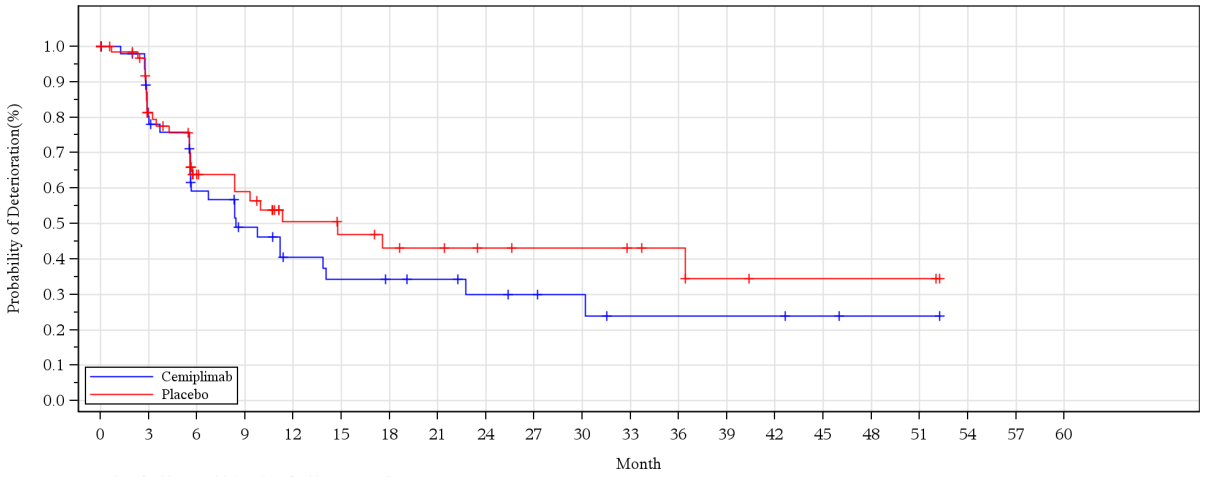
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	58 (15)	45 (20)	37 (23)	27 (29)	24 (29)	20 (31)	17 (33)	14 (35)	12 (37)	9 (39)	6 (42)	5 (43)	4 (44)	3 (45)	2 (46)	1 (47)	0 (48)	0 (48)	0 (48)
Placebo	89 (0)	52 (25)	42 (30)	34 (32)	23 (42)	18 (44)	16 (45)	12 (47)	9 (50)	8 (50)	7 (51)	6 (52)	3 (55)	3 (55)	3 (55)	2 (56)	1 (57)	1 (57)	0 (58)	0 (58)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



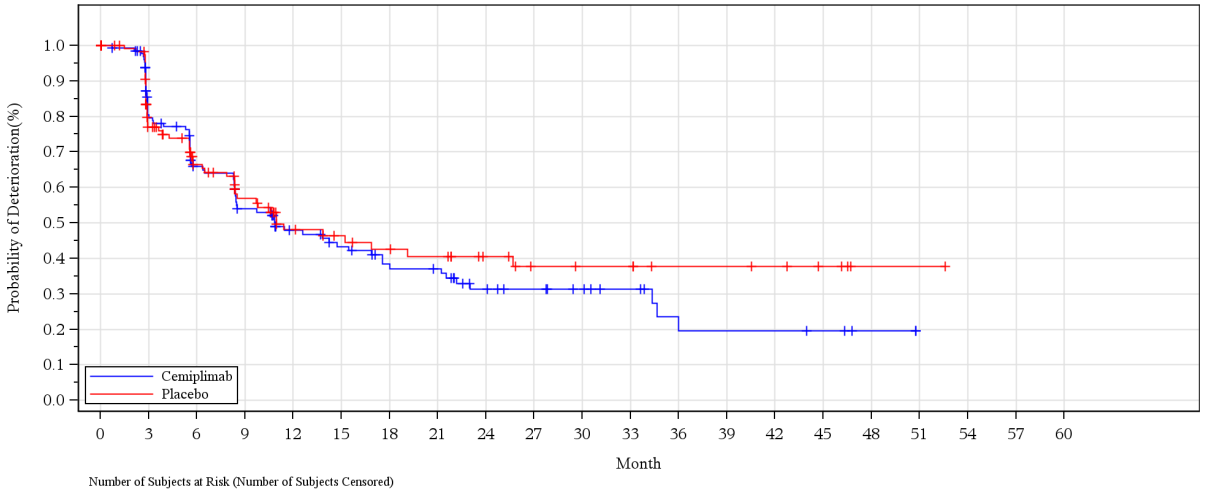
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	36 (11)	24 (14)	18 (16)	13 (18)	11 (18)	10 (19)	9 (20)	7 (21)	6 (22)	5 (23)	3 (24)	3 (24)	3 (24)	3 (24)	2 (25)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	44 (10)	28 (17)	24 (19)	15 (25)	13 (26)	11 (27)	10 (28)	8 (30)	7 (31)	7 (31)	6 (32)	5 (33)	3 (34)	2 (35)	2 (35)	2 (35)	2 (35)	0 (37)	0 (37)	0 (37)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



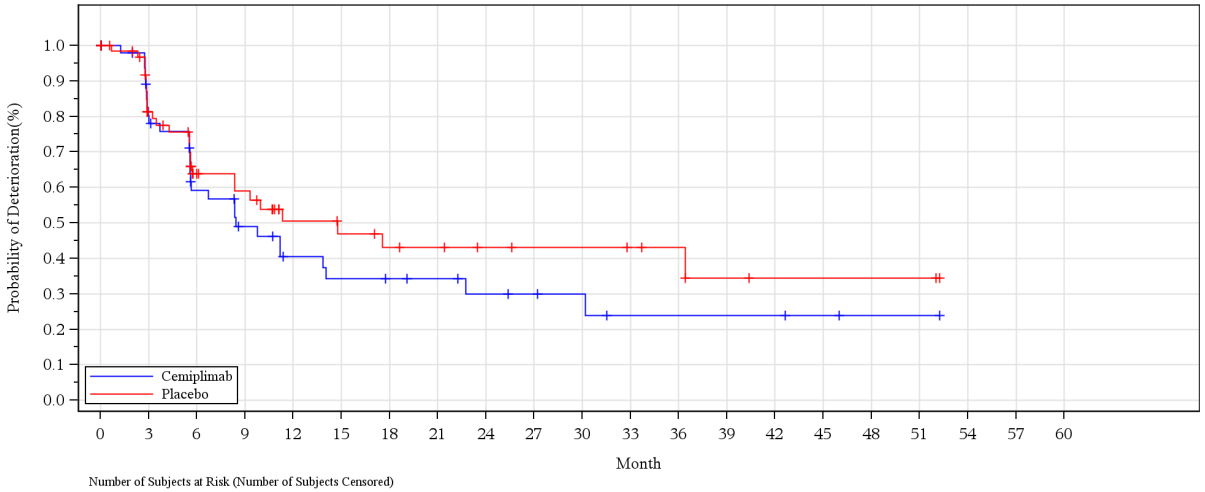
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	96 (33)	73 (39)	57 (42)	43 (50)	37 (52)	30 (55)	28 (56)	19 (61)	16 (64)	13 (67)	10 (70)	5 (72)	5 (72)	5 (72)	4 (73)	2 (75)	0 (77)	0 (77)	0 (77)	0 (77)
Placebo	141 (0)	81 (34)	59 (46)	44 (53)	29 (62)	25 (65)	22 (66)	20 (67)	15 (72)	11 (75)	10 (76)	10 (76)	7 (79)	7 (79)	6 (80)	4 (82)	1 (85)	1 (85)	0 (86)	0 (86)	0 (86)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



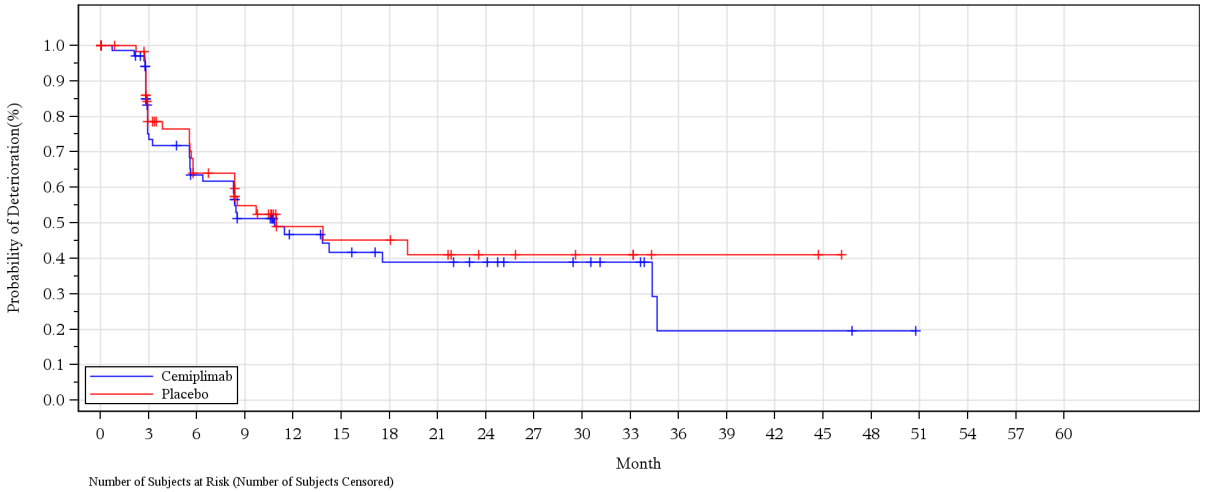
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	36 (11)	24 (14)	18 (16)	13 (18)	11 (18)	10 (19)	9 (20)	7 (21)	6 (22)	5 (23)	3 (24)	3 (24)	3 (24)	3 (24)	2 (25)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	44 (10)	28 (17)	24 (19)	15 (25)	13 (26)	11 (27)	10 (28)	8 (30)	7 (31)	7 (31)	6 (32)	5 (33)	3 (34)	2 (35)	2 (35)	2 (35)	2 (35)	0 (37)	0 (37)	0 (37)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



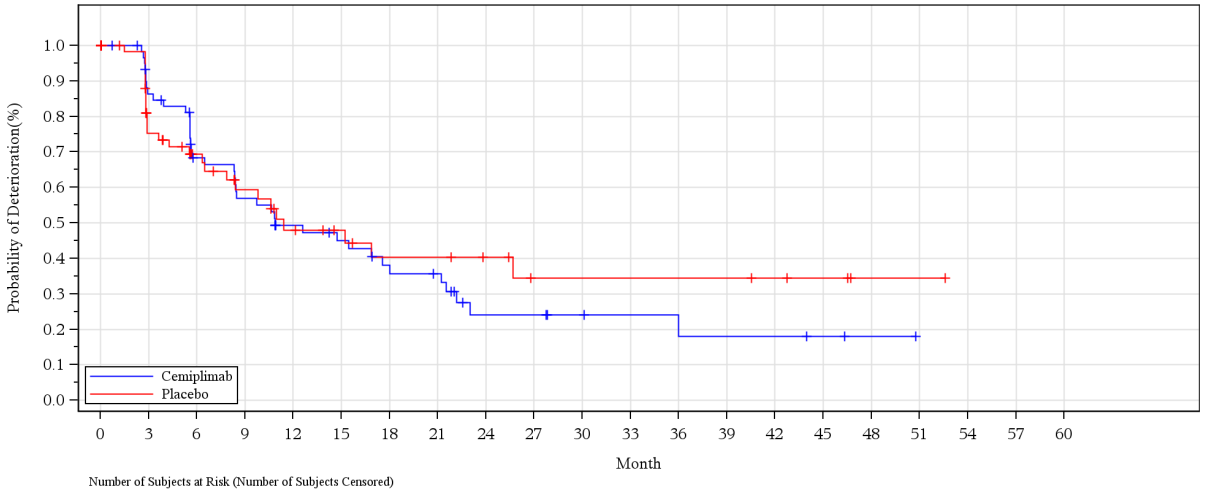
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	46 (18)	37 (20)	27 (23)	20 (28)	17 (29)	14 (31)	14 (31)	12 (33)	9 (36)	8 (37)	6 (39)	2 (41)	2 (41)	2 (41)	2 (41)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	69 (0)	41 (16)	30 (20)	22 (24)	13 (31)	12 (31)	12 (31)	10 (32)	7 (35)	6 (36)	5 (37)	5 (37)	2 (40)	2 (40)	2 (40)	1 (41)	0 (42)	0 (42)	0 (42)	0 (42)	0 (42)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



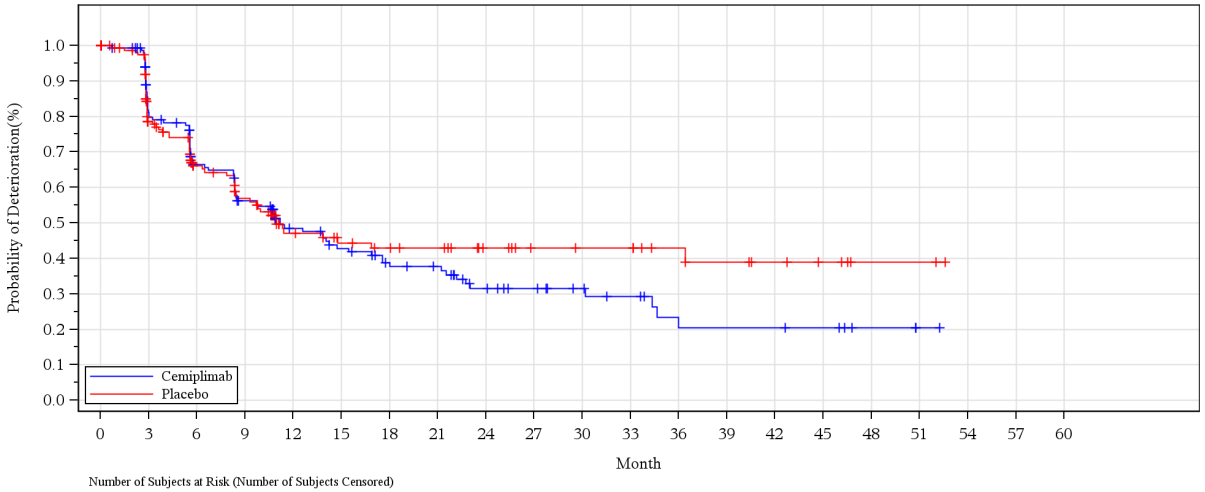
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	50 (15)	36 (19)	30 (19)	23 (22)	20 (23)	16 (24)	14 (25)	7 (28)	7 (28)	5 (30)	4 (31)	3 (31)	3 (31)	3 (31)	2 (32)	1 (33)	0 (34)	0 (34)	0 (34)	0 (34)
Placebo	72 (0)	40 (18)	29 (26)	22 (29)	16 (31)	13 (34)	10 (35)	10 (35)	8 (37)	5 (39)	5 (39)	5 (39)	5 (39)	5 (39)	4 (40)	3 (41)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



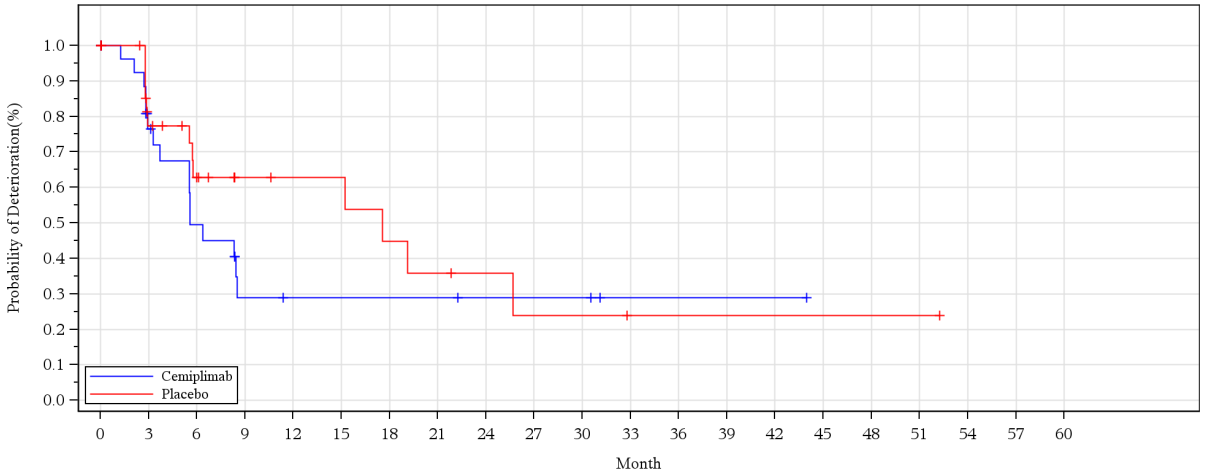
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	114 (33)	86 (41)	70 (44)	52 (53)	44 (55)	36 (59)	33 (61)	23 (66)	19 (70)	15 (74)	12 (76)	7 (78)	7 (78)	7 (78)	6 (79)	3 (82)	1 (84)	0 (85)	0 (85)	0 (85)
Placebo	174 (0)	106 (37)	74 (53)	60 (57)	37 (71)	31 (75)	28 (77)	26 (79)	20 (85)	16 (89)	15 (90)	15 (90)	11 (94)	9 (95)	7 (97)	5 (99)	2 (102)	2 (102)	0 (104)	0 (104)	0 (104)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



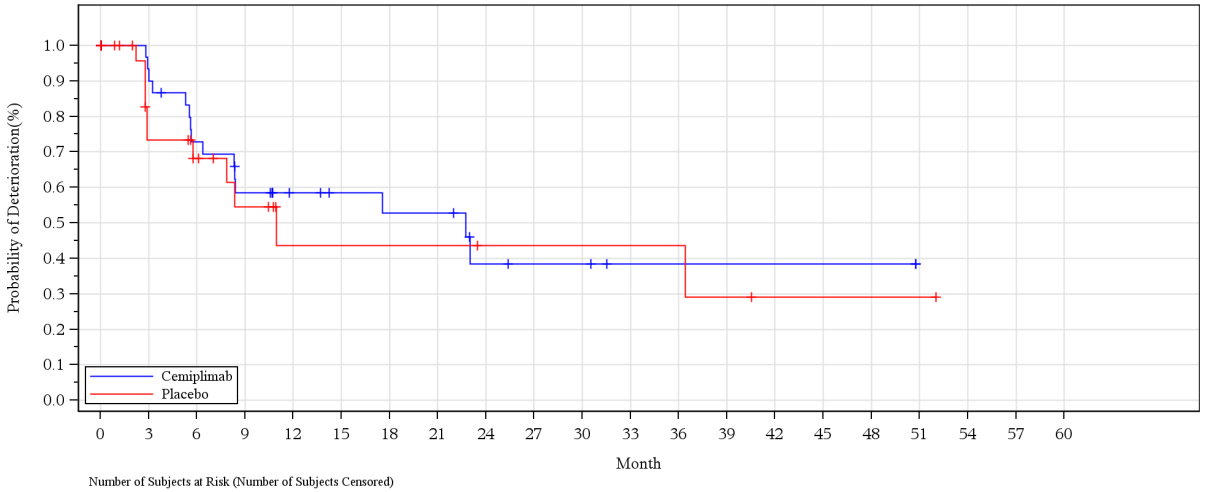
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	18 (11)	11 (12)	5 (14)	4 (15)	4 (15)	4 (15)	4 (15)	3 (16)	3 (16)	3 (16)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	32 (0)	19 (7)	13 (10)	8 (15)	7 (16)	7 (16)	5 (16)	4 (16)	3 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



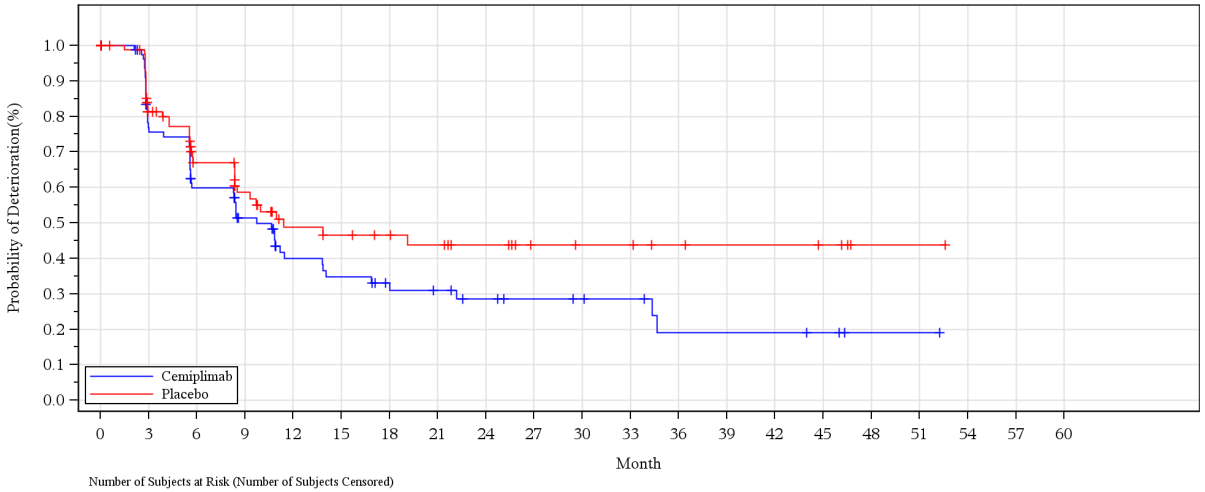
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	28 (7)	21 (8)	16 (9)	12 (13)	10 (15)	9 (15)	9 (15)	5 (17)	4 (18)	4 (18)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	0 (22)	0 (22)	0 (22)	0 (22)
Placebo	31 (0)	16 (9)	12 (12)	8 (14)	4 (17)	4 (17)	4 (17)	4 (17)	3 (18)	3 (18)	3 (18)	3 (18)	3 (18)	2 (18)	1 (19)	1 (19)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	59 (13)	44 (15)	34 (19)	23 (23)	20 (23)	16 (26)	14 (27)	11 (29)	9 (31)	8 (32)	7 (33)	4 (34)	4 (34)	4 (34)	3 (35)	1 (37)	1 (37)	0 (38)	0 (38)	0 (38)
Placebo	90 (0)	61 (14)	42 (23)	33 (27)	22 (33)	20 (34)	18 (36)	16 (37)	13 (40)	9 (44)	8 (45)	8 (45)	6 (47)	5 (48)	5 (48)	4 (49)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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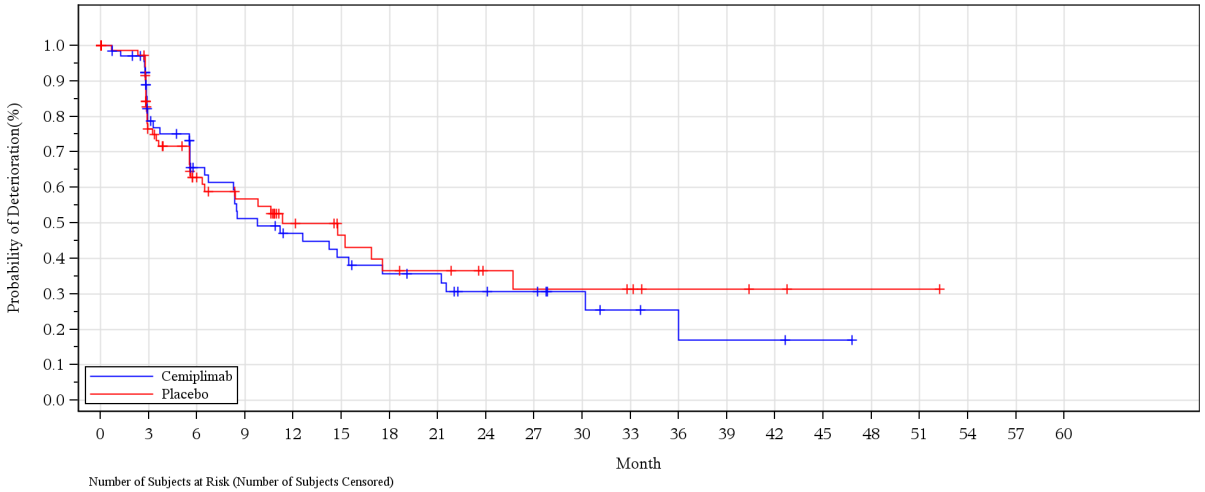
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	45 (24)	32 (30)	25 (30)	21 (32)	18 (32)	15 (33)	14 (34)	10 (36)	9 (37)	6 (40)	4 (41)	2 (42)	2 (42)	2 (42)	1 (43)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)
Placebo	85 (0)	48 (21)	33 (28)	27 (31)	18 (37)	14 (40)	11 (40)	10 (41)	7 (44)	6 (44)	6 (44)	5 (45)	3 (47)	3 (47)	2 (48)	1 (49)	1 (49)	1 (49)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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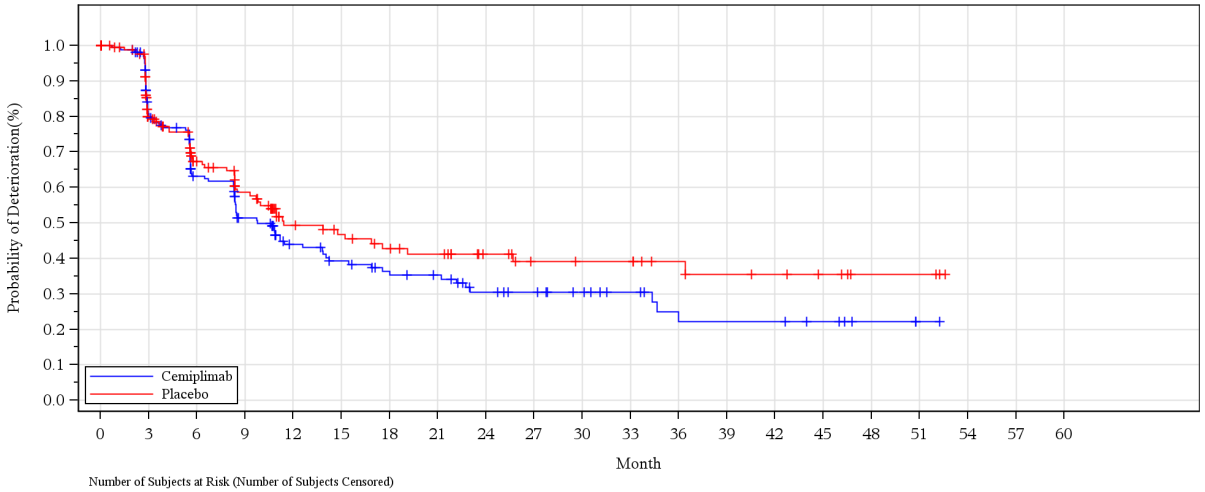
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	123 (36)	88 (45)	67 (50)	48 (60)	41 (62)	35 (65)	32 (67)	24 (71)	21 (74)	17 (78)	13 (82)	8 (84)	8 (84)	8 (84)	6 (86)	3 (89)	1 (91)	0 (92)	0 (92)	0 (92)
Placebo	189 (0)	115 (43)	82 (59)	64 (67)	41 (81)	36 (84)	31 (86)	28 (88)	21 (95)	16 (99)	15 (100)	15 (100)	11 (104)	9 (105)	8 (106)	6 (108)	3 (111)	3 (111)	0 (114)	0 (114)	0 (114)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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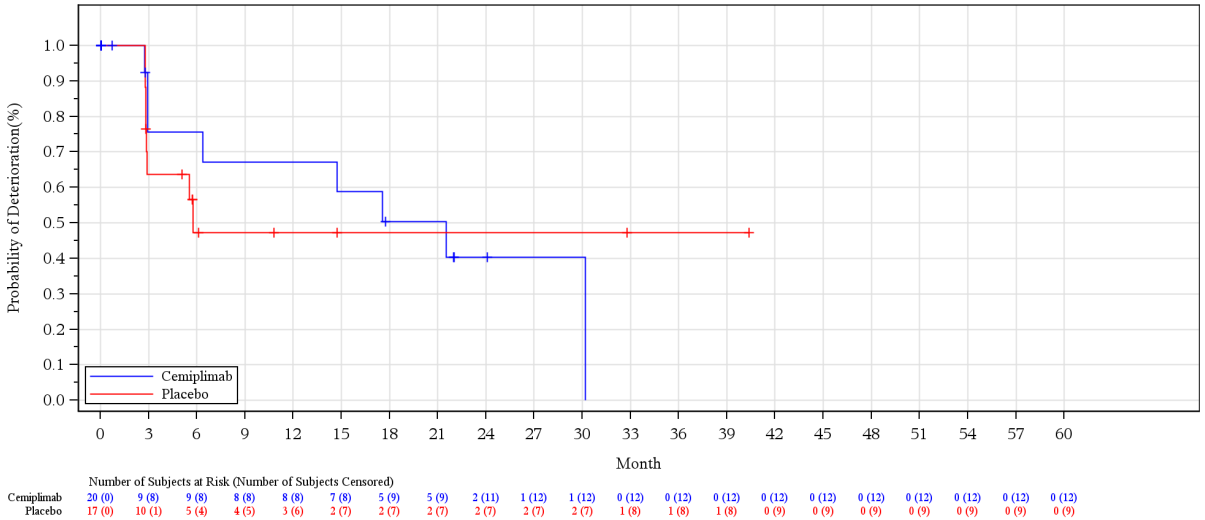
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



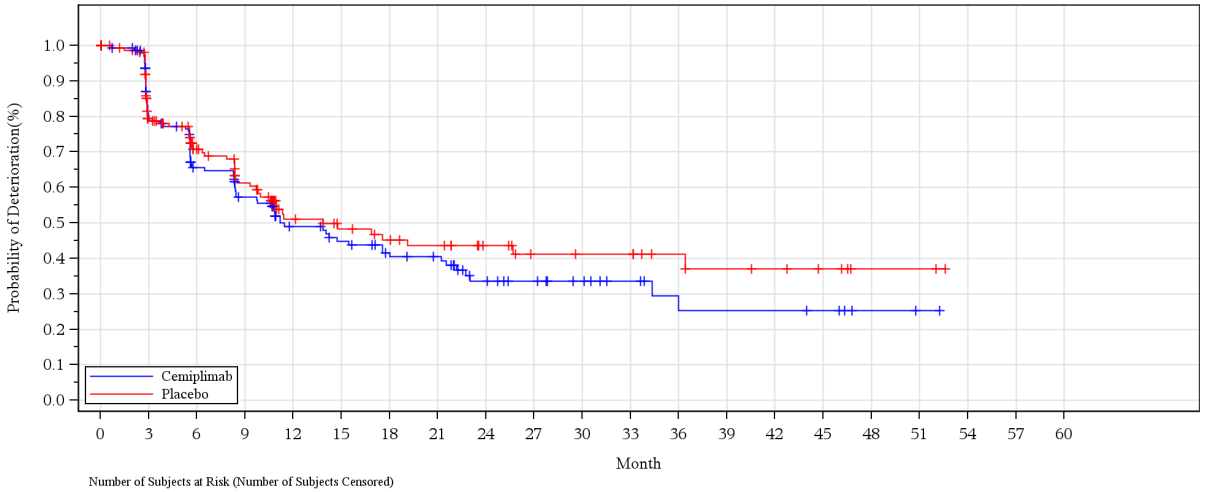
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (8)	9 (8)	8 (8)	8 (8)	7 (8)	5 (9)	5 (9)	2 (11)	1 (12)	1 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)
Placebo	17 (0)	10 (1)	5 (4)	4 (5)	3 (6)	2 (7)	2 (7)	2 (7)	2 (7)	2 (7)	2 (7)	1 (8)	1 (8)	1 (8)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	107 (32)	81 (39)	67 (43)	49 (52)	43 (54)	36 (58)	33 (60)	22 (66)	18 (70)	14 (74)	10 (78)	6 (80)	6 (80)	6 (80)	5 (81)	2 (84)	1 (85)	0 (86)	0 (86)	0 (86)
Placebo	177 (0)	109 (38)	80 (56)	62 (64)	39 (78)	33 (82)	29 (84)	26 (86)	20 (92)	15 (96)	14 (97)	14 (97)	10 (101)	8 (102)	7 (103)	5 (105)	2 (108)	2 (108)	0 (110)	0 (110)	0 (110)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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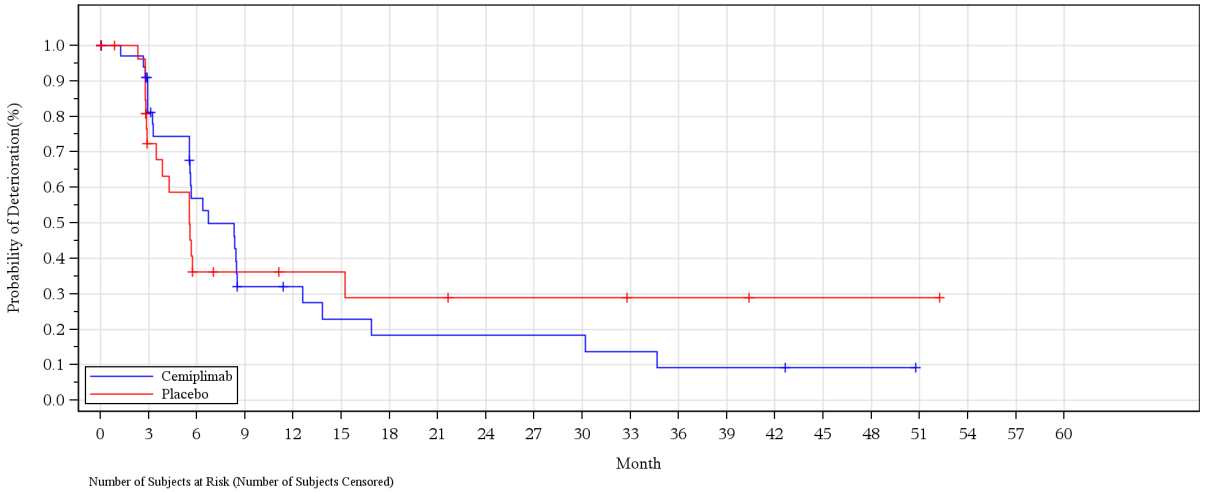
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



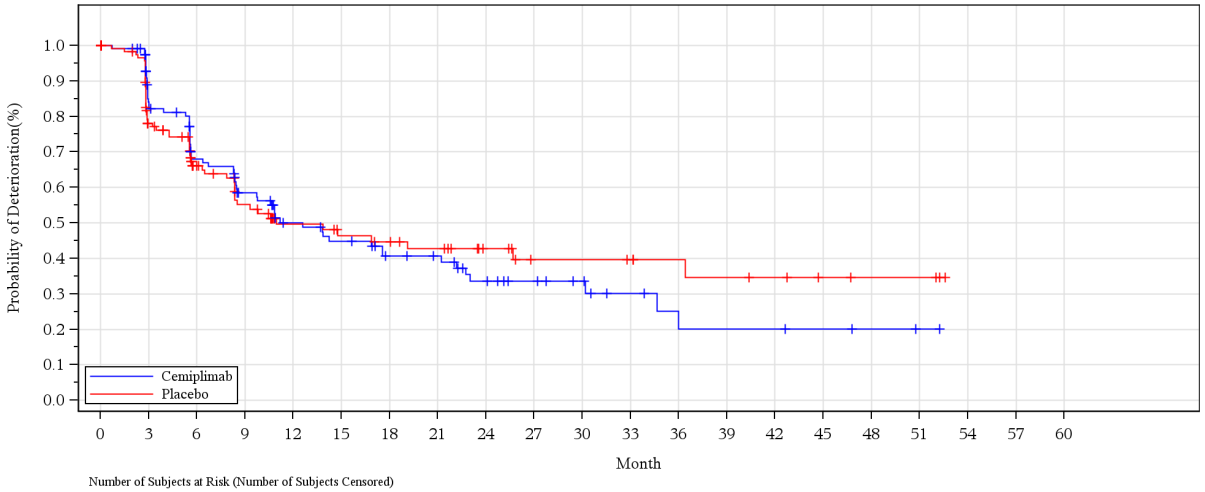
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	25 (12)	16 (14)	8 (15)	7 (16)	5 (16)	4 (16)	4 (16)	4 (16)	4 (16)	4 (16)	3 (16)	2 (16)	2 (16)	2 (16)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	29 (0)	16 (6)	7 (7)	6 (8)	5 (9)	5 (9)	4 (9)	4 (9)	3 (10)	3 (10)	3 (10)	2 (11)	2 (11)	2 (11)	1 (12)	1 (12)	1 (12)	1 (12)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



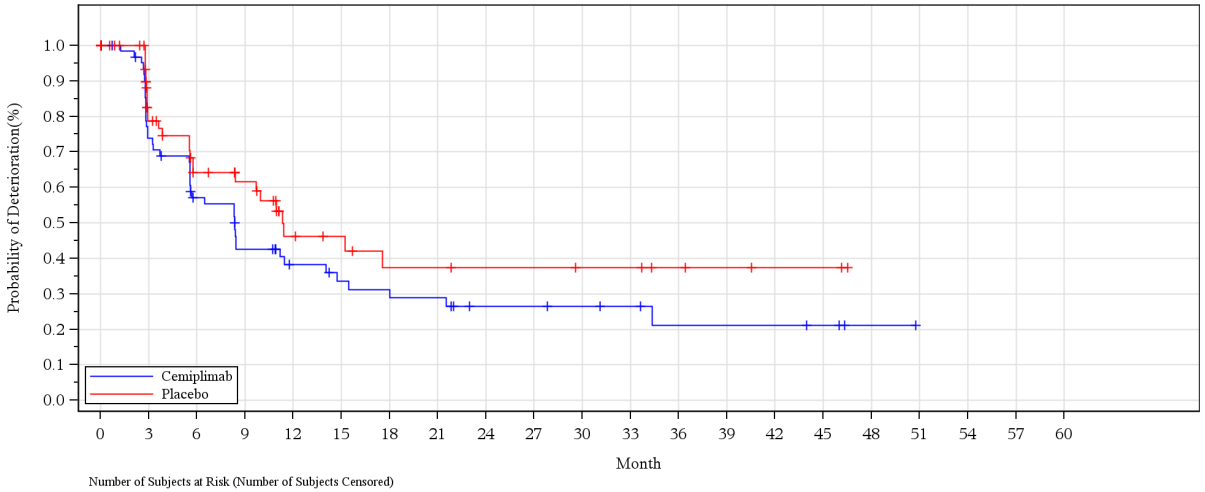
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	87 (29)	65 (35)	52 (39)	39 (45)	34 (46)	27 (50)	25 (52)	18 (55)	14 (59)	11 (62)	7 (65)	4 (66)	4 (66)	4 (66)	3 (67)	2 (68)	1 (69)	0 (70)	0 (70)	0 (70)
Placebo	131 (0)	84 (22)	58 (36)	44 (41)	31 (50)	27 (52)	25 (53)	22 (55)	16 (61)	11 (65)	11 (65)	10 (66)	8 (68)	7 (68)	6 (69)	4 (71)	3 (72)	3 (72)	0 (75)	0 (75)	0 (75)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	45 (15)	32 (18)	23 (19)	17 (23)	14 (24)	13 (24)	12 (24)	8 (27)	8 (27)	7 (28)	6 (29)	4 (30)	4 (30)	4 (30)	3 (31)	1 (33)	0 (34)	0 (34)	0 (34)	0 (34)
Placebo	75 (0)	41 (22)	29 (27)	24 (31)	13 (37)	11 (39)	8 (40)	8 (40)	7 (41)	7 (41)	6 (42)	6 (42)	4 (44)	3 (45)	2 (46)	2 (46)	0 (48)	0 (48)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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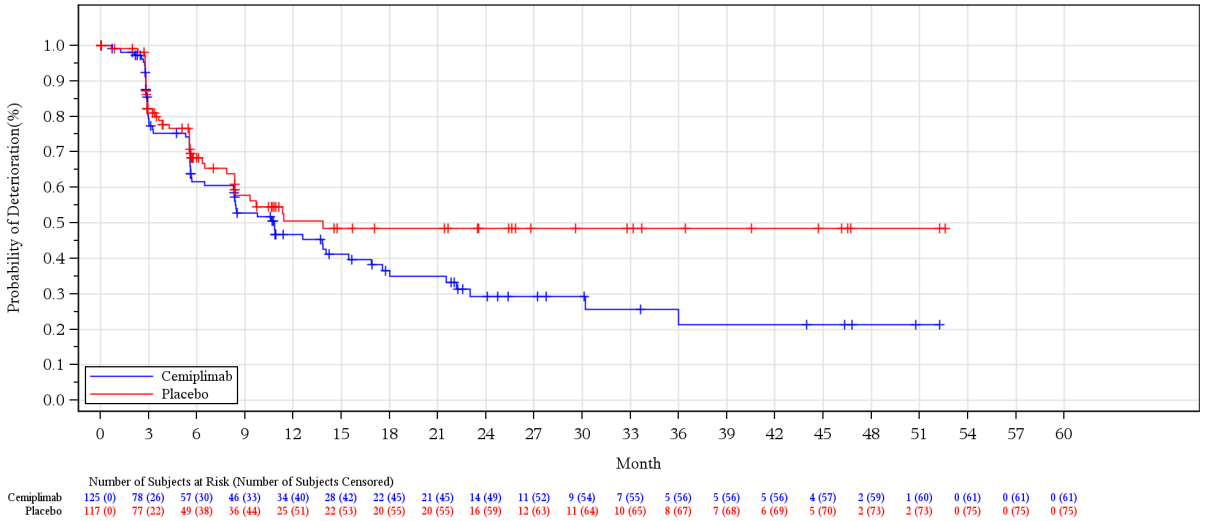
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	78 (26)	57 (30)	46 (33)	34 (40)	28 (42)	22 (45)	21 (45)	14 (49)	11 (52)	9 (54)	7 (55)	5 (56)	5 (56)	5 (56)	4 (57)	2 (59)	1 (60)	0 (61)	0 (61)	0 (61)
Placebo	117 (0)	77 (22)	49 (38)	36 (44)	25 (51)	22 (53)	20 (55)	20 (55)	16 (59)	12 (63)	11 (64)	10 (65)	8 (67)	7 (68)	6 (69)	5 (70)	2 (73)	2 (73)	0 (75)	0 (75)	0 (75)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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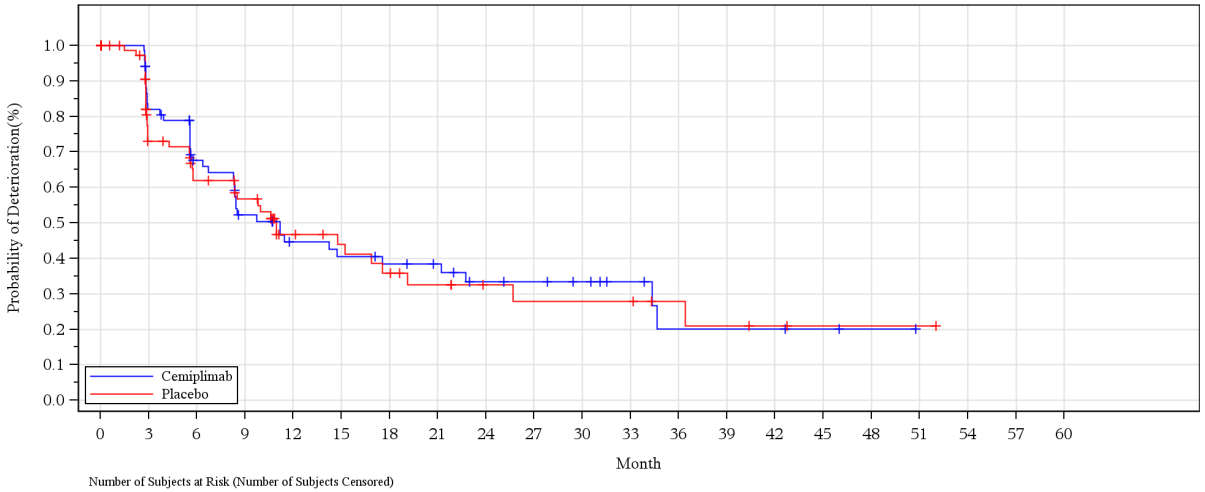
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



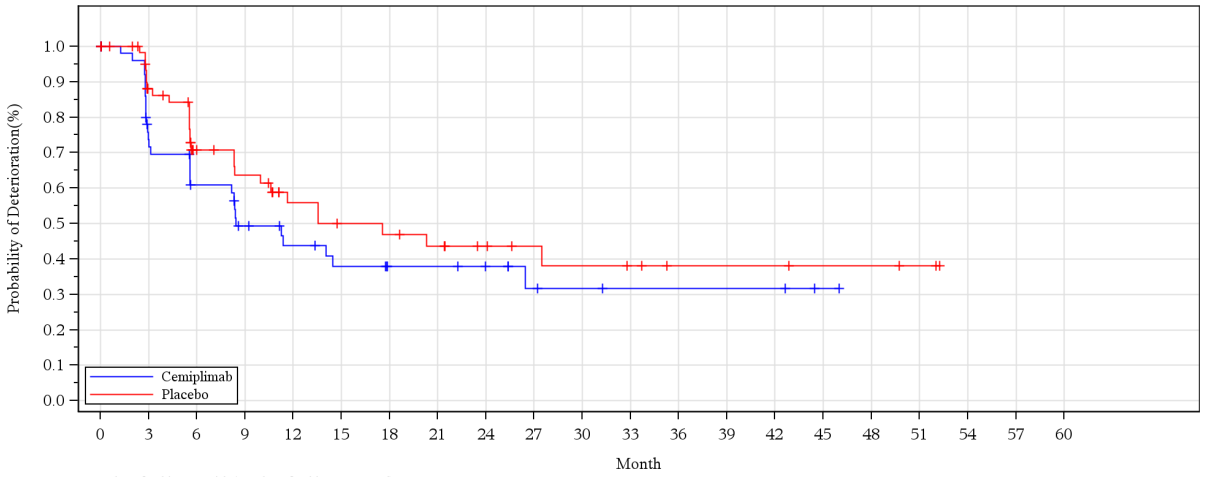
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	54 (18)	40 (23)	29 (25)	22 (28)	20 (28)	18 (29)	16 (31)	12 (33)	11 (34)	9 (36)	6 (39)	3 (40)	3 (40)	3 (40)	2 (41)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	89 (0)	48 (22)	38 (25)	32 (28)	19 (36)	16 (38)	13 (38)	10 (40)	7 (43)	6 (43)	6 (43)	6 (43)	4 (45)	3 (45)	2 (46)	1 (47)	1 (47)	1 (47)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



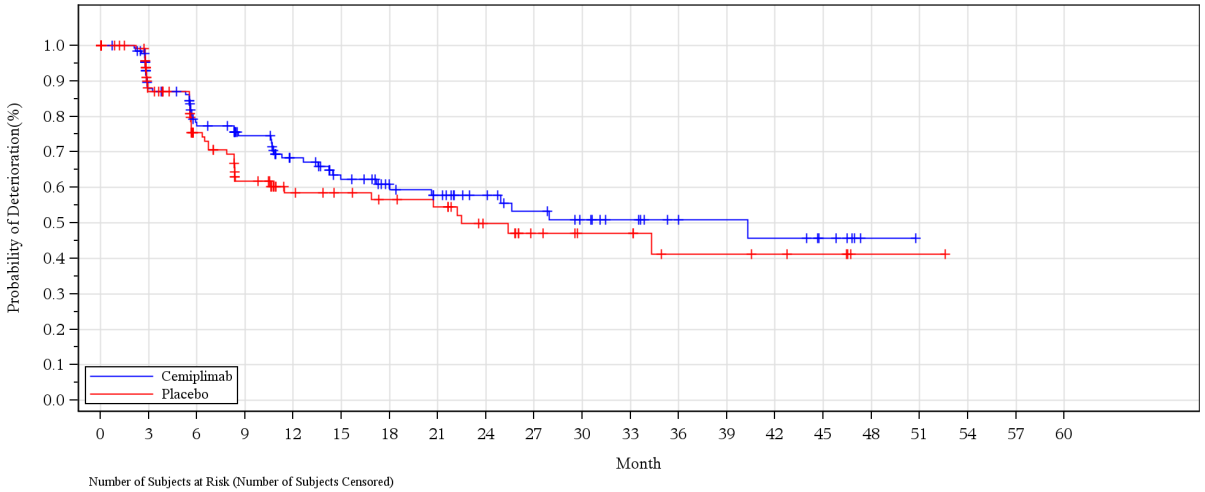
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	35 (8)	27 (10)	20 (12)	16 (14)	13 (15)	10 (18)	10 (18)	8 (20)	5 (22)	4 (23)	3 (24)	3 (24)	3 (24)	3 (24)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	48 (10)	32 (17)	27 (19)	19 (24)	16 (25)	15 (25)	13 (26)	10 (29)	8 (31)	7 (31)	6 (32)	4 (34)	4 (34)	4 (34)	3 (35)	3 (35)	2 (36)	0 (38)	0 (38)	0 (38)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	105 (33)	86 (40)	74 (49)	60 (57)	49 (63)	40 (71)	35 (74)	28 (81)	23 (84)	19 (87)	15 (91)	10 (96)	10 (96)	9 (96)	6 (99)	1 (104)	0 (105)	0 (105)	0 (105)	0 (105)
Placebo	141 (0)	89 (38)	63 (53)	46 (59)	34 (69)	31 (72)	28 (74)	26 (75)	19 (80)	13 (85)	10 (88)	10 (88)	6 (91)	6 (91)	5 (92)	4 (93)	1 (96)	1 (96)	0 (97)	0 (97)	0 (97)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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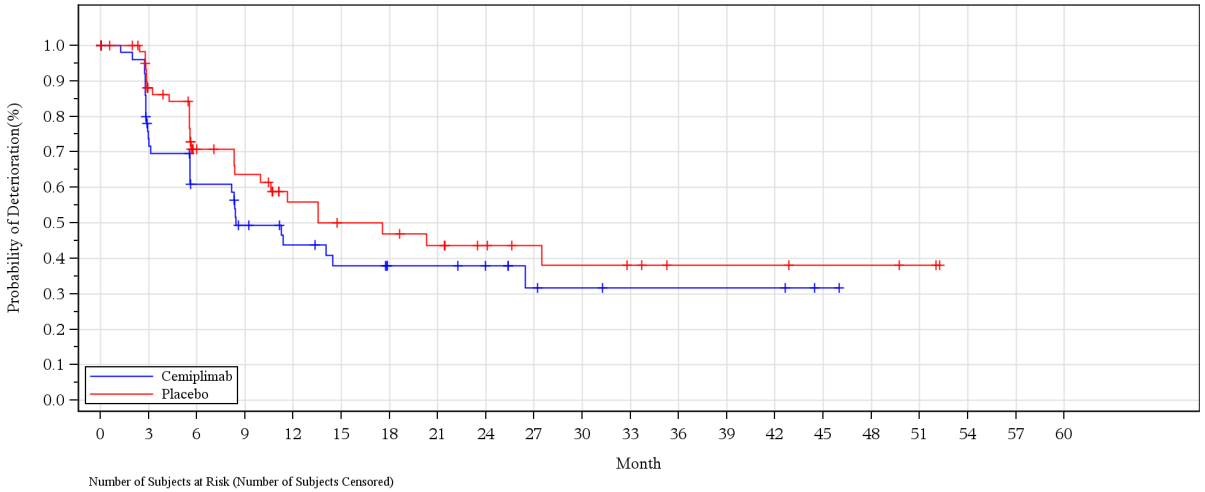
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	35 (8)	27 (10)	20 (12)	16 (14)	13 (15)	10 (18)	10 (18)	8 (20)	5 (22)	4 (23)	3 (24)	3 (24)	3 (24)	3 (24)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	48 (10)	32 (17)	27 (19)	19 (24)	16 (25)	15 (25)	13 (26)	10 (29)	8 (31)	7 (31)	6 (32)	4 (34)	4 (34)	4 (34)	3 (35)	3 (35)	2 (36)	0 (38)	0 (38)	0 (38)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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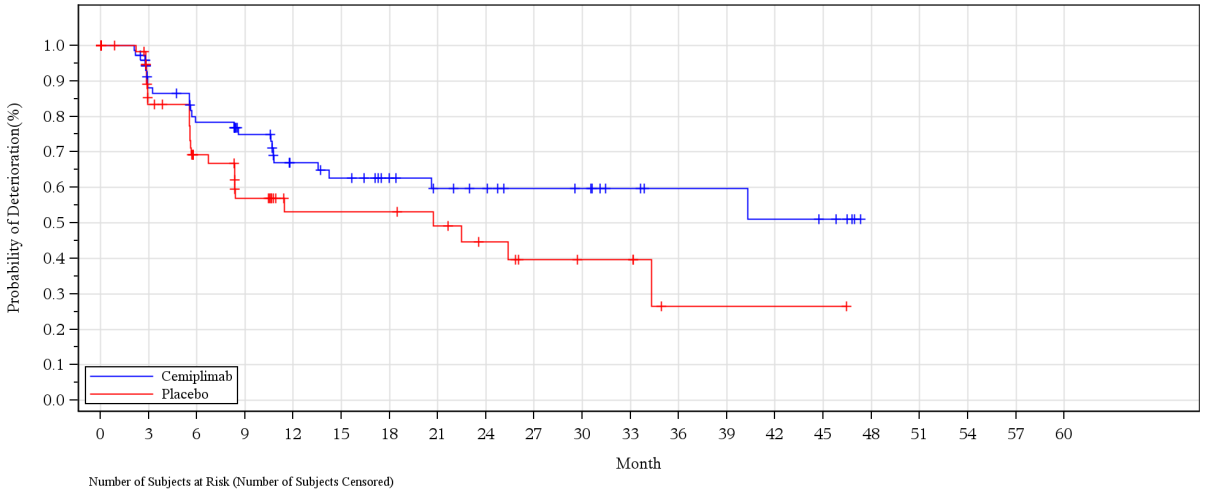
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	56 (16)	48 (18)	40 (24)	31 (29)	28 (30)	22 (36)	19 (38)	17 (40)	14 (43)	13 (44)	9 (48)	7 (50)	7 (50)	6 (50)	5 (51)	0 (56)	0 (56)	0 (56)	0 (56)	0 (56)
Placebo	69 (0)	43 (17)	30 (23)	22 (26)	14 (33)	14 (33)	14 (33)	12 (34)	9 (36)	6 (38)	5 (39)	5 (39)	1 (42)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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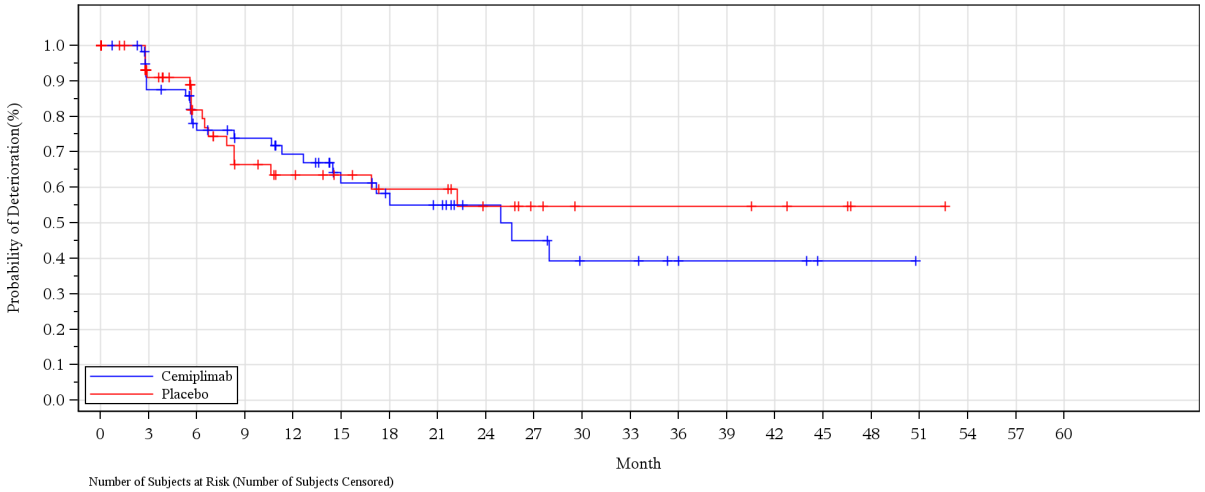
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	49 (17)	38 (22)	34 (25)	29 (28)	21 (33)	18 (35)	16 (36)	11 (41)	9 (41)	6 (43)	6 (43)	3 (46)	3 (46)	3 (46)	1 (48)	1 (48)	0 (49)	0 (49)	0 (49)	0 (49)
Placebo	72 (0)	46 (21)	33 (30)	24 (33)	20 (36)	17 (39)	14 (41)	14 (41)	10 (44)	7 (47)	5 (49)	5 (49)	5 (49)	5 (49)	4 (50)	3 (51)	1 (53)	1 (53)	0 (54)	0 (54)	0 (54)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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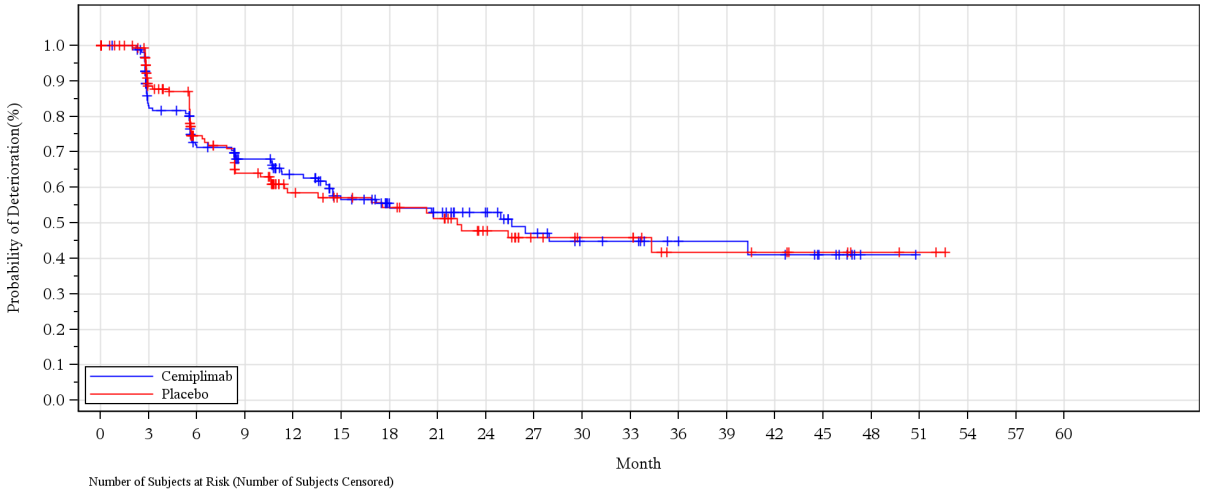
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	118 (31)	93 (40)	81 (48)	68 (56)	54 (63)	43 (73)	39 (75)	31 (83)	23 (88)	18 (92)	17 (93)	12 (98)	12 (98)	11 (98)	7 (102)	1 (108)	0 (109)	0 (109)	0 (109)	0 (109)
Placebo	174 (0)	116 (42)	80 (61)	64 (66)	46 (79)	41 (83)	38 (84)	34 (86)	25 (93)	17 (100)	14 (103)	14 (103)	8 (108)	8 (108)	7 (109)	5 (111)	3 (113)	2 (114)	0 (116)	0 (116)	0 (116)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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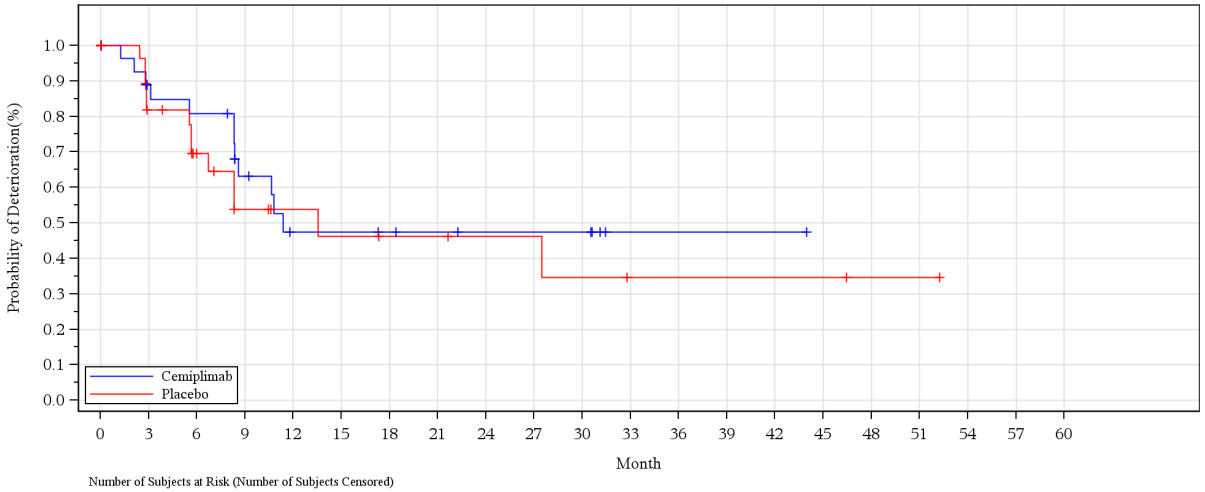
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



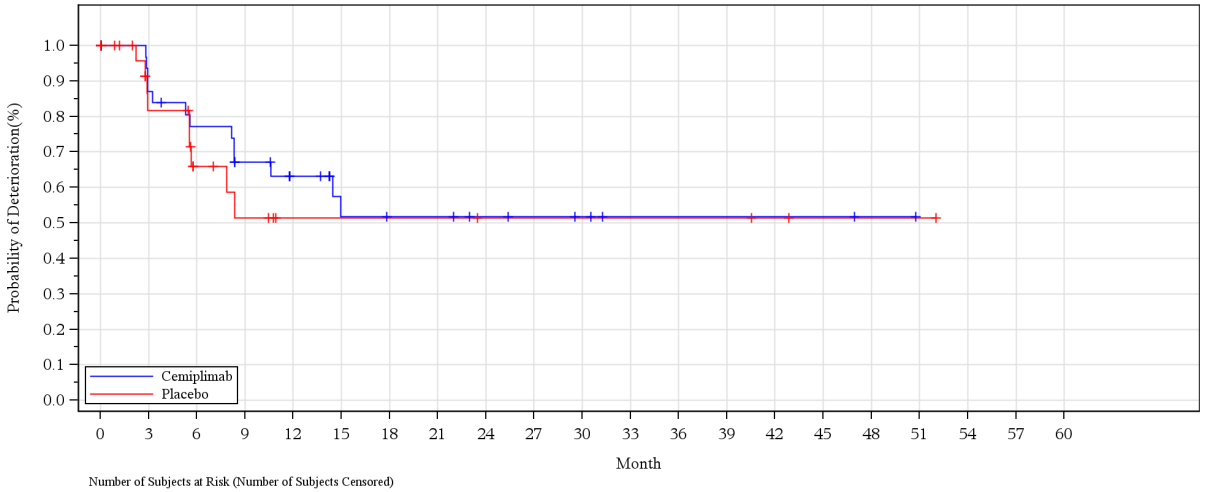
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	22 (10)	20 (10)	13 (13)	8 (15)	8 (15)	7 (16)	6 (17)	5 (18)	5 (18)	5 (18)	1 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	32 (0)	21 (6)	15 (9)	9 (12)	7 (14)	6 (14)	5 (15)	5 (15)	4 (16)	4 (16)	3 (16)	2 (17)	2 (17)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



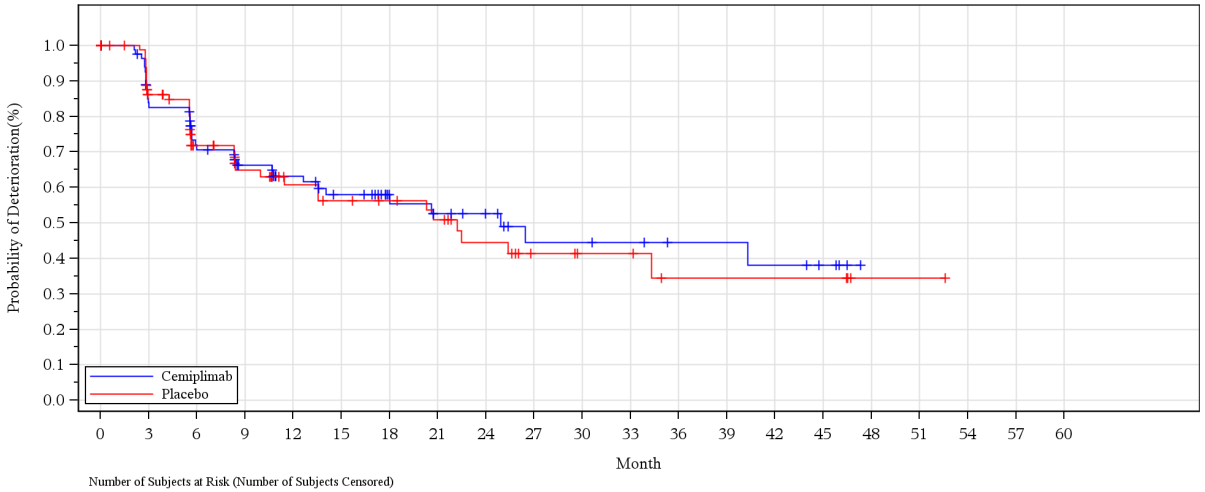
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	27 (6)	23 (7)	18 (9)	14 (12)	9 (15)	8 (16)	8 (16)	6 (18)	5 (19)	4 (20)	2 (22)	2 (22)	2 (22)	2 (22)	2 (22)	1 (23)	0 (24)	0 (24)	0 (24)	0 (24)
Placebo	31 (0)	17 (10)	10 (14)	7 (15)	4 (18)	4 (18)	4 (18)	4 (18)	3 (19)	3 (19)	3 (19)	3 (19)	3 (19)	3 (19)	2 (20)	1 (21)	1 (21)	1 (21)	0 (22)	0 (22)	0 (22)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	66 (11)	52 (15)	43 (21)	37 (25)	31 (28)	22 (37)	18 (39)	15 (42)	10 (45)	10 (45)	9 (46)	7 (48)	7 (48)	6 (48)	4 (50)	0 (54)	0 (54)	0 (54)	0 (54)	0 (54)
Placebo	90 (0)	64 (15)	44 (25)	35 (30)	27 (36)	24 (37)	22 (39)	19 (40)	14 (43)	9 (47)	7 (49)	7 (49)	4 (51)	4 (51)	4 (51)	4 (51)	1 (54)	1 (54)	0 (55)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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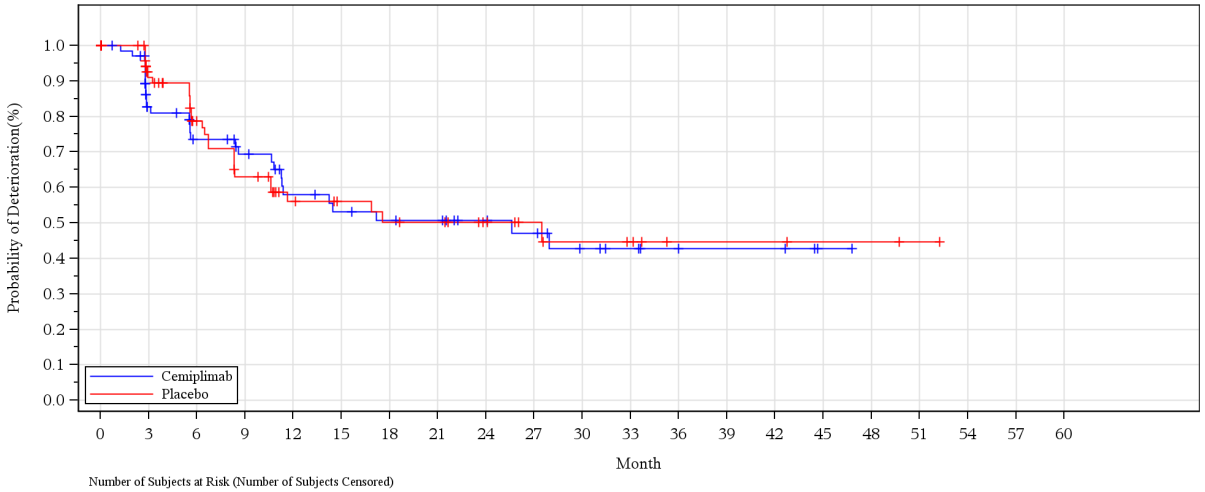
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



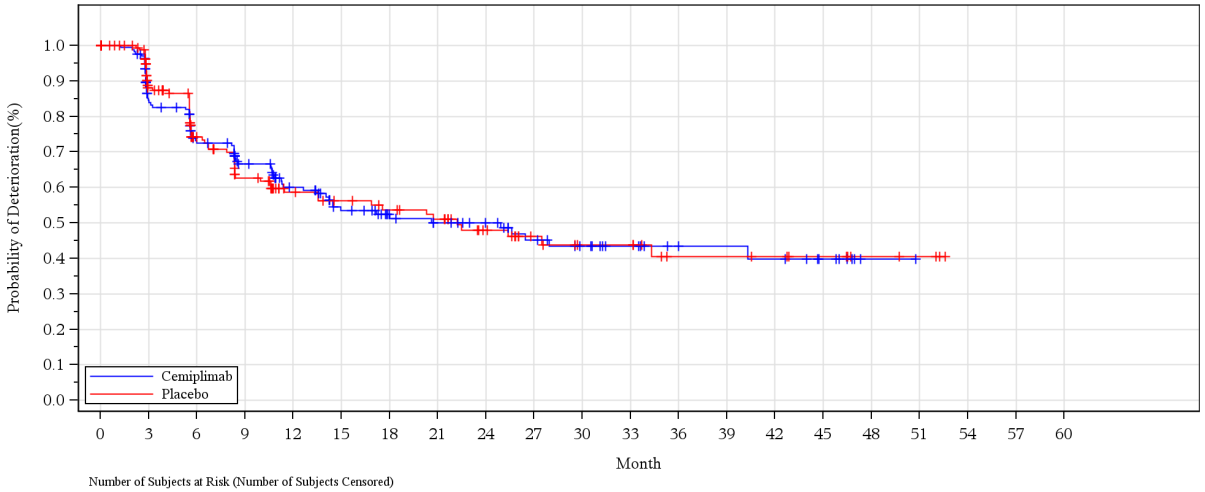
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	47 (24)	38 (28)	33 (31)	25 (34)	22 (35)	20 (36)	19 (37)	15 (41)	13 (42)	9 (45)	7 (47)	4 (50)	4 (50)	4 (50)	1 (53)	0 (54)	0 (54)	0 (54)	0 (54)	0 (54)
Placebo	85 (0)	56 (23)	41 (31)	31 (33)	22 (39)	19 (42)	17 (42)	16 (43)	12 (47)	9 (50)	7 (51)	6 (52)	3 (55)	3 (55)	3 (55)	2 (56)	2 (56)	1 (57)	0 (58)	0 (58)	0 (58)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	131 (33)	104 (42)	86 (52)	69 (61)	55 (68)	44 (78)	39 (81)	34 (86)	27 (90)	22 (94)	17 (99)	12 (104)	12 (104)	11 (104)	7 (108)	1 (114)	0 (115)	0 (115)	0 (115)	0 (115)
Placebo	189 (0)	124 (47)	87 (66)	67 (73)	51 (85)	46 (88)	42 (90)	38 (92)	28 (100)	20 (107)	16 (110)	16 (110)	10 (115)	10 (115)	9 (116)	7 (118)	4 (121)	3 (122)	0 (125)	0 (125)	0 (125)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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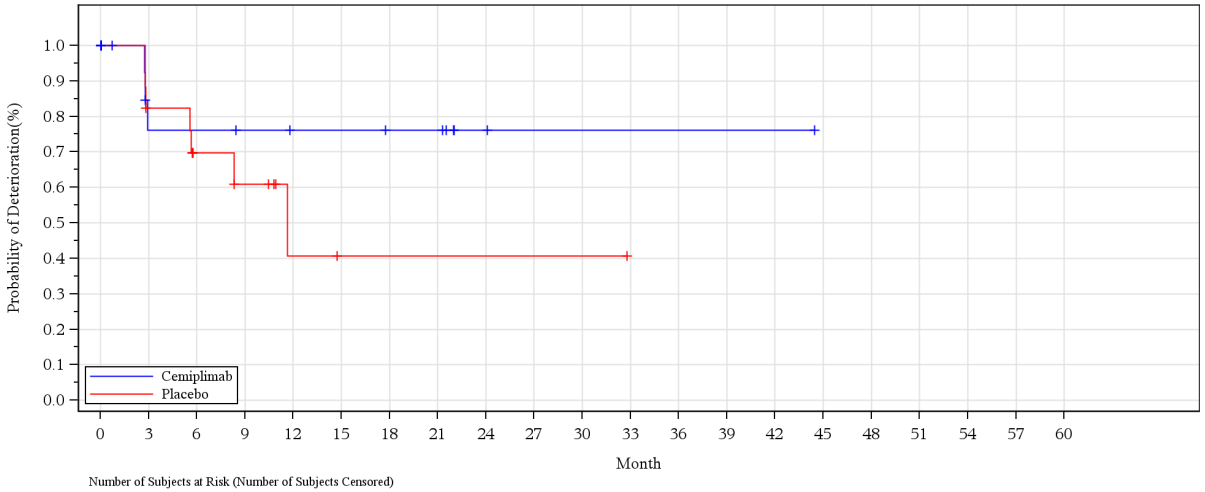
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (8)	9 (8)	8 (9)	7 (10)	7 (10)	6 (11)	6 (11)	2 (15)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	17 (0)	13 (1)	8 (4)	6 (5)	2 (8)	1 (9)	1 (9)	1 (9)	1 (9)	1 (9)	1 (9)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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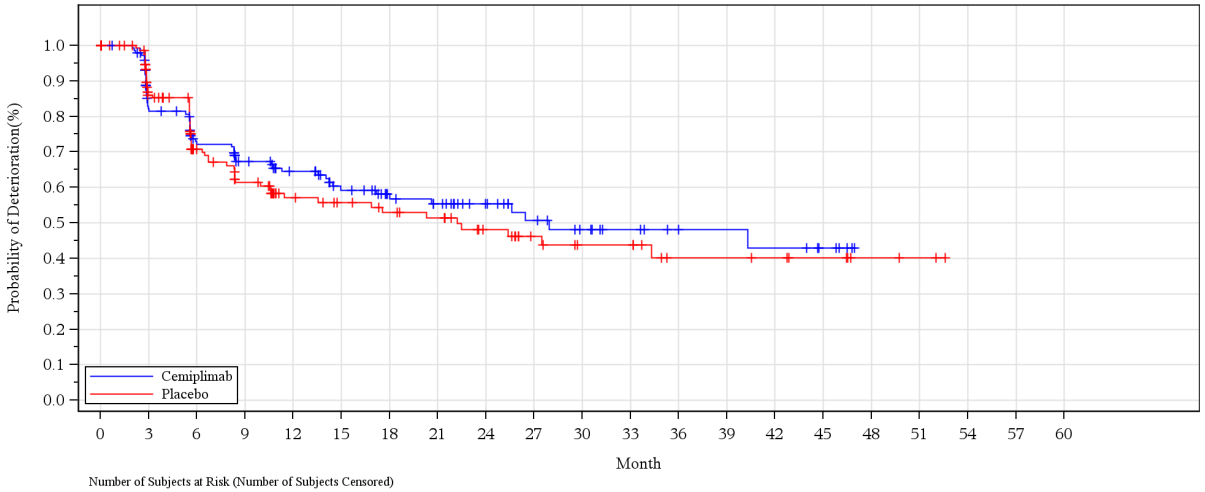
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	111 (30)	91 (37)	77 (45)	66 (53)	54 (60)	43 (70)	38 (73)	29 (82)	22 (87)	17 (91)	13 (95)	9 (99)	9 (99)	8 (99)	5 (102)	0 (107)	0 (107)	0 (107)	0 (107)	0 (107)
Placebo	177 (0)	116 (41)	77 (61)	62 (66)	46 (78)	41 (82)	37 (84)	34 (86)	26 (92)	19 (98)	15 (101)	15 (101)	9 (106)	9 (106)	8 (107)	6 (109)	3 (112)	2 (113)	0 (115)	0 (115)	0 (115)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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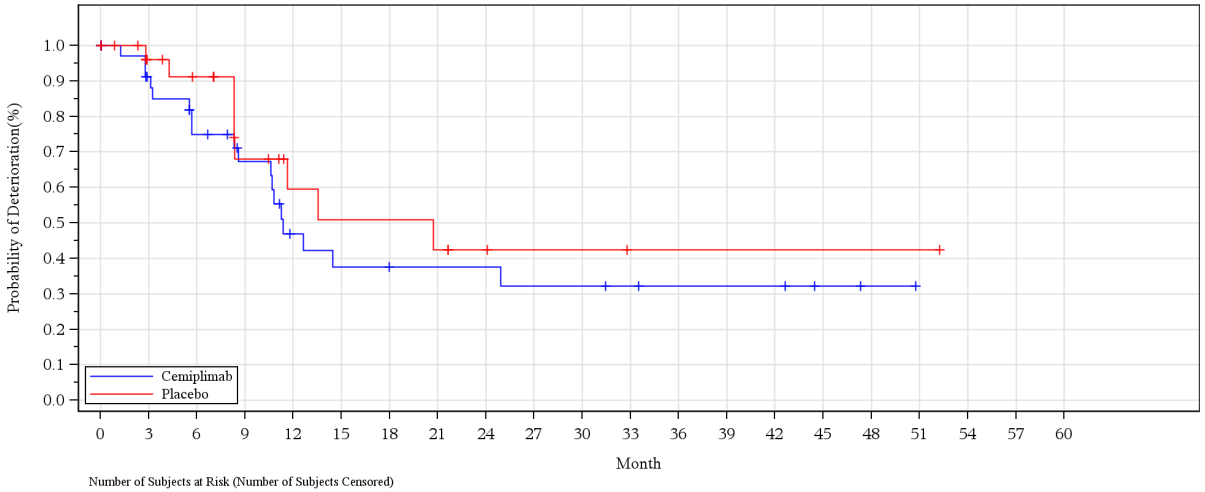
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (11)	22 (13)	17 (16)	10 (18)	8 (18)	7 (19)	7 (19)	7 (19)	6 (19)	6 (19)	5 (20)	4 (21)	4 (21)	4 (21)	2 (23)	1 (24)	0 (25)	0 (25)	0 (25)	0 (25)
Placebo	29 (0)	21 (7)	18 (9)	11 (12)	7 (15)	6 (15)	6 (15)	5 (15)	3 (17)	2 (18)	2 (18)	1 (19)	1 (19)	1 (19)	1 (19)	1 (19)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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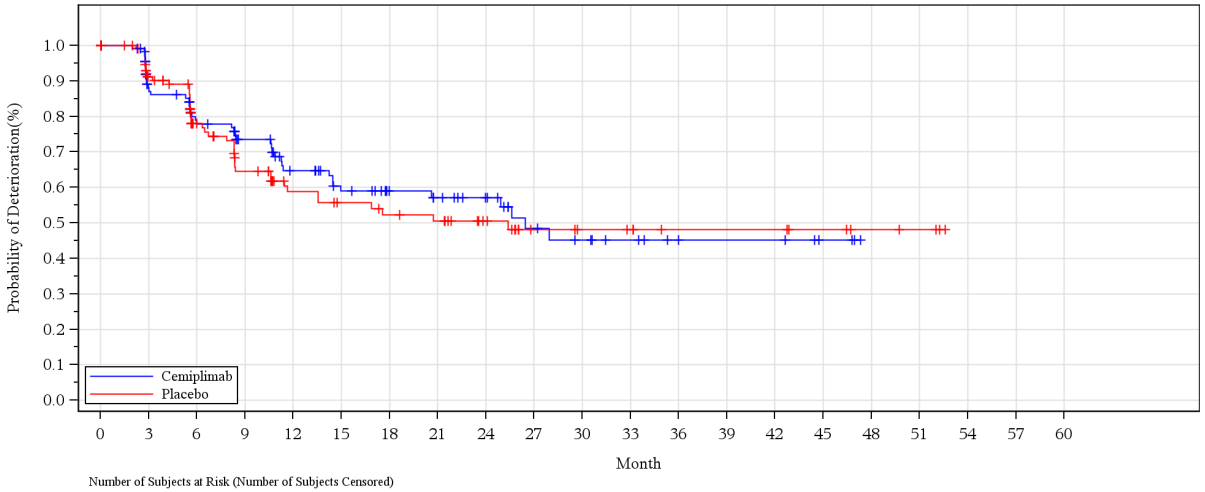
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	90 (30)	74 (36)	62 (44)	49 (50)	40 (55)	32 (63)	29 (65)	24 (70)	16 (75)	13 (77)	10 (80)	6 (84)	6 (84)	6 (84)	3 (87)	0 (90)	0 (90)	0 (90)	0 (90)	0 (90)
Placebo	131 (0)	96 (25)	68 (40)	51 (46)	38 (55)	34 (57)	31 (58)	29 (59)	22 (66)	14 (73)	12 (75)	11 (76)	8 (79)	8 (79)	8 (79)	6 (81)	4 (83)	3 (84)	0 (87)	0 (87)	0 (87)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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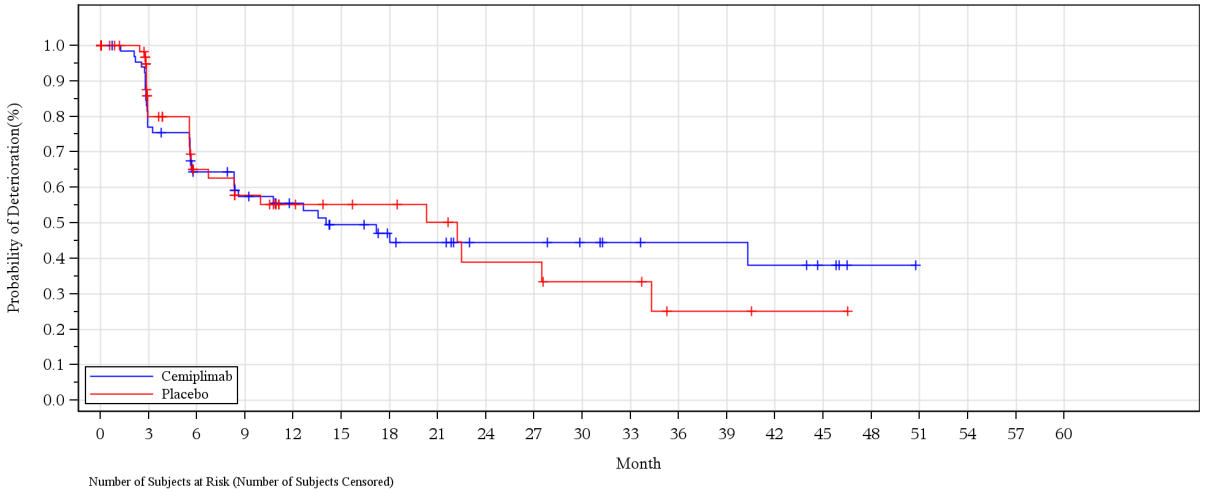
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	50 (11)	39 (14)	32 (17)	27 (21)	22 (23)	18 (26)	16 (27)	12 (31)	12 (31)	10 (33)	8 (35)	7 (36)	7 (36)	6 (36)	4 (38)	1 (41)	0 (42)	0 (42)	0 (42)	0 (42)
Placebo	75 (0)	41 (23)	27 (30)	22 (32)	15 (38)	13 (40)	12 (41)	10 (42)	7 (43)	7 (43)	5 (44)	5 (44)	2 (46)	2 (46)	1 (47)	1 (47)	0 (48)	0 (48)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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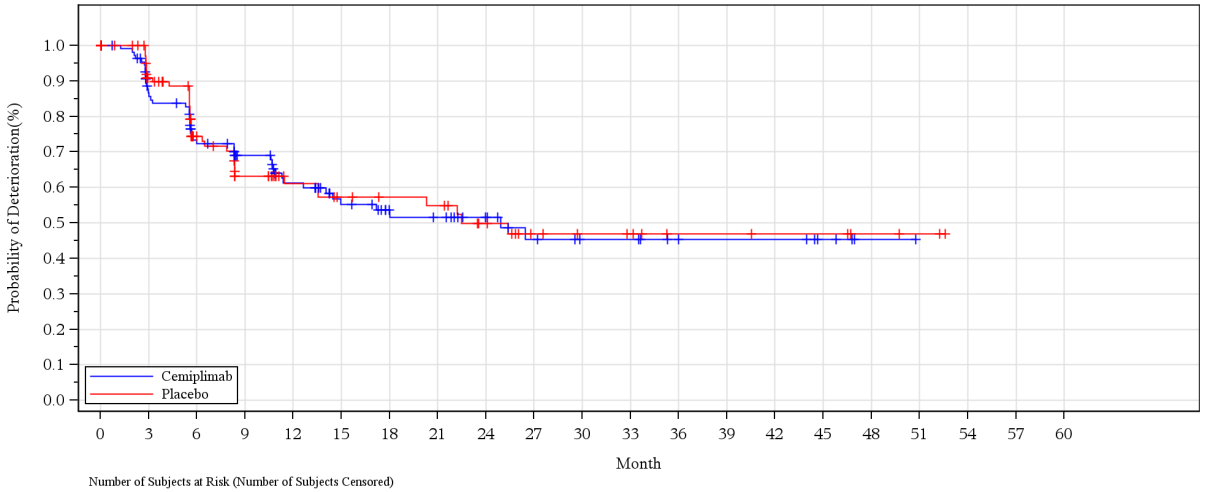
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	87 (24)	68 (29)	57 (37)	45 (43)	35 (49)	27 (56)	25 (57)	19 (63)	14 (66)	11 (69)	11 (69)	7 (73)	7 (73)	7 (73)	4 (76)	1 (79)	0 (80)	0 (80)	0 (80)	0 (80)
Placebo	117 (0)	84 (24)	55 (39)	41 (45)	31 (54)	27 (56)	25 (58)	24 (58)	18 (62)	12 (67)	10 (69)	9 (70)	6 (73)	6 (73)	5 (74)	5 (74)	3 (76)	2 (77)	0 (79)	0 (79)	0 (79)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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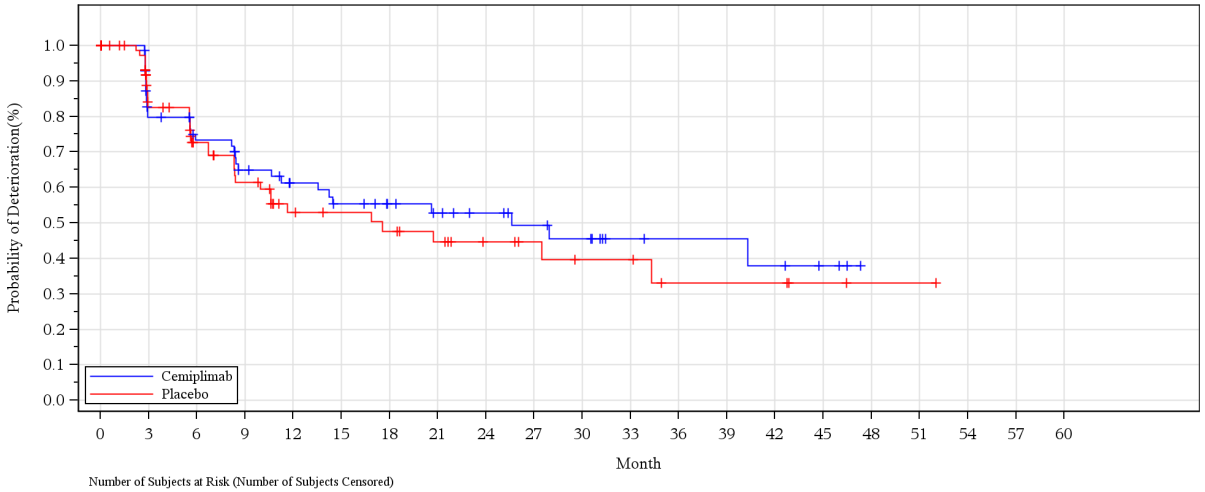
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	53 (17)	45 (21)	37 (24)	31 (28)	27 (29)	23 (33)	20 (35)	17 (38)	14 (40)	12 (41)	7 (46)	6 (47)	6 (47)	5 (47)	3 (49)	0 (52)	0 (52)	0 (52)	0 (52)	0 (52)
Placebo	89 (0)	53 (24)	40 (31)	32 (33)	22 (39)	20 (41)	18 (41)	15 (43)	11 (47)	9 (49)	7 (50)	7 (50)	4 (52)	4 (52)	4 (52)	2 (54)	1 (55)	1 (55)	0 (56)	0 (56)	0 (56)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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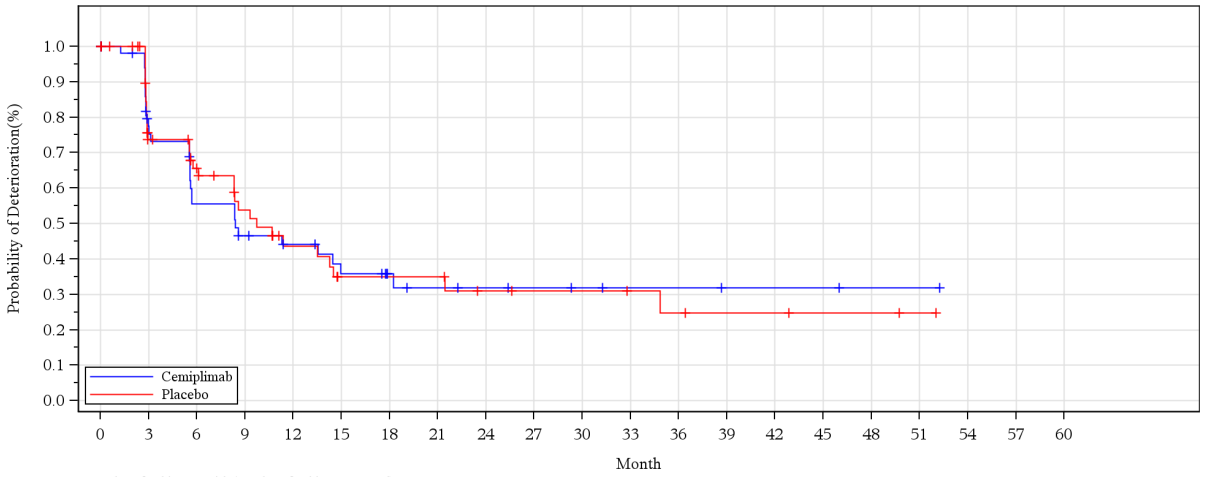
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



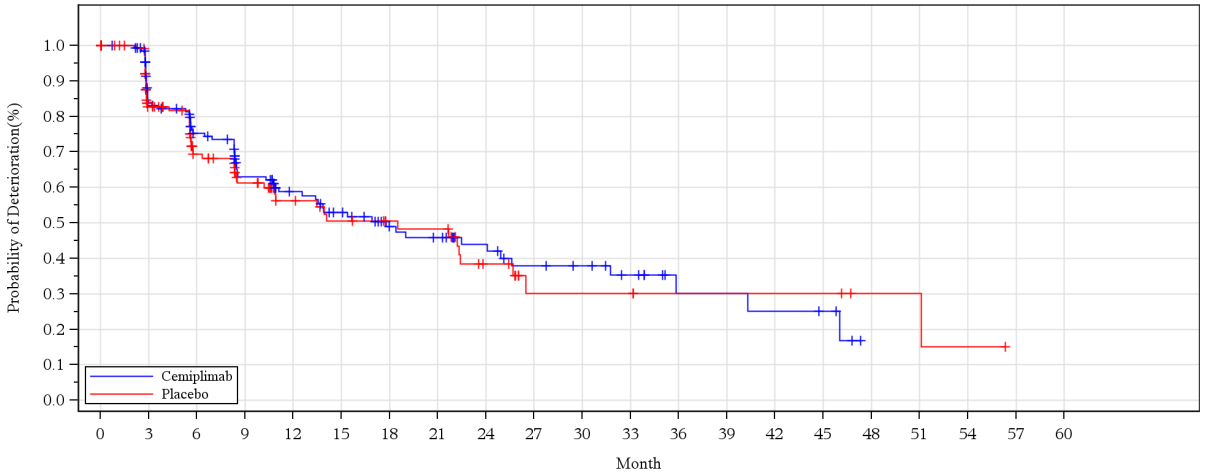
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	36 (9)	25 (10)	20 (11)	17 (13)	13 (14)	9 (18)	7 (19)	6 (20)	5 (21)	4 (22)	3 (23)	3 (23)	2 (24)	2 (24)	2 (24)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)
Placebo	65 (0)	39 (11)	31 (15)	22 (19)	15 (22)	10 (24)	10 (24)	10 (24)	7 (26)	6 (27)	6 (27)	5 (28)	4 (28)	3 (29)	3 (29)	2 (30)	2 (30)	1 (31)	0 (32)	0 (32)	0 (32)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



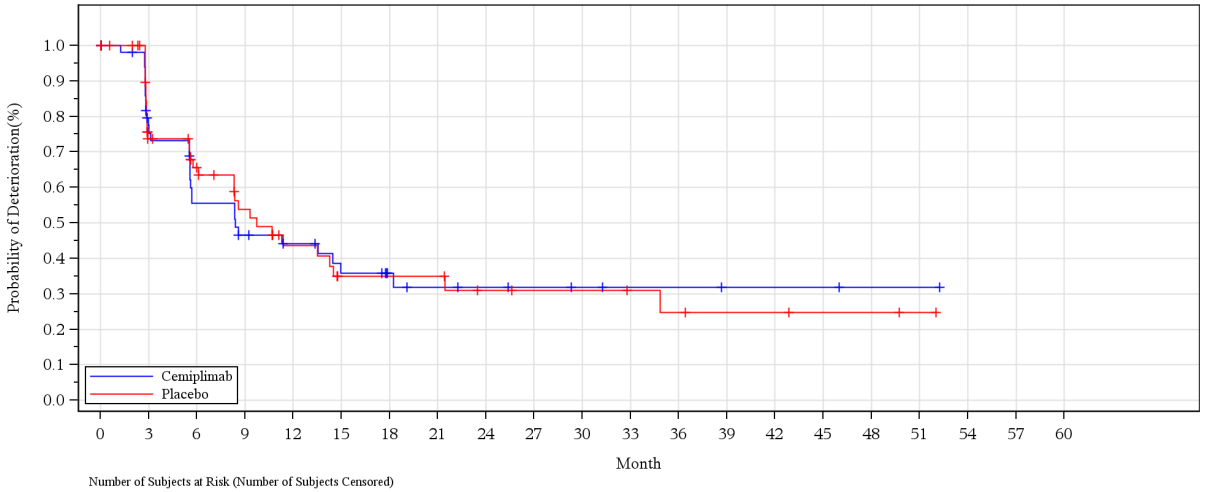
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	102 (31)	84 (39)	64 (46)	51 (55)	43 (58)	32 (66)	29 (67)	23 (72)	18 (74)	16 (76)	12 (79)	6 (84)	6 (84)	5 (84)	4 (85)	0 (88)	0 (88)	0 (88)	0 (88)	0 (88)
Placebo	141 (0)	83 (39)	57 (53)	43 (61)	31 (70)	26 (72)	23 (75)	22 (75)	13 (80)	6 (85)	6 (85)	6 (85)	4 (87)	4 (87)	4 (87)	4 (87)	2 (89)	2 (89)	1 (89)	0 (90)	0 (90)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



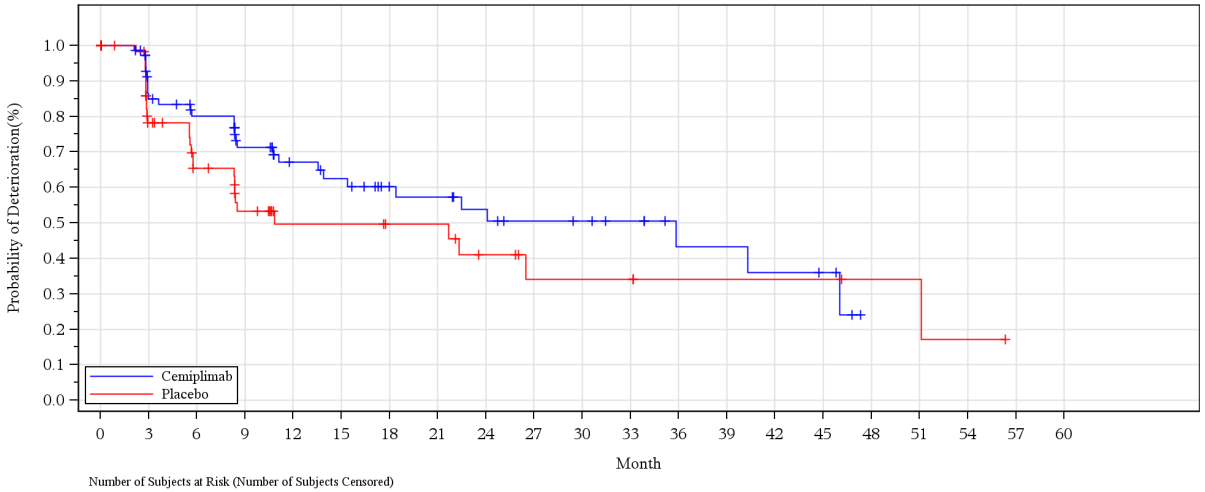
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	36 (9)	25 (10)	20 (11)	17 (13)	13 (14)	9 (18)	7 (19)	6 (20)	5 (21)	4 (22)	3 (23)	3 (23)	2 (24)	2 (24)	2 (24)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)
Placebo	65 (0)	39 (11)	31 (15)	22 (19)	15 (22)	10 (24)	10 (24)	10 (24)	7 (26)	6 (27)	6 (27)	5 (28)	4 (28)	3 (29)	3 (29)	2 (30)	2 (30)	1 (31)	0 (32)	0 (32)	0 (32)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



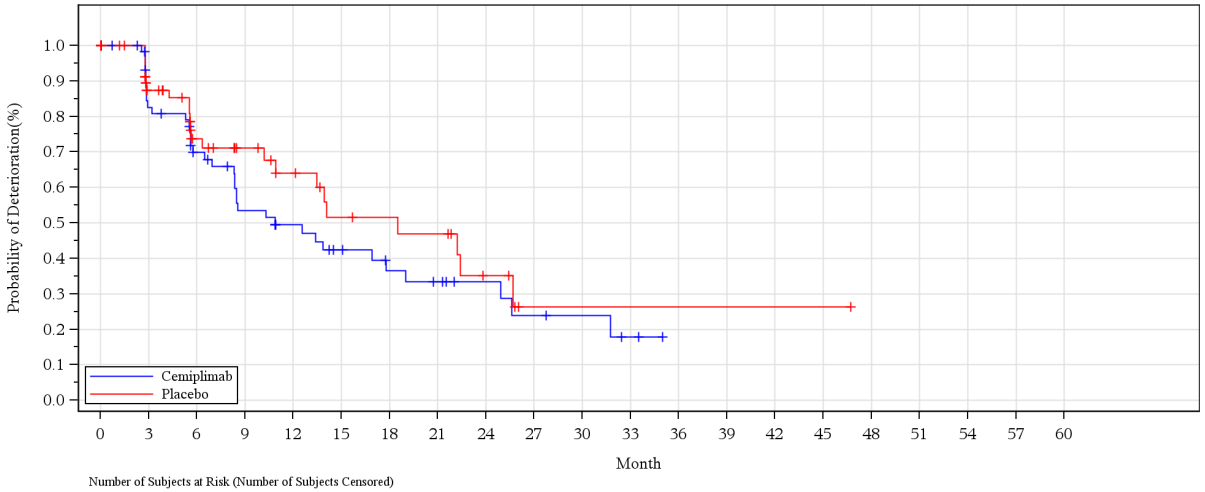
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	55 (15)	48 (19)	38 (24)	30 (30)	27 (31)	20 (37)	19 (37)	16 (39)	13 (41)	12 (42)	10 (44)	6 (47)	6 (47)	5 (47)	4 (48)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	69 (0)	40 (17)	29 (22)	21 (25)	14 (31)	14 (31)	12 (33)	12 (33)	8 (35)	5 (37)	5 (37)	5 (37)	3 (39)	3 (39)	3 (39)	3 (39)	2 (40)	2 (40)	1 (40)	0 (41)	0 (41)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



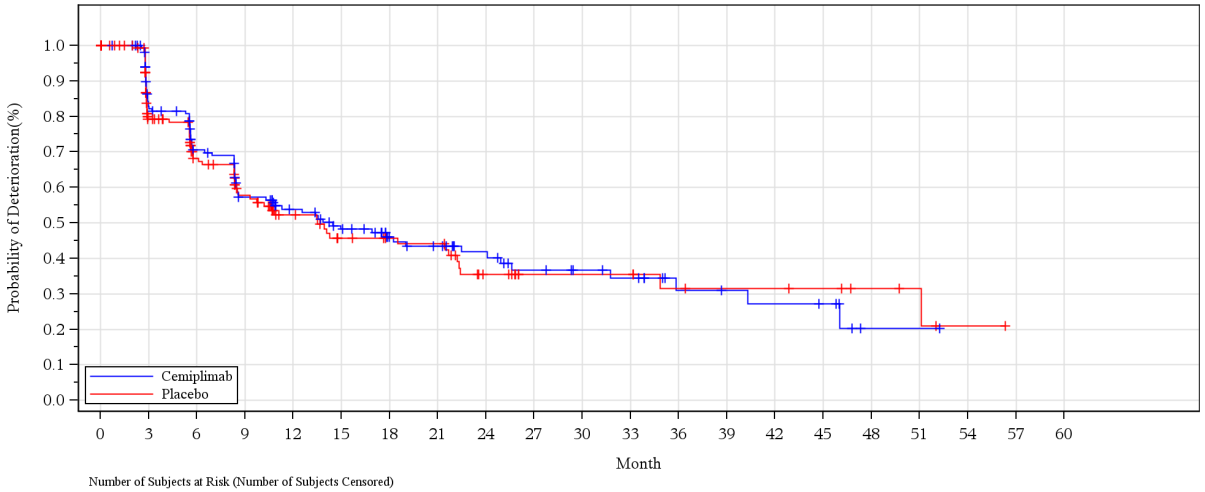
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	47 (16)	36 (20)	26 (22)	21 (25)	16 (27)	12 (29)	10 (30)	7 (33)	5 (33)	4 (34)	2 (35)	0 (37)	0 (37)	0 (37)	0 (37)	0 (37)	0 (37)	0 (37)	0 (37)
Placebo	72 (0)	43 (22)	28 (31)	22 (36)	17 (39)	12 (41)	11 (42)	10 (42)	5 (45)	1 (48)	1 (48)	1 (48)	1 (48)	1 (48)	1 (48)	1 (48)	0 (49)	0 (49)	0 (49)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



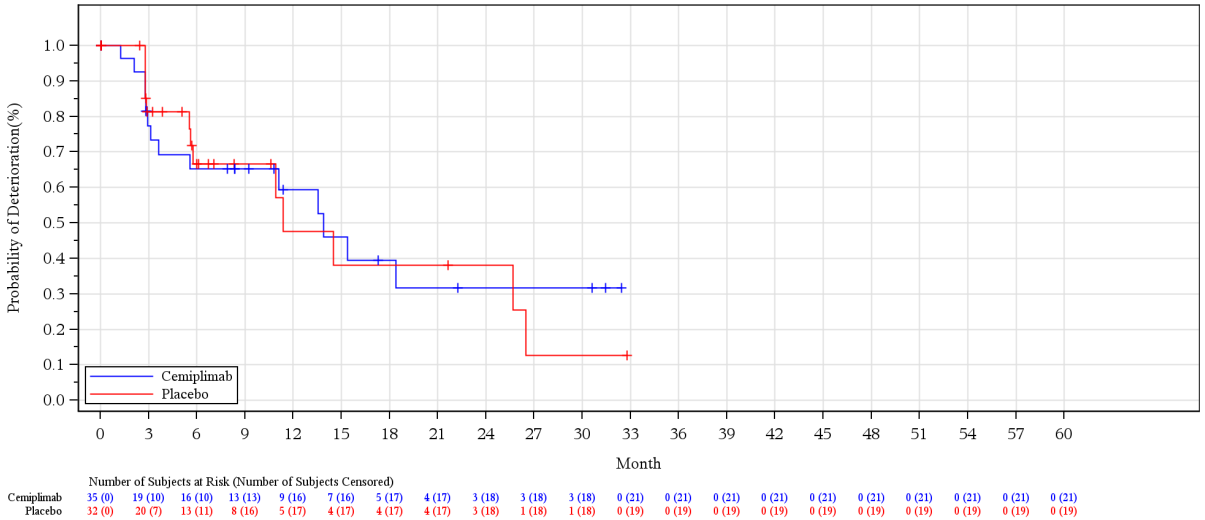
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	119 (30)	93 (39)	71 (44)	59 (52)	49 (56)	36 (67)	32 (69)	26 (74)	20 (77)	17 (80)	15 (81)	9 (86)	8 (87)	7 (87)	6 (88)	1 (92)	1 (92)	0 (93)	0 (93)	0 (93)
Placebo	174 (0)	102 (43)	75 (57)	57 (64)	41 (75)	32 (79)	29 (82)	28 (82)	17 (88)	11 (94)	11 (94)	11 (94)	8 (96)	7 (97)	7 (97)	6 (98)	4 (100)	3 (101)	1 (102)	0 (103)	0 (103)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



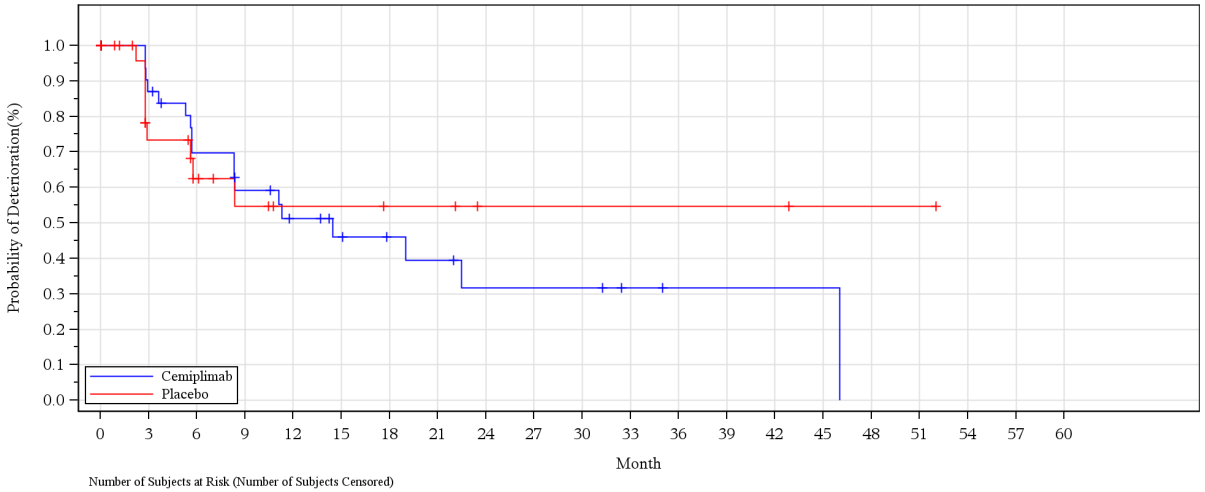
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	19 (10)	16 (10)	13 (13)	9 (16)	7 (16)	5 (17)	4 (17)	3 (18)	3 (18)	3 (18)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)
Placebo	32 (0)	20 (7)	13 (11)	8 (16)	5 (17)	4 (17)	4 (17)	4 (17)	3 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup (Full Analysis Set)

Geographic region group (EDC): North America



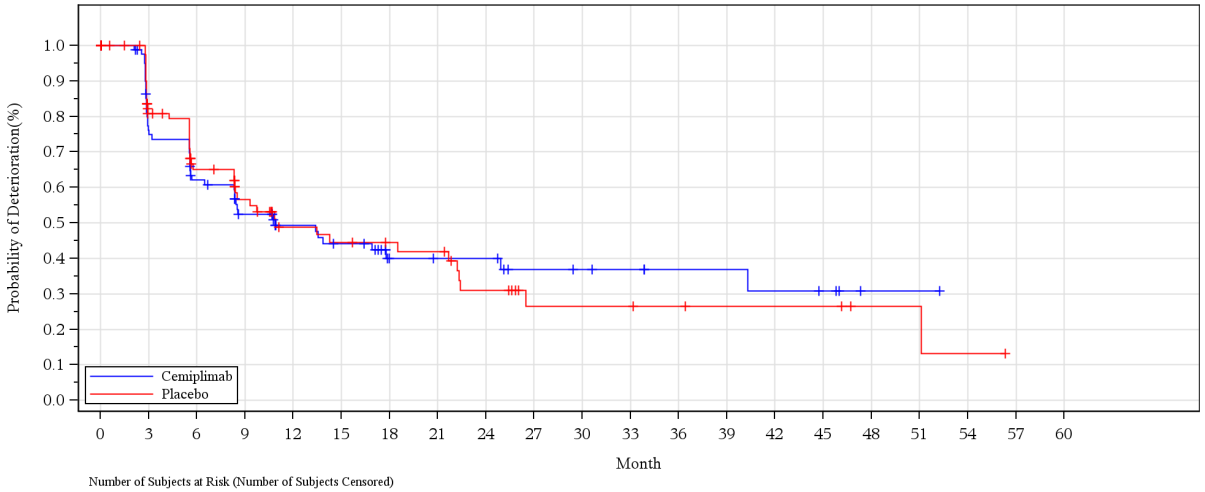
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	27 (6)	20 (8)	16 (9)	12 (11)	9 (13)	7 (15)	6 (15)	4 (16)	4 (16)	4 (16)	2 (18)	1 (19)	1 (19)	1 (19)	1 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	31 (0)	15 (10)	10 (13)	7 (15)	5 (17)	5 (17)	4 (18)	4 (18)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	1 (21)	1 (21)	1 (21)	0 (22)	0 (22)	0 (22)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



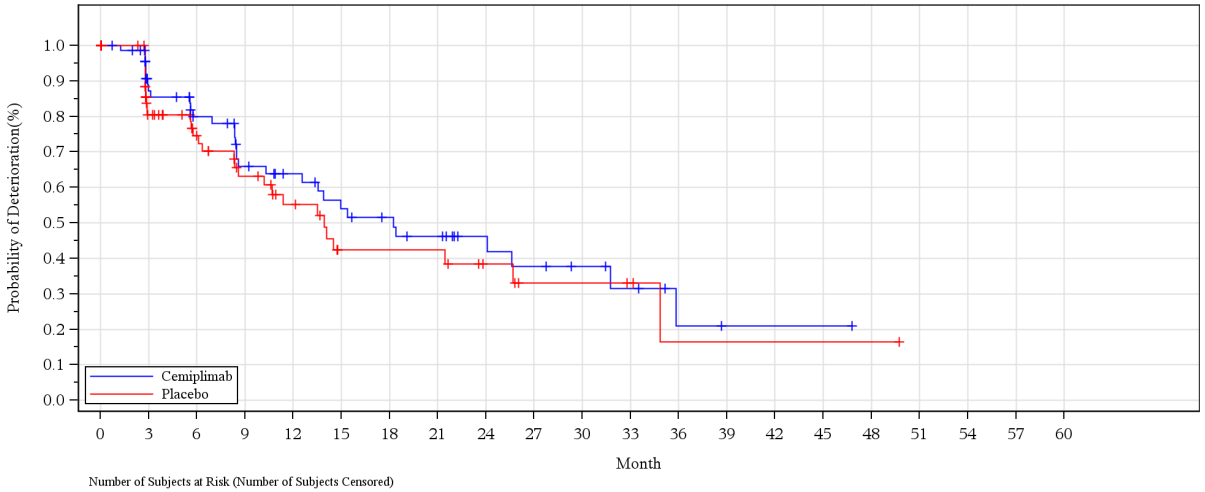
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	60 (11)	47 (13)	36 (17)	29 (22)	25 (23)	15 (31)	14 (32)	14 (32)	10 (35)	9 (36)	8 (37)	6 (39)	6 (39)	5 (39)	4 (40)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)
Placebo	90 (0)	59 (16)	42 (22)	32 (27)	22 (33)	20 (33)	18 (35)	17 (35)	11 (37)	6 (41)	6 (41)	6 (41)	5 (42)	4 (43)	4 (43)	4 (43)	2 (45)	2 (45)	1 (45)	0 (46)	0 (46)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup (Full Analysis Set)

Geographic region group (EDC): Rest of World



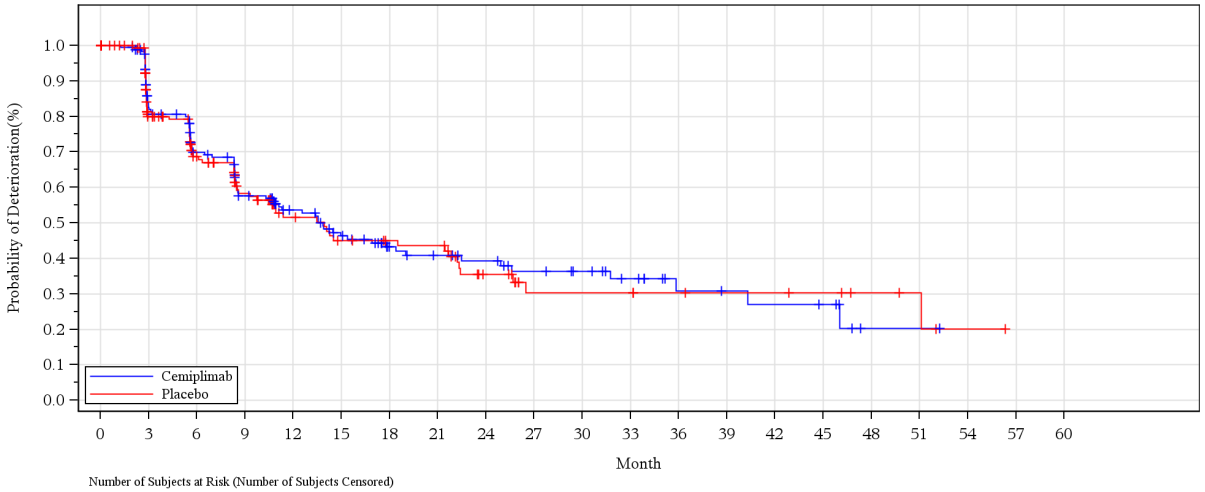
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	51 (23)	42 (28)	32 (31)	27 (35)	22 (36)	19 (38)	16 (39)	11 (44)	9 (44)	7 (46)	5 (47)	2 (49)	1 (50)	1 (50)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	85 (0)	48 (24)	36 (33)	26 (38)	19 (42)	11 (46)	11 (46)	11 (46)	7 (49)	4 (51)	4 (51)	3 (52)	1 (53)	1 (53)	1 (53)	1 (53)	1 (53)	0 (54)	0 (54)	0 (54)	0 (54)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	129 (32)	101 (41)	77 (48)	61 (59)	49 (63)	35 (74)	31 (76)	28 (78)	23 (81)	20 (84)	15 (88)	9 (93)	8 (94)	7 (94)	6 (95)	1 (99)	1 (99)	0 (100)	0 (100)	0 (100)
Placebo	189 (0)	110 (49)	80 (65)	58 (76)	41 (87)	34 (89)	31 (92)	30 (92)	18 (99)	10 (105)	10 (105)	10 (105)	8 (107)	7 (108)	7 (108)	6 (109)	4 (111)	3 (112)	1 (113)	0 (114)	0 (114)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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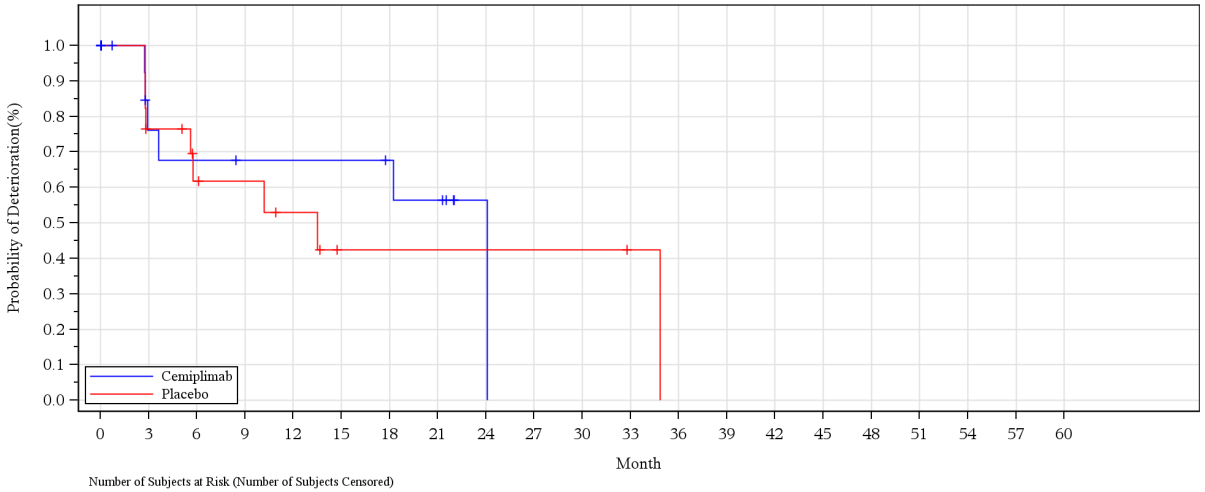
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (8)	8 (8)	7 (9)	7 (9)	7 (9)	6 (10)	5 (10)	1 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)
Placebo	17 (0)	12 (1)	8 (3)	7 (4)	5 (5)	2 (7)	2 (7)	2 (7)	2 (7)	2 (7)	2 (7)	1 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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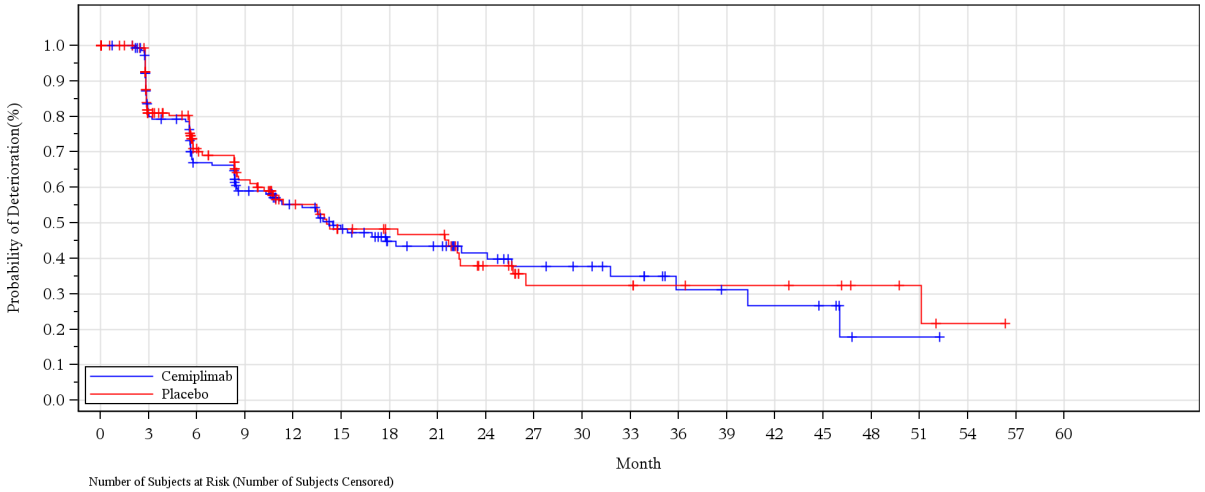
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



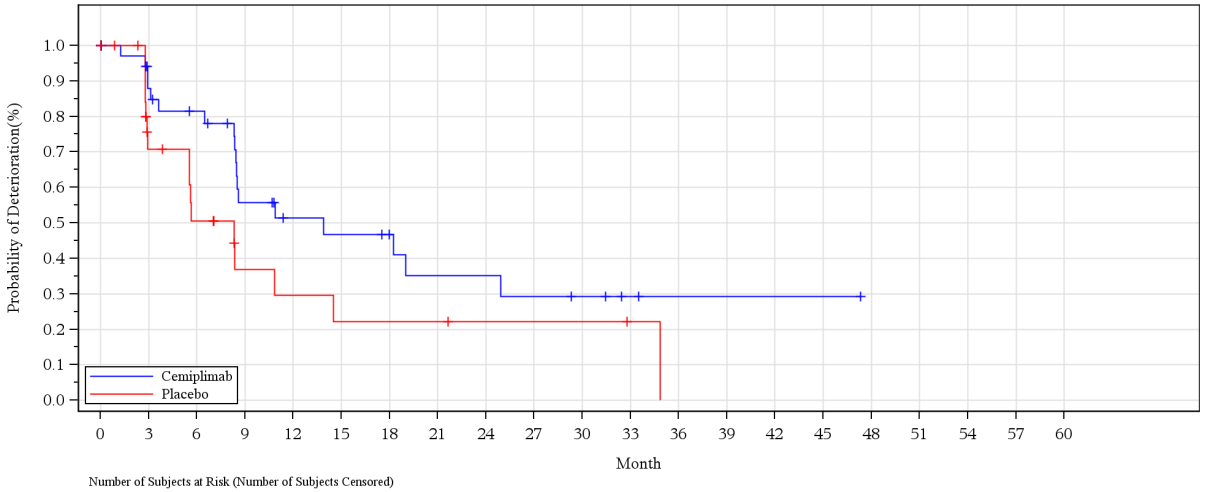
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	110 (29)	85 (36)	69 (42)	57 (50)	46 (54)	33 (64)	30 (66)	23 (72)	18 (75)	16 (77)	13 (79)	8 (83)	7 (84)	6 (84)	5 (85)	1 (88)	1 (88)	0 (89)	0 (89)	0 (89)
Placebo	177 (0)	107 (43)	78 (60)	60 (69)	42 (81)	33 (85)	30 (88)	29 (88)	18 (94)	10 (100)	10 (100)	10 (100)	8 (102)	7 (103)	7 (103)	6 (104)	4 (106)	3 (107)	1 (108)	0 (109)	0 (109)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



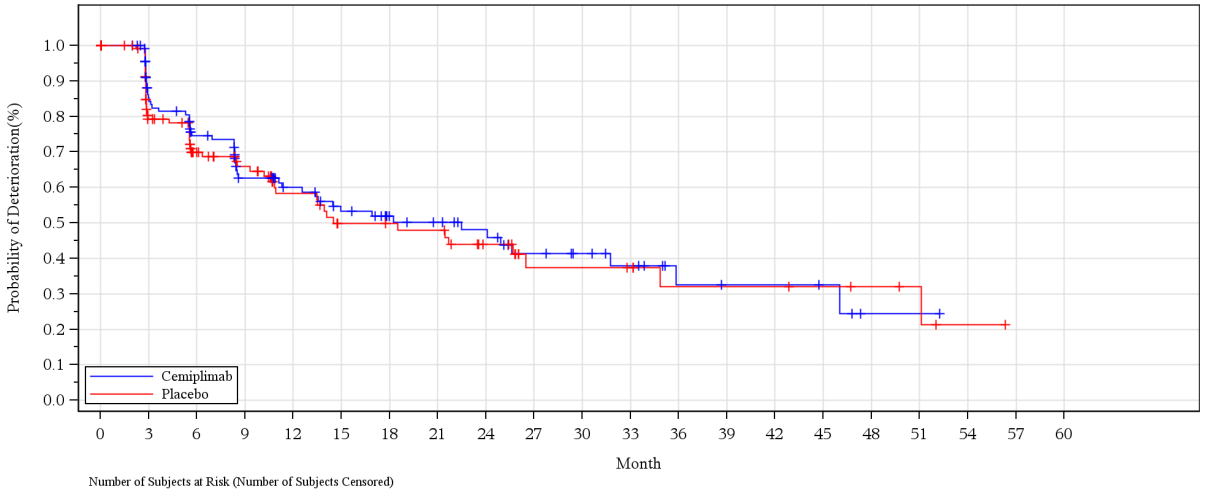
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	28 (11)	24 (13)	15 (15)	11 (18)	10 (18)	8 (20)	6 (20)	6 (20)	5 (20)	4 (21)	2 (23)	1 (24)	1 (24)	1 (24)	1 (24)	0 (25)	0 (25)	0 (25)	0 (25)	0 (25)
Placebo	29 (0)	15 (7)	10 (8)	5 (11)	4 (11)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	2 (12)	1 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



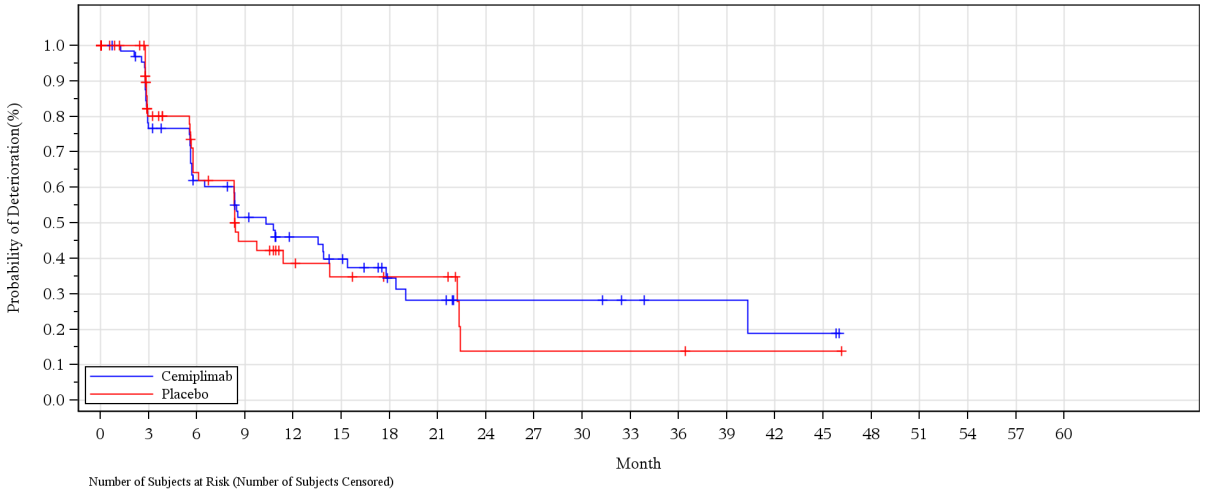
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	89 (28)	72 (34)	55 (40)	46 (47)	38 (50)	30 (57)	27 (59)	23 (62)	17 (65)	14 (68)	11 (70)	6 (74)	5 (75)	5 (75)	4 (76)	1 (78)	1 (78)	0 (79)	0 (79)	0 (79)
Placebo	131 (0)	82 (26)	60 (39)	48 (48)	35 (56)	27 (59)	26 (60)	25 (60)	18 (65)	10 (71)	10 (71)	9 (72)	6 (74)	6 (74)	6 (74)	5 (75)	4 (76)	3 (77)	1 (78)	0 (79)	0 (79)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



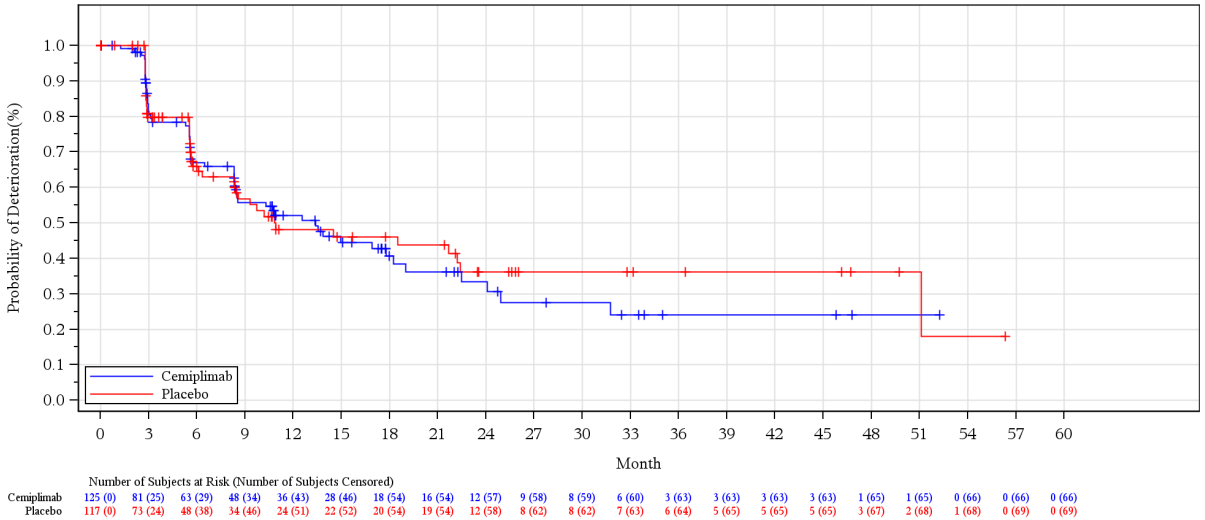
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	49 (12)	37 (15)	29 (17)	22 (21)	18 (22)	11 (27)	9 (27)	6 (30)	6 (30)	6 (30)	4 (32)	3 (33)	3 (33)	2 (33)	2 (33)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)
Placebo	75 (0)	40 (24)	28 (29)	17 (32)	11 (36)	9 (37)	7 (39)	7 (39)	2 (41)	2 (41)	2 (41)	2 (41)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	81 (25)	63 (29)	48 (34)	36 (43)	28 (46)	18 (54)	16 (54)	12 (57)	9 (58)	8 (59)	6 (60)	3 (63)	3 (63)	3 (63)	3 (63)	1 (65)	1 (65)	0 (66)	0 (66)	0 (66)
Placebo	117 (0)	73 (24)	48 (38)	34 (46)	24 (51)	22 (52)	20 (54)	19 (54)	12 (58)	8 (62)	8 (62)	7 (63)	6 (64)	5 (65)	5 (65)	5 (65)	3 (67)	2 (68)	1 (68)	0 (69)	0 (69)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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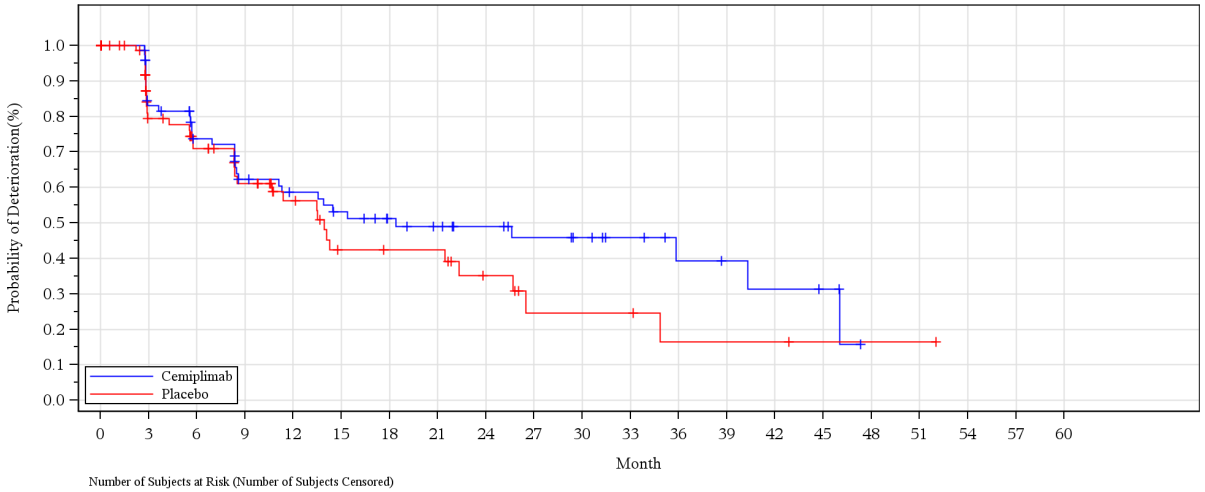
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



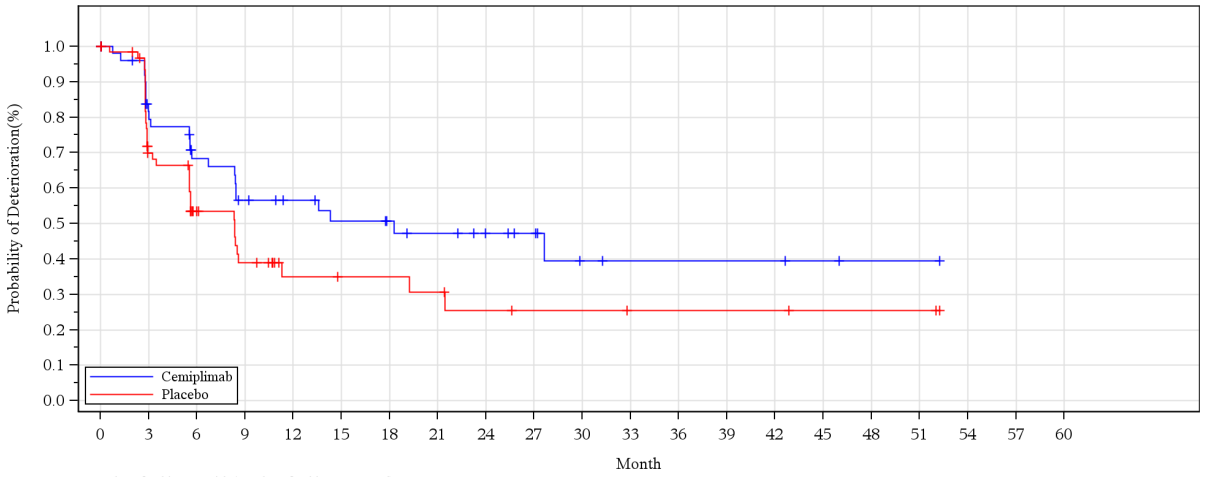
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	57 (15)	46 (20)	36 (23)	32 (25)	28 (26)	23 (30)	20 (32)	17 (35)	14 (37)	12 (39)	9 (42)	6 (44)	5 (45)	4 (45)	3 (46)	0 (48)	0 (48)	0 (48)	0 (48)	0 (48)
Placebo	89 (0)	49 (26)	40 (30)	31 (34)	22 (41)	14 (44)	13 (45)	13 (45)	8 (48)	4 (50)	4 (50)	4 (50)	2 (51)	2 (51)	2 (51)	1 (52)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



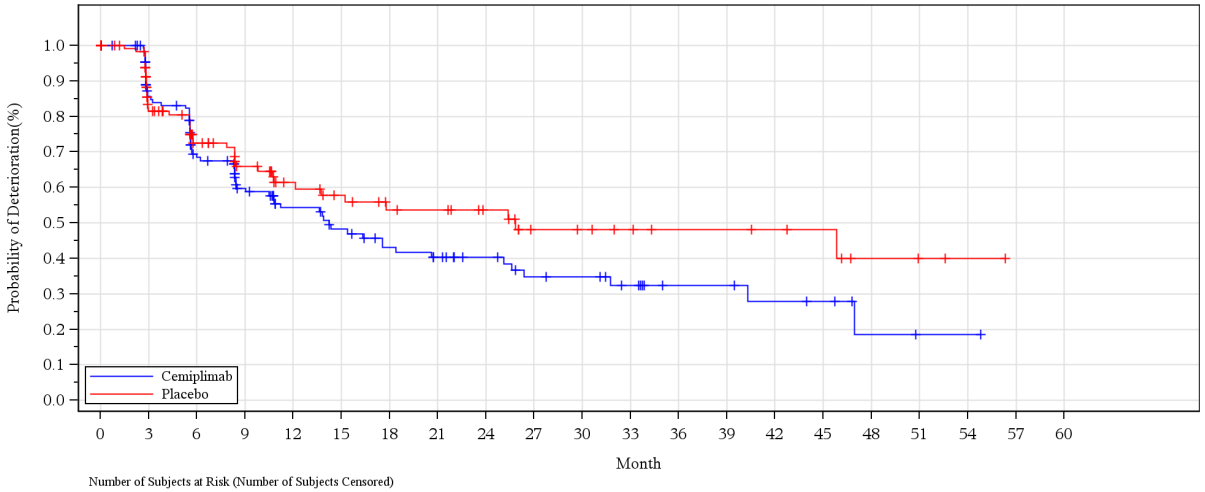
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (9)	29 (12)	23 (13)	20 (16)	17 (17)	15 (19)	13 (20)	10 (23)	8 (25)	4 (28)	3 (29)	3 (29)	3 (29)	3 (29)	2 (30)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)
Placebo	65 (0)	39 (8)	24 (14)	16 (16)	9 (22)	8 (23)	8 (23)	7 (23)	5 (24)	4 (25)	4 (25)	3 (26)	3 (26)	3 (26)	3 (26)	2 (27)	2 (27)	2 (27)	0 (29)	0 (29)	0 (29)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



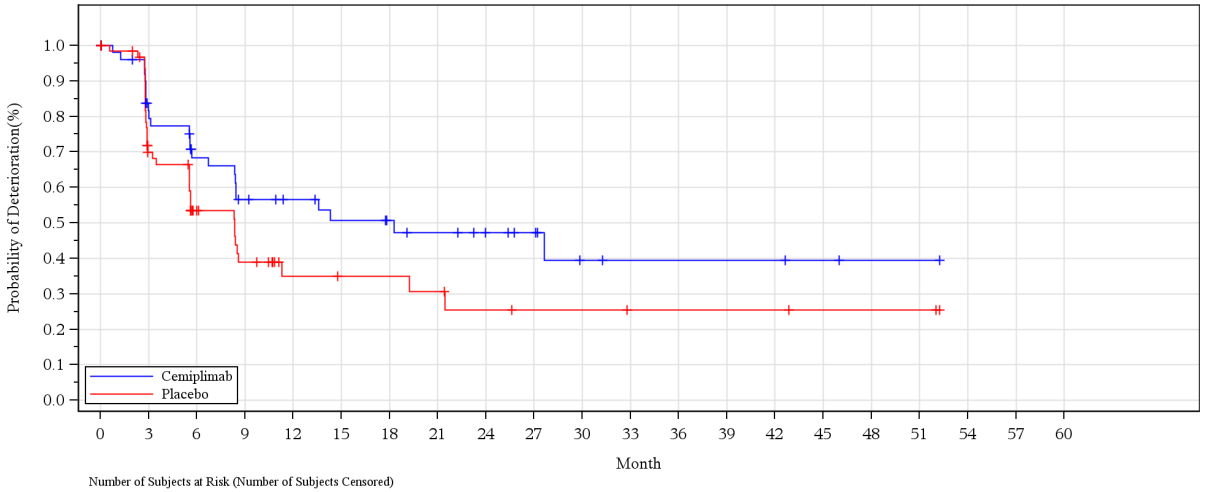
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	103 (32)	76 (39)	58 (48)	46 (55)	39 (57)	32 (60)	28 (62)	23 (67)	18 (69)	17 (70)	13 (73)	8 (78)	8 (78)	6 (79)	5 (80)	2 (82)	1 (83)	1 (83)	0 (84)	0 (84)
Placebo	141 (0)	82 (39)	60 (53)	47 (61)	35 (70)	30 (73)	25 (76)	24 (77)	20 (81)	13 (86)	12 (87)	10 (89)	8 (91)	8 (91)	7 (92)	6 (93)	3 (95)	2 (96)	1 (97)	0 (98)	0 (98)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



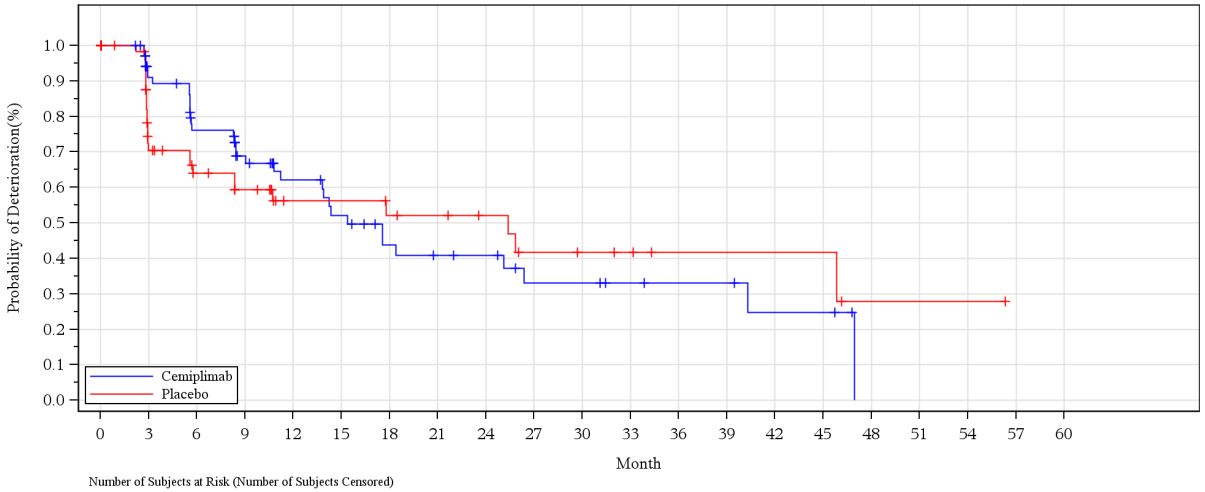
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (9)	29 (12)	23 (13)	20 (16)	17 (17)	15 (19)	13 (20)	10 (23)	8 (25)	4 (28)	3 (29)	3 (29)	3 (29)	3 (29)	2 (30)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)
Placebo	65 (0)	39 (8)	24 (14)	16 (16)	9 (22)	8 (23)	8 (23)	7 (23)	5 (24)	4 (25)	4 (25)	3 (26)	3 (26)	3 (26)	3 (26)	2 (27)	2 (27)	2 (27)	0 (29)	0 (29)	0 (29)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



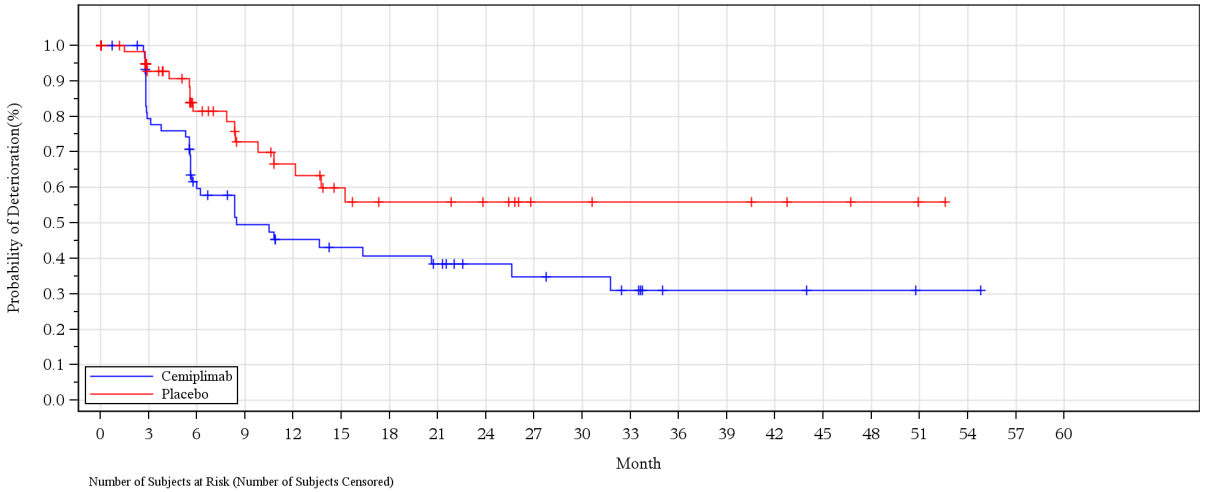
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	57 (17)	45 (20)	34 (27)	26 (32)	21 (33)	15 (36)	13 (37)	12 (38)	8 (40)	8 (40)	6 (42)	5 (43)	5 (43)	3 (44)	3 (44)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)
Placebo	69 (0)	36 (17)	28 (22)	23 (25)	15 (32)	15 (32)	13 (33)	12 (34)	10 (36)	7 (37)	6 (38)	5 (39)	3 (41)	3 (41)	3 (41)	3 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	46 (15)	31 (19)	24 (21)	20 (23)	18 (24)	17 (24)	15 (25)	11 (29)	10 (29)	9 (30)	7 (31)	3 (35)	3 (35)	3 (35)	2 (36)	2 (36)	1 (37)	1 (37)	0 (38)	0 (38)
Placebo	72 (0)	46 (22)	32 (31)	24 (36)	20 (38)	15 (41)	12 (43)	12 (43)	10 (45)	6 (49)	6 (49)	5 (50)	5 (50)	5 (50)	4 (51)	3 (52)	2 (53)	1 (54)	0 (55)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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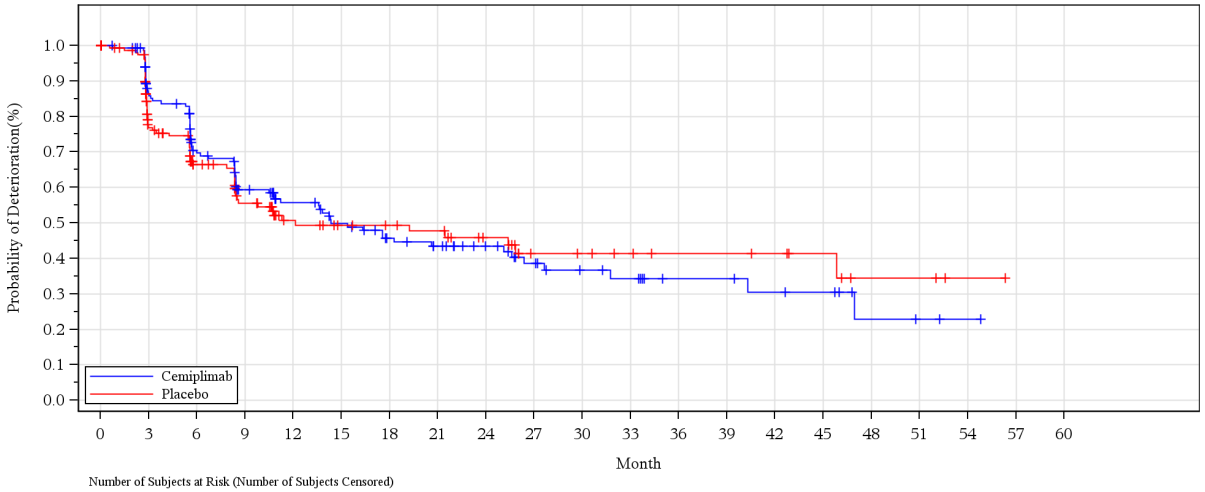
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	123 (31)	90 (41)	71 (47)	59 (55)	50 (58)	41 (63)	36 (66)	29 (73)	22 (77)	17 (81)	15 (82)	10 (87)	10 (87)	8 (88)	7 (89)	3 (92)	2 (93)	1 (94)	0 (95)	0 (95)
Placebo	174 (0)	101 (40)	72 (56)	54 (63)	37 (76)	32 (80)	30 (82)	28 (83)	22 (88)	14 (94)	13 (95)	11 (97)	9 (99)	9 (99)	8 (100)	6 (102)	3 (104)	3 (104)	1 (106)	0 (107)	0 (107)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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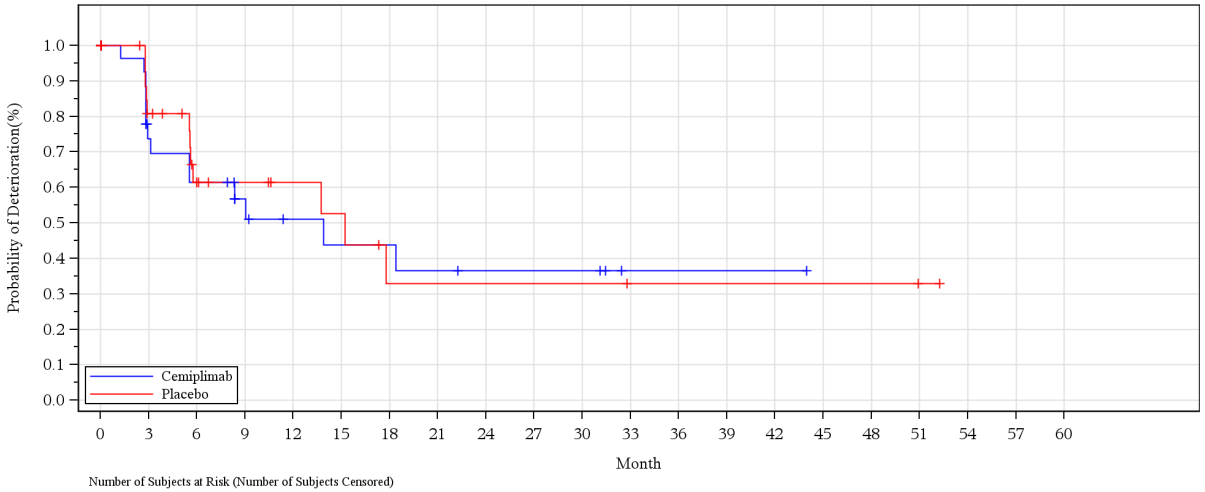
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



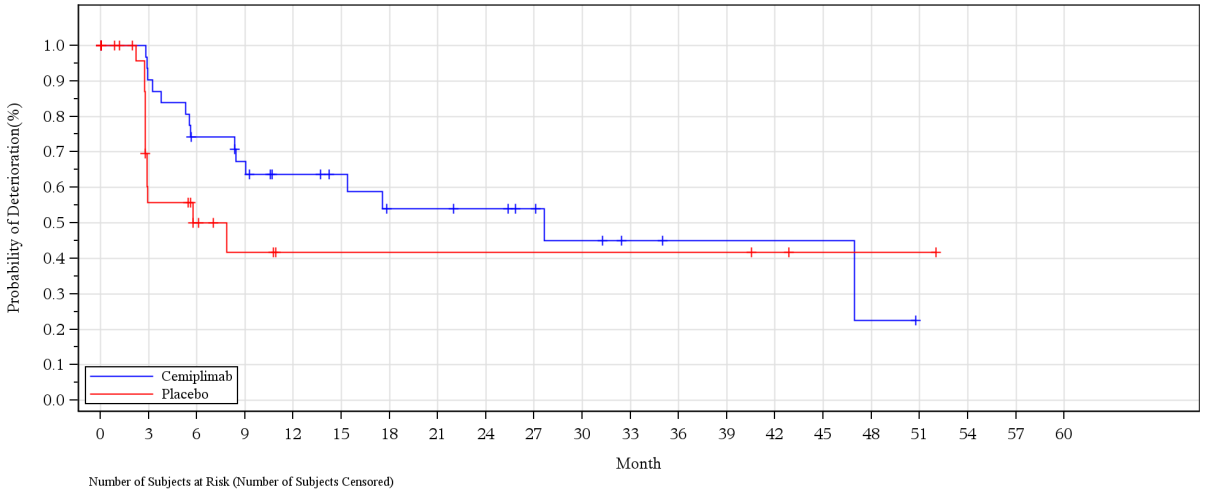
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	18 (10)	15 (10)	10 (14)	7 (16)	6 (16)	6 (16)	5 (16)	4 (17)	4 (17)	4 (17)	1 (20)	1 (20)	1 (20)	1 (20)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)
Placebo	32 (0)	20 (7)	12 (11)	9 (14)	7 (16)	6 (16)	3 (17)	3 (17)	3 (17)	3 (17)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



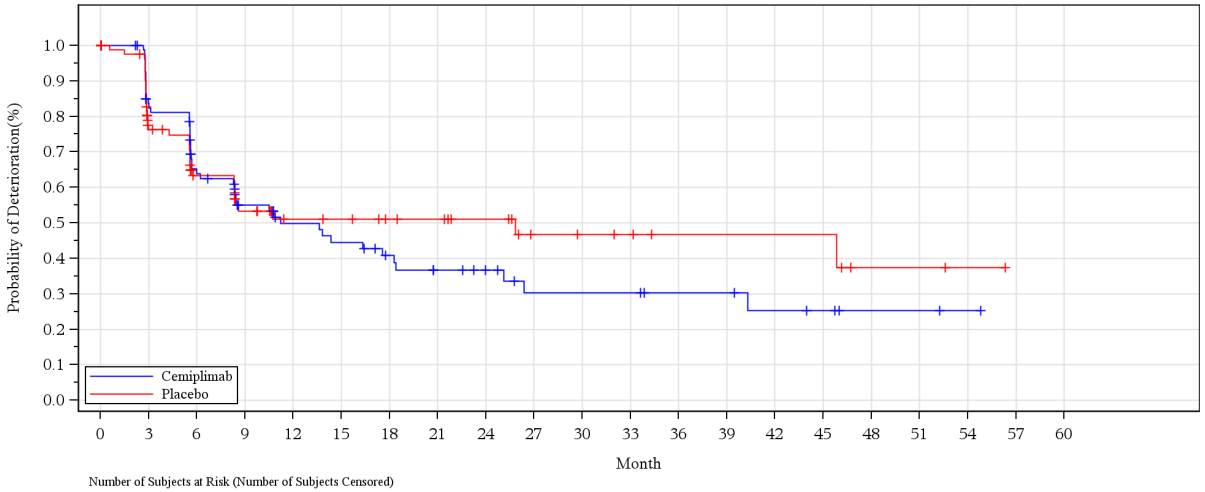
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	28 (6)	22 (7)	19 (8)	15 (11)	13 (13)	10 (14)	10 (14)	9 (15)	7 (17)	5 (18)	3 (20)	2 (21)	2 (21)	2 (21)	2 (21)	1 (21)	0 (22)	0 (22)	0 (22)	0 (22)
Placebo	31 (0)	12 (9)	8 (12)	5 (14)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	2 (17)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



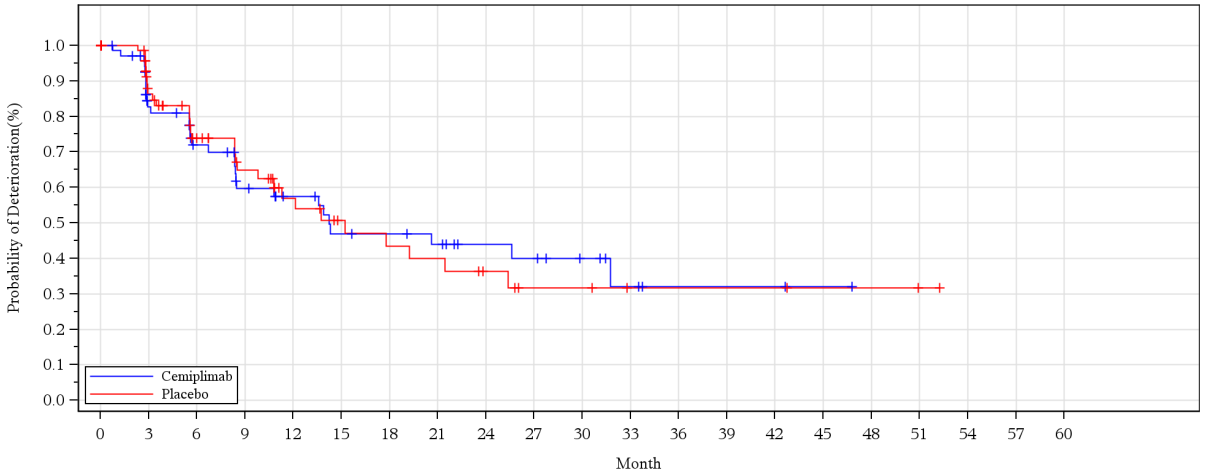
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	65 (12)	46 (16)	34 (22)	28 (25)	25 (25)	20 (28)	16 (30)	13 (33)	9 (35)	9 (35)	9 (35)	7 (37)	7 (37)	5 (38)	4 (39)	2 (41)	2 (41)	1 (42)	0 (43)	0 (43)
Placebo	90 (0)	56 (15)	39 (23)	30 (26)	22 (33)	21 (34)	18 (37)	17 (38)	14 (41)	9 (45)	8 (46)	7 (47)	5 (49)	5 (49)	5 (49)	5 (49)	2 (51)	2 (51)	1 (52)	0 (53)	0 (53)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	48 (23)	37 (28)	28 (31)	23 (35)	18 (36)	17 (37)	15 (38)	11 (42)	10 (42)	7 (45)	4 (47)	2 (49)	2 (49)	2 (49)	1 (50)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	85 (0)	53 (23)	37 (32)	28 (37)	19 (43)	14 (46)	12 (46)	11 (46)	8 (48)	5 (50)	5 (50)	3 (52)	3 (52)	3 (52)	3 (52)	2 (53)	2 (53)	1 (54)	0 (55)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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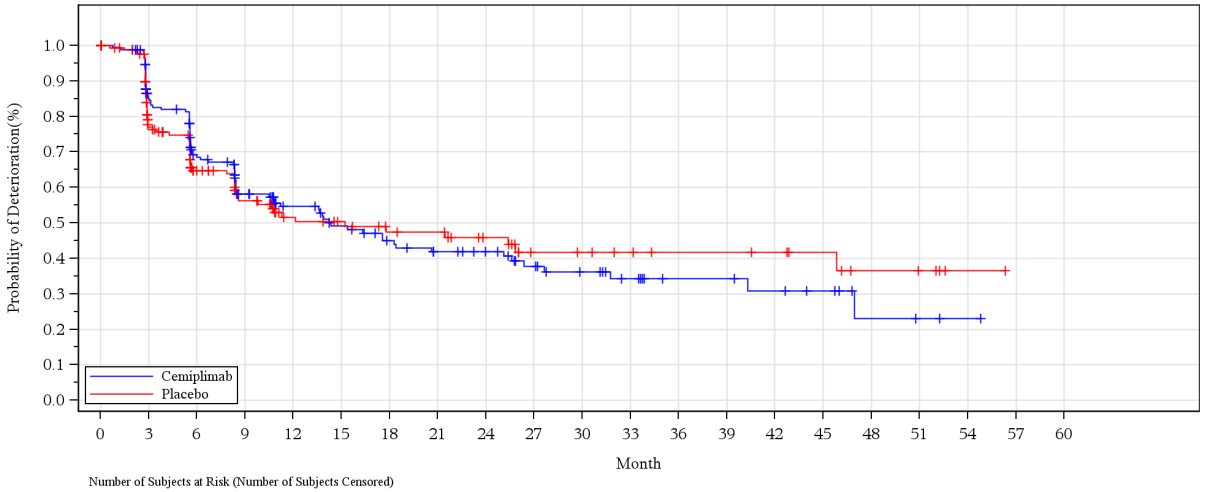
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



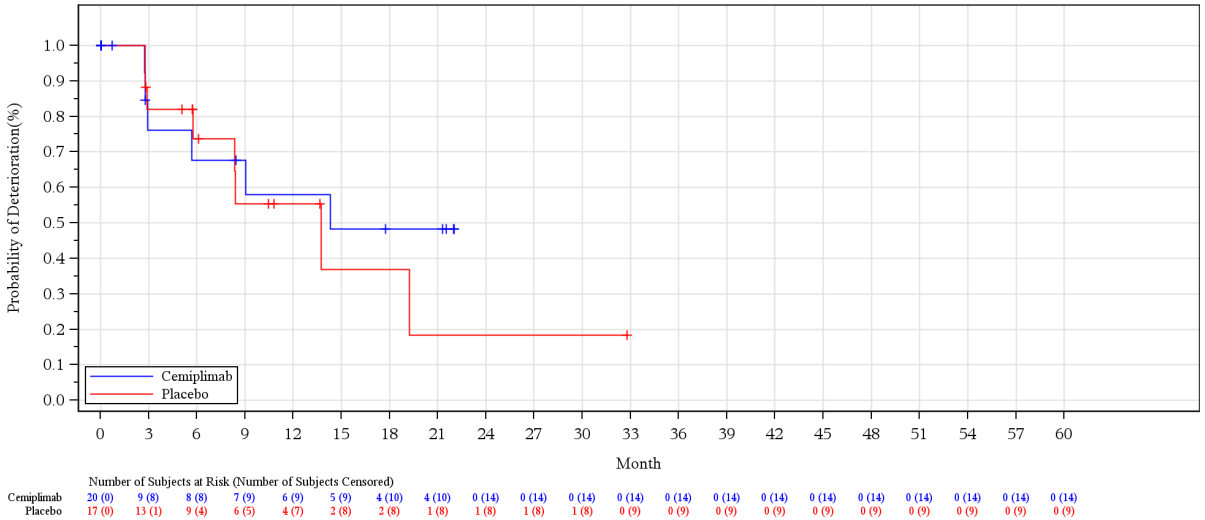
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	132 (33)	97 (43)	74 (52)	60 (62)	51 (65)	43 (69)	37 (72)	33 (76)	26 (80)	21 (84)	16 (88)	11 (93)	11 (93)	9 (94)	7 (96)	3 (99)	2 (100)	1 (101)	0 (102)	0 (102)
Placebo	189 (0)	108 (46)	75 (63)	57 (72)	40 (85)	36 (88)	31 (91)	30 (92)	24 (97)	16 (103)	15 (104)	13 (106)	11 (108)	11 (108)	10 (109)	8 (111)	5 (113)	4 (114)	1 (117)	0 (118)	0 (118)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



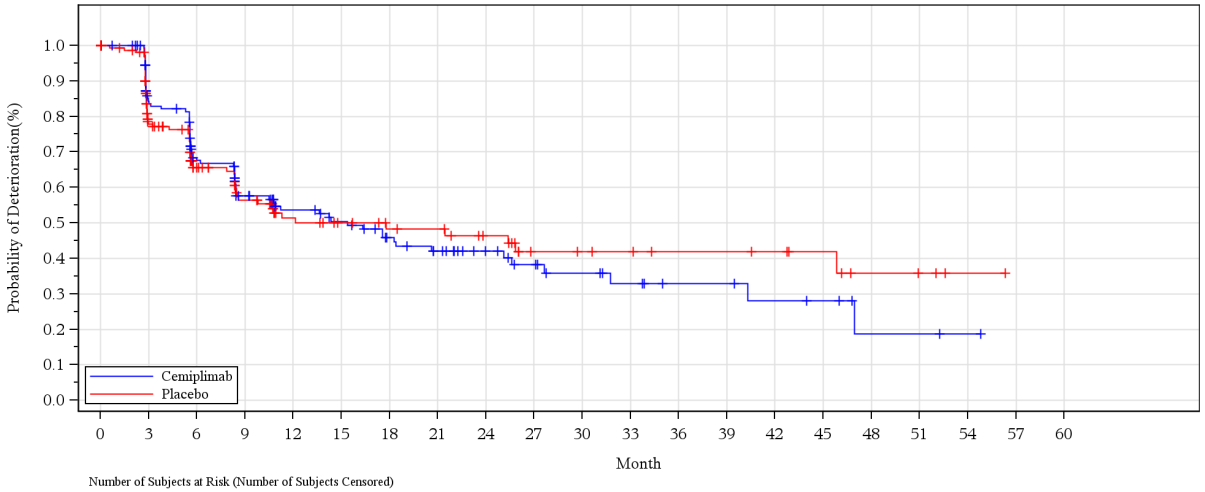
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (8)	8 (8)	7 (9)	6 (9)	5 (9)	4 (10)	4 (10)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)
Placebo	17 (0)	13 (1)	9 (4)	6 (5)	4 (7)	2 (8)	2 (8)	1 (8)	1 (8)	1 (8)	1 (8)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



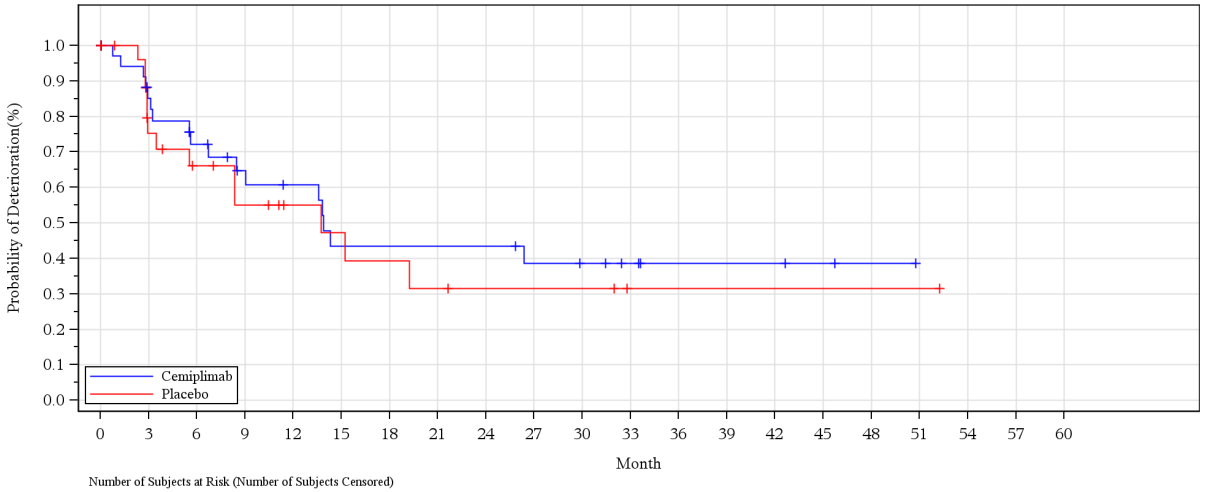
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	114 (30)	84 (38)	65 (45)	52 (54)	46 (57)	37 (62)	31 (65)	23 (73)	18 (76)	14 (79)	11 (81)	8 (84)	8 (84)	6 (85)	5 (86)	2 (88)	2 (88)	1 (89)	0 (90)	0 (90)
Placebo	177 (0)	104 (41)	71 (59)	53 (68)	37 (80)	32 (84)	28 (87)	27 (88)	22 (92)	14 (98)	13 (99)	12 (100)	10 (102)	10 (102)	9 (103)	7 (105)	4 (107)	3 (108)	1 (110)	0 (111)	0 (111)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



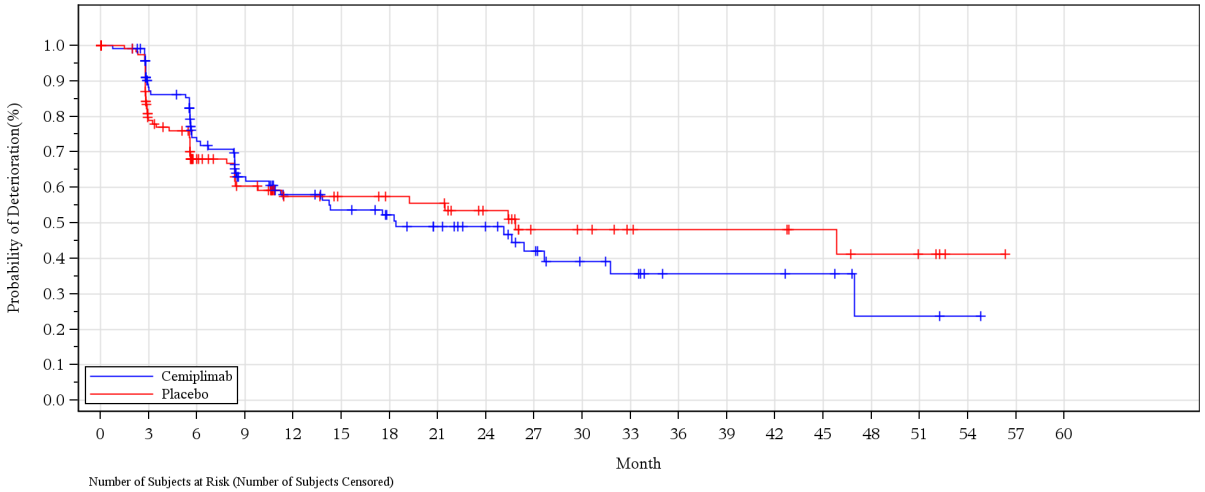
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	27 (11)	21 (13)	16 (16)	14 (17)	10 (17)	10 (17)	10 (17)	10 (17)	8 (18)	7 (19)	5 (21)	3 (23)	3 (23)	3 (23)	2 (24)	1 (25)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	29 (0)	17 (6)	13 (8)	10 (9)	7 (12)	6 (12)	5 (12)	4 (12)	3 (13)	3 (13)	3 (13)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



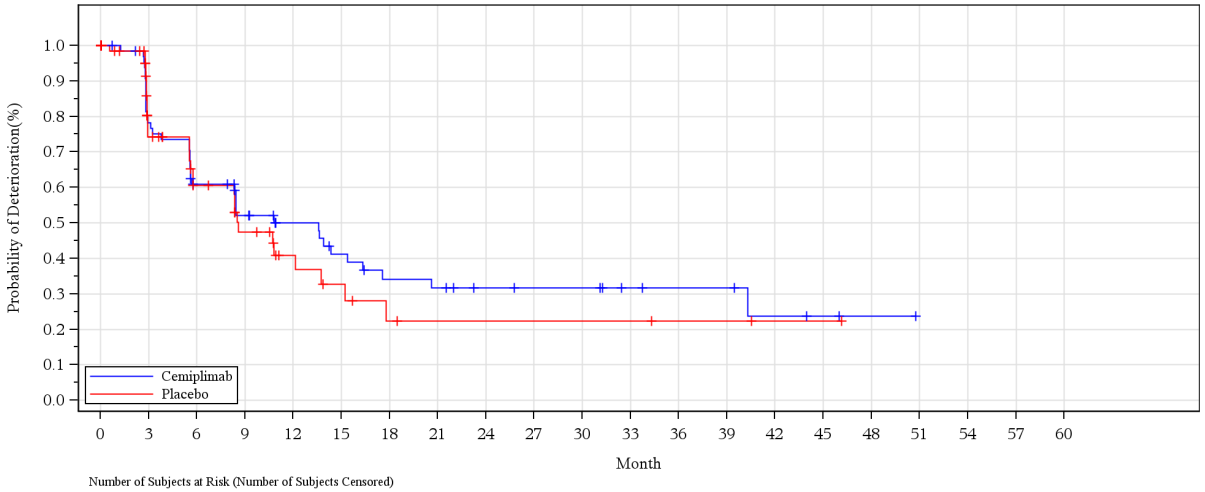
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	91 (29)	68 (37)	52 (44)	43 (49)	38 (51)	33 (55)	28 (58)	23 (63)	17 (66)	12 (70)	10 (71)	6 (75)	6 (75)	6 (75)	5 (76)	2 (78)	2 (78)	1 (79)	0 (80)	0 (80)
Placebo	131 (0)	84 (23)	59 (37)	46 (44)	34 (54)	31 (57)	29 (59)	28 (59)	22 (64)	14 (70)	13 (71)	10 (74)	9 (75)	9 (75)	9 (75)	7 (77)	5 (78)	4 (79)	1 (82)	0 (83)	0 (83)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	50 (12)	37 (14)	29 (17)	23 (22)	18 (23)	14 (24)	13 (24)	10 (27)	9 (28)	9 (28)	6 (31)	5 (32)	5 (32)	3 (33)	2 (34)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)
Placebo	75 (0)	37 (24)	25 (30)	17 (33)	10 (38)	7 (39)	4 (40)	3 (41)	3 (41)	3 (41)	3 (41)	3 (41)	2 (42)	2 (42)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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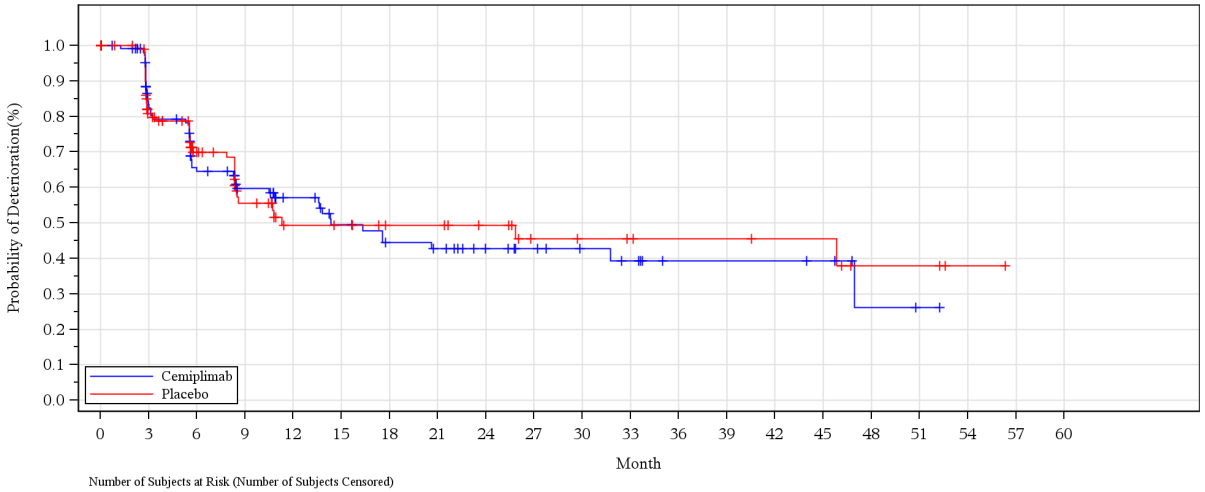
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	82 (26)	59 (31)	48 (38)	39 (45)	31 (48)	26 (50)	24 (51)	18 (57)	15 (60)	12 (63)	10 (64)	6 (68)	6 (68)	6 (68)	5 (69)	2 (71)	1 (72)	0 (73)	0 (73)	0 (73)
Placebo	117 (0)	74 (24)	49 (40)	32 (48)	22 (55)	21 (56)	18 (59)	18 (59)	15 (62)	10 (66)	9 (67)	8 (68)	7 (69)	7 (69)	6 (70)	6 (70)	3 (72)	3 (72)	1 (74)	0 (75)	0 (75)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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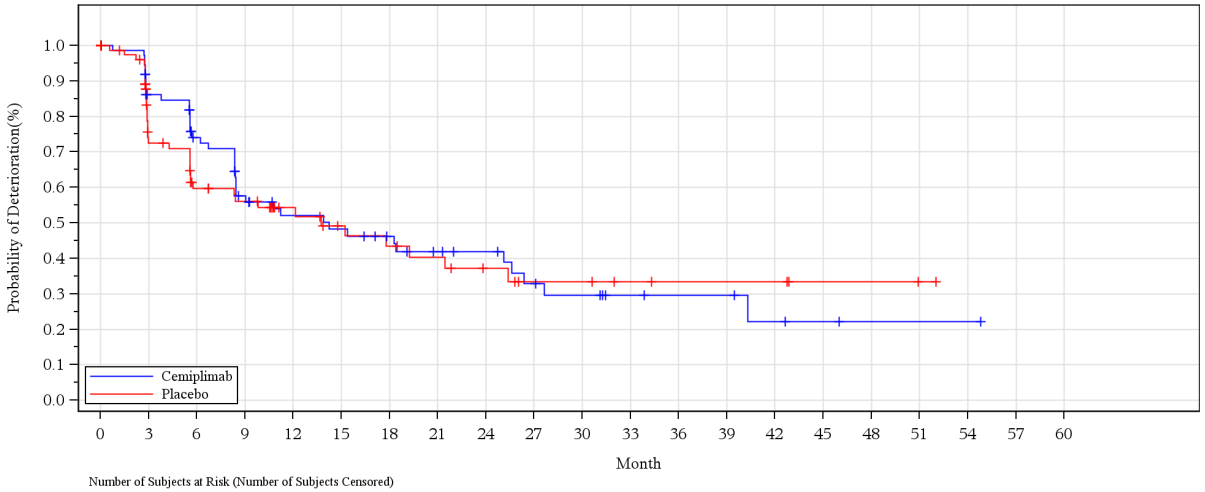
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



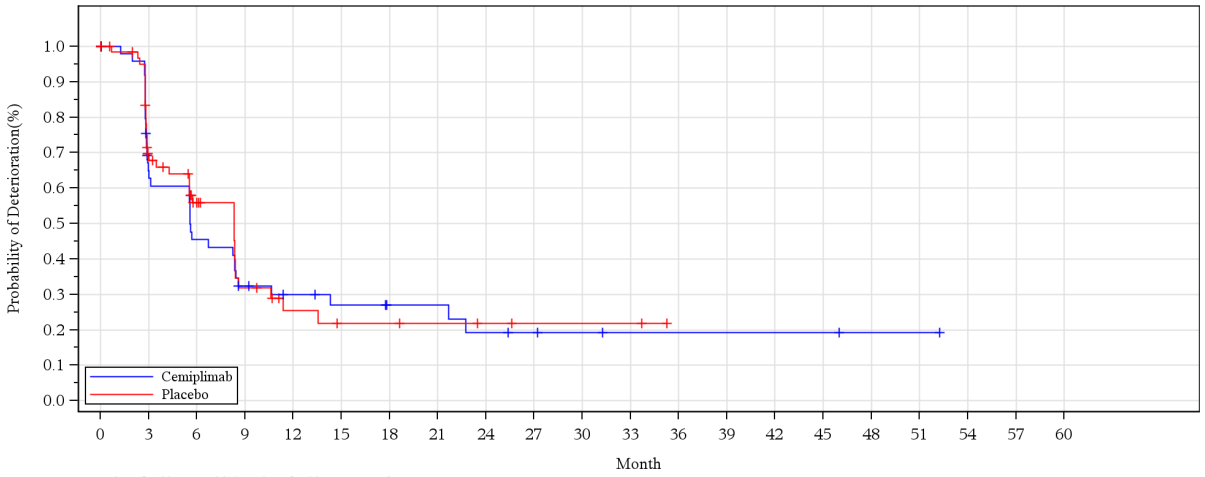
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	59 (15)	46 (20)	33 (23)	27 (26)	25 (26)	21 (29)	17 (31)	15 (33)	11 (34)	9 (35)	6 (38)	5 (39)	5 (39)	3 (40)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)
Placebo	89 (0)	47 (23)	35 (27)	31 (29)	22 (37)	17 (40)	15 (40)	13 (41)	10 (43)	7 (45)	7 (45)	5 (47)	4 (48)	4 (48)	4 (48)	2 (50)	2 (50)	1 (51)	0 (52)	0 (52)	0 (52)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



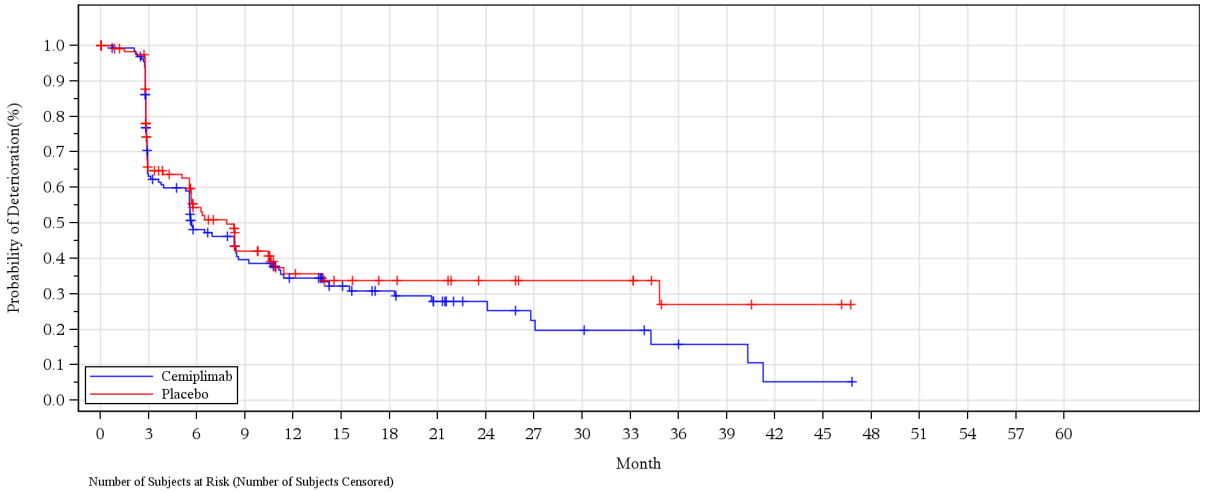
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	30 (9)	21 (9)	14 (10)	11 (12)	9 (13)	7 (15)	7 (15)	5 (15)	4 (16)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)
Placebo	65 (0)	38 (9)	24 (16)	12 (19)	7 (22)	5 (23)	5 (23)	4 (24)	3 (25)	2 (26)	2 (26)	2 (26)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



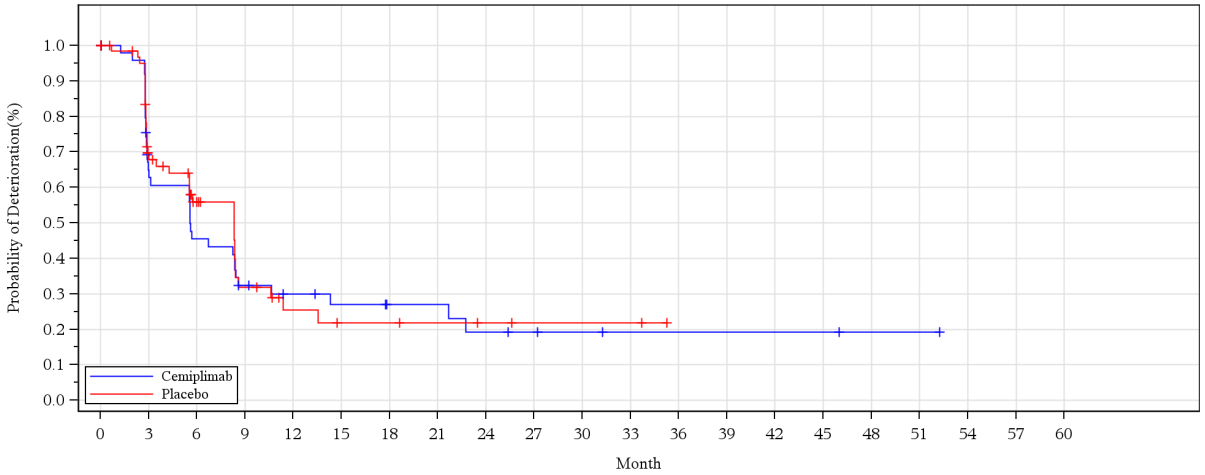
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	78 (28)	54 (34)	41 (38)	32 (42)	26 (46)	21 (50)	16 (53)	11 (58)	8 (59)	7 (59)	6 (60)	3 (62)	3 (62)	1 (62)	1 (62)	0 (63)	0 (63)	0 (63)	0 (63)	0 (63)
Placebo	141 (0)	67 (35)	48 (44)	31 (51)	20 (58)	16 (61)	14 (63)	13 (64)	10 (67)	8 (69)	8 (69)	8 (69)	3 (73)	3 (73)	2 (74)	2 (74)	0 (76)	0 (76)	0 (76)	0 (76)	0 (76)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



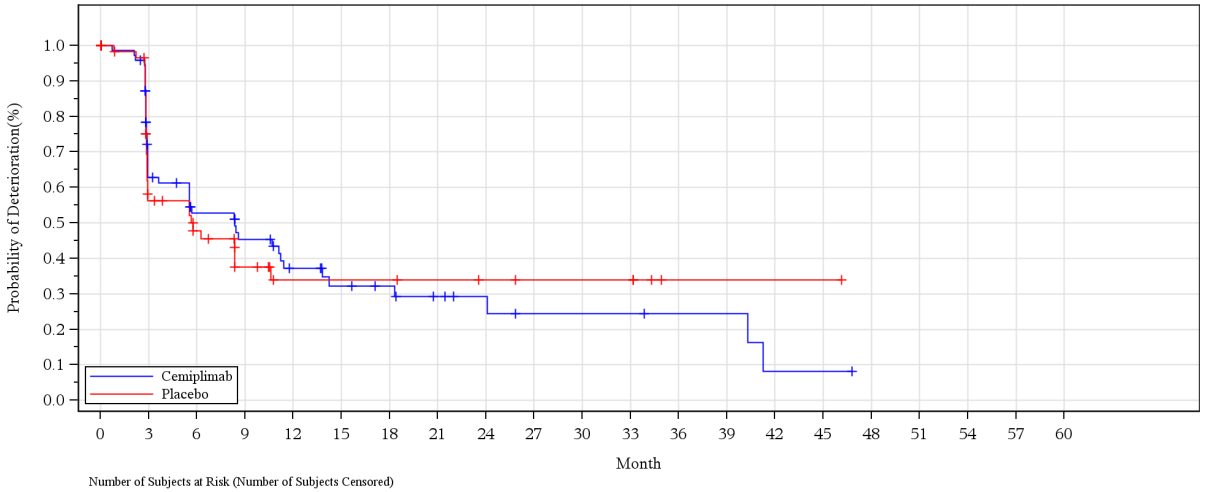
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	30 (9)	21 (9)	14 (10)	11 (12)	9 (13)	7 (15)	7 (15)	5 (15)	4 (16)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)
Placebo	65 (0)	38 (9)	24 (16)	12 (19)	7 (22)	5 (23)	5 (23)	4 (24)	3 (25)	2 (26)	2 (26)	2 (26)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



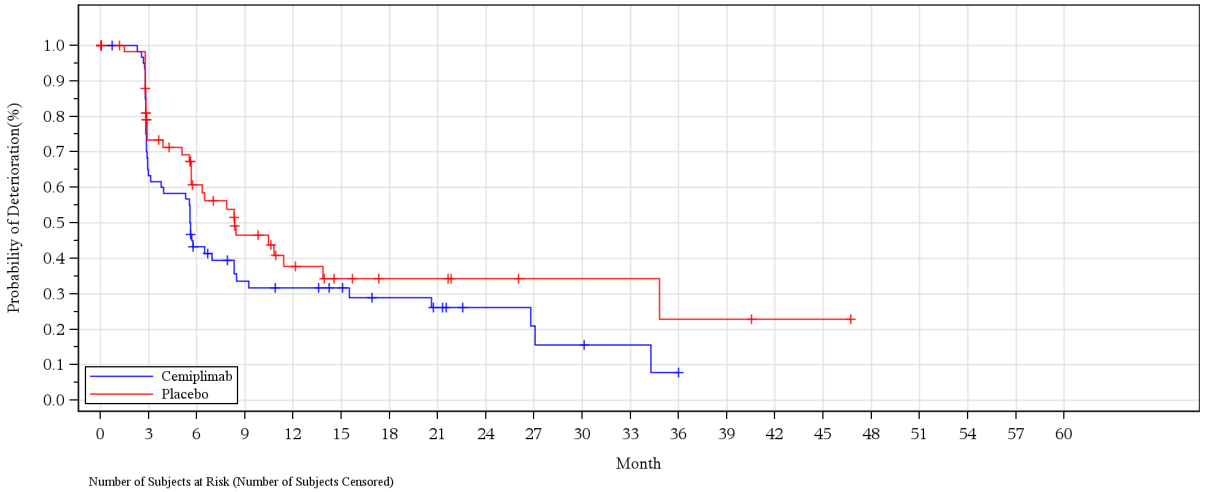
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	40 (15)	30 (19)	24 (21)	17 (24)	13 (26)	11 (28)	8 (30)	6 (32)	4 (33)	4 (33)	4 (33)	3 (34)	3 (34)	1 (34)	1 (34)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)
Placebo	69 (0)	29 (16)	21 (20)	13 (24)	8 (28)	8 (28)	8 (28)	7 (29)	6 (30)	5 (31)	5 (31)	5 (31)	1 (35)	1 (35)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)	0 (36)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



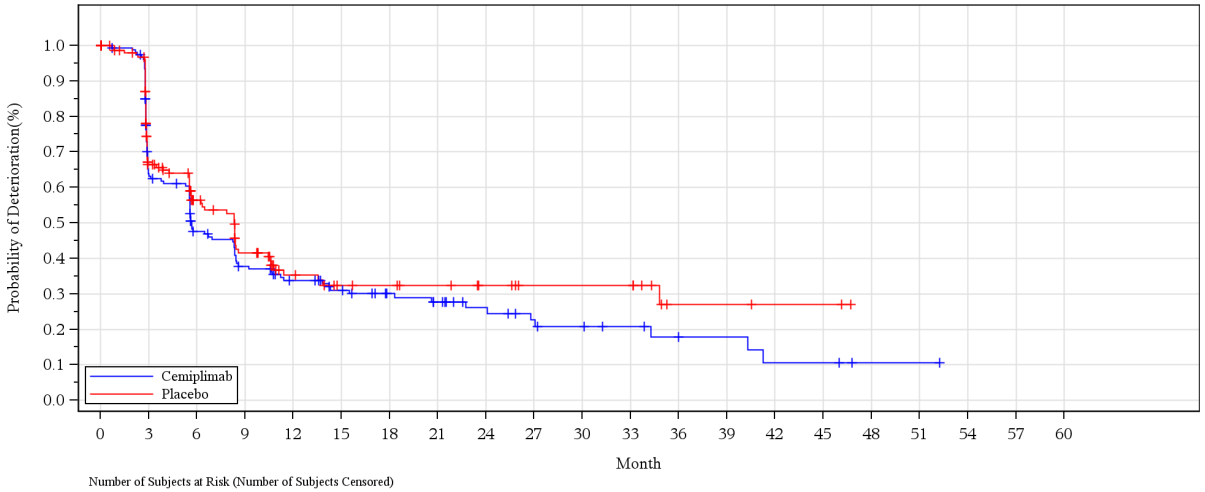
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	38 (13)	24 (15)	17 (17)	15 (18)	13 (20)	10 (22)	8 (23)	5 (26)	4 (26)	3 (26)	2 (27)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	72 (0)	38 (19)	27 (24)	18 (27)	12 (30)	8 (33)	6 (35)	6 (35)	4 (37)	3 (38)	3 (38)	3 (38)	2 (38)	2 (38)	1 (39)	1 (39)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Gender group: Male



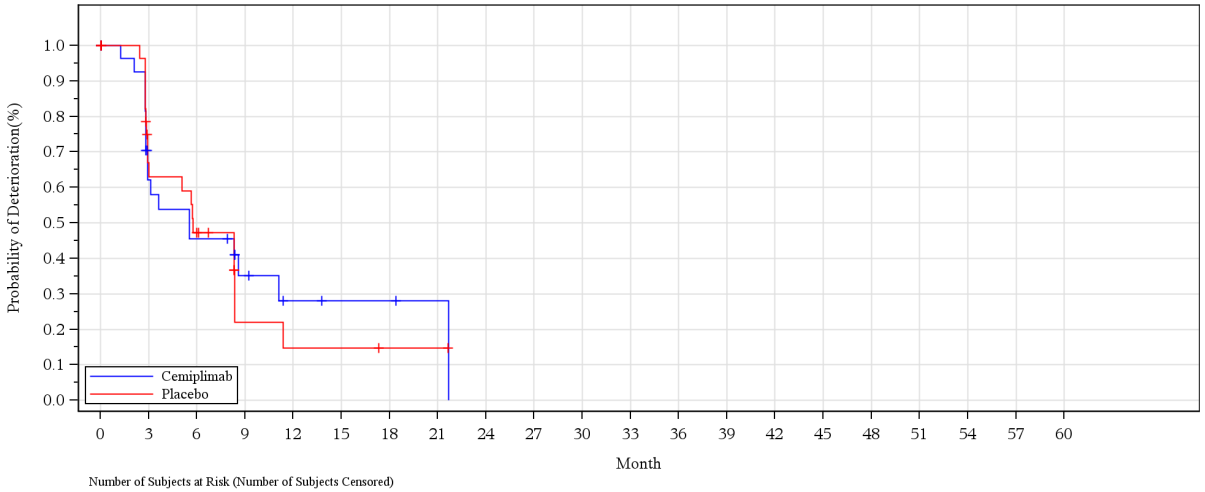
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	93 (27)	64 (33)	49 (35)	40 (39)	33 (43)	26 (49)	22 (51)	16 (56)	12 (58)	10 (59)	8 (61)	5 (63)	5 (63)	3 (63)	3 (63)	1 (65)	1 (65)	0 (66)	0 (66)	0 (66)
Placebo	174 (0)	88 (38)	60 (54)	40 (59)	25 (69)	19 (73)	18 (74)	16 (76)	13 (79)	10 (82)	10 (82)	10 (82)	3 (88)	3 (88)	2 (89)	2 (89)	0 (91)	0 (91)	0 (91)	0 (91)	0 (91)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Gender group: Female



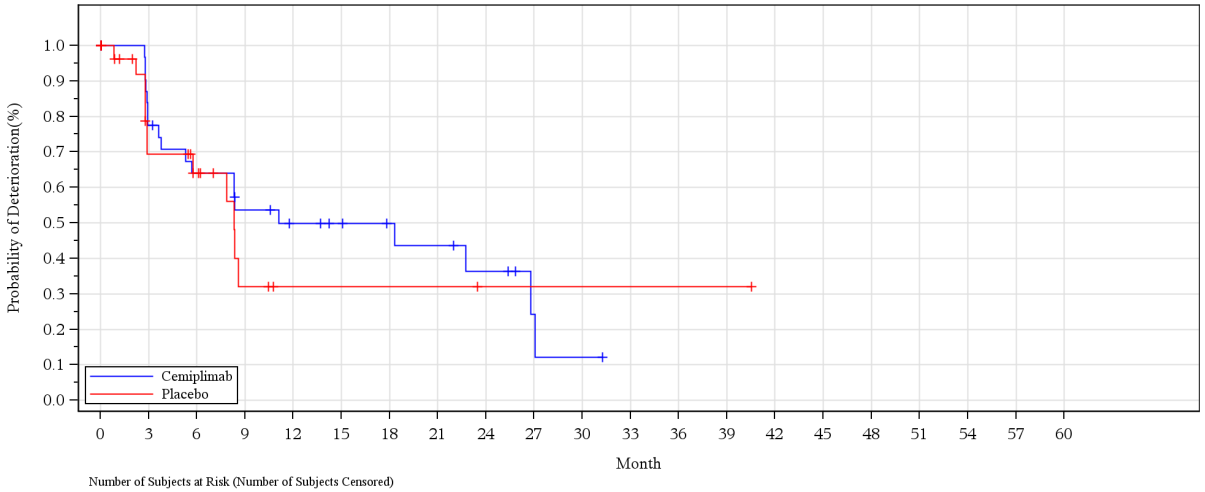
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	15 (10)	11 (10)	6 (13)	3 (15)	2 (16)	2 (16)	1 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	32 (0)	17 (6)	12 (6)	3 (11)	2 (11)	2 (11)	1 (12)	1 (12)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



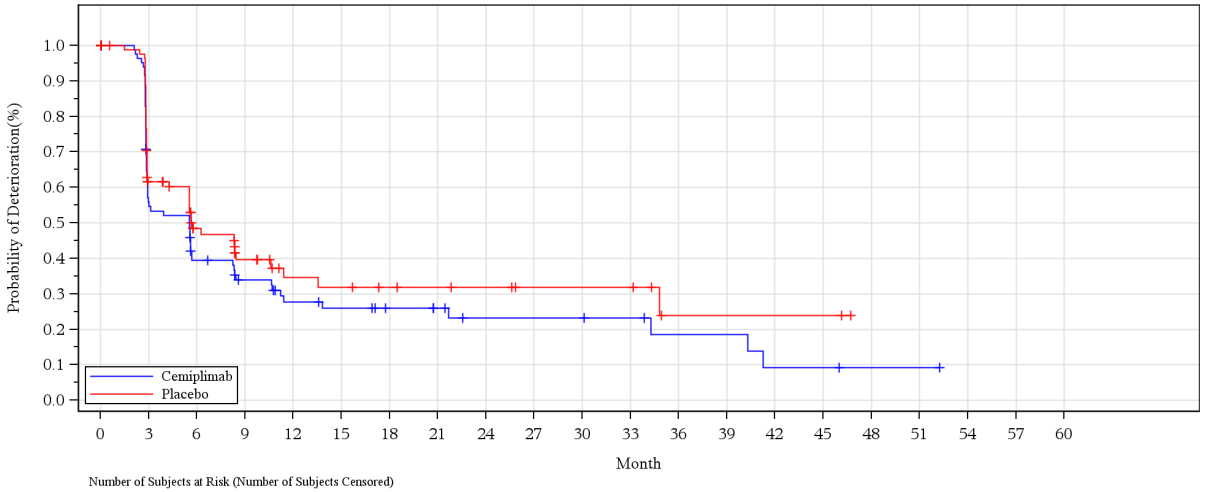
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	24 (6)	19 (7)	15 (8)	12 (10)	10 (12)	8 (14)	7 (14)	5 (15)	2 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	31 (0)	15 (9)	11 (12)	4 (15)	2 (17)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



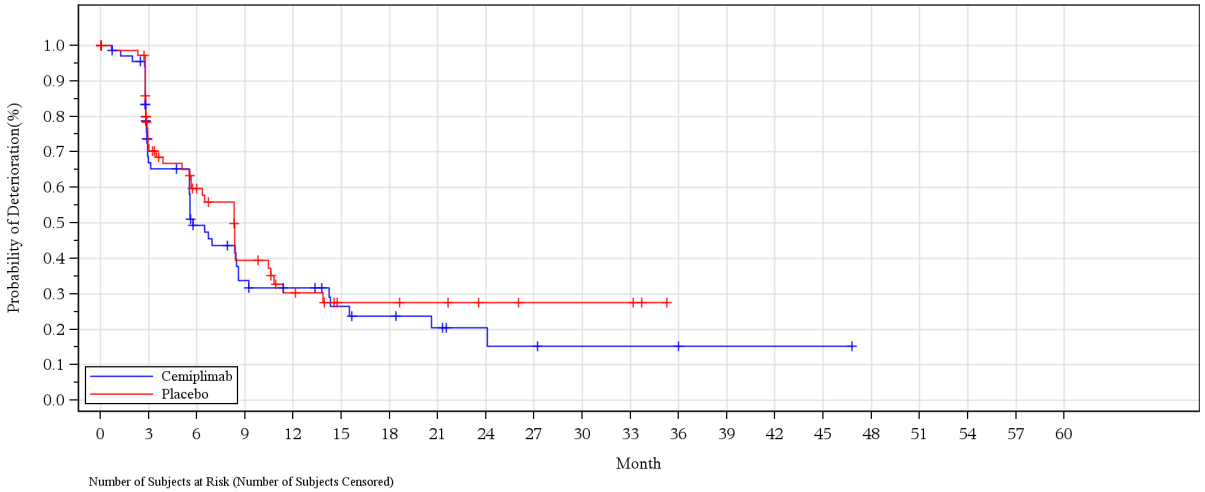
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	45 (9)	30 (11)	23 (14)	17 (16)	15 (17)	12 (20)	10 (22)	7 (24)	7 (24)	7 (24)	6 (25)	4 (26)	4 (26)	2 (26)	2 (26)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)
Placebo	90 (0)	46 (13)	29 (21)	20 (25)	13 (30)	12 (30)	10 (32)	9 (33)	8 (34)	6 (36)	6 (36)	6 (36)	2 (39)	2 (39)	2 (39)	2 (39)	0 (41)	0 (41)	0 (41)	0 (41)	0 (41)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	39 (22)	26 (25)	17 (26)	14 (28)	10 (30)	8 (31)	6 (32)	4 (34)	3 (34)	2 (35)	2 (35)	1 (36)	1 (36)	1 (36)	1 (36)	0 (37)	0 (37)	0 (37)	0 (37)	0 (37)
Placebo	85 (0)	44 (22)	32 (27)	19 (30)	12 (33)	7 (37)	7 (37)	6 (38)	4 (40)	3 (41)	3 (41)	3 (41)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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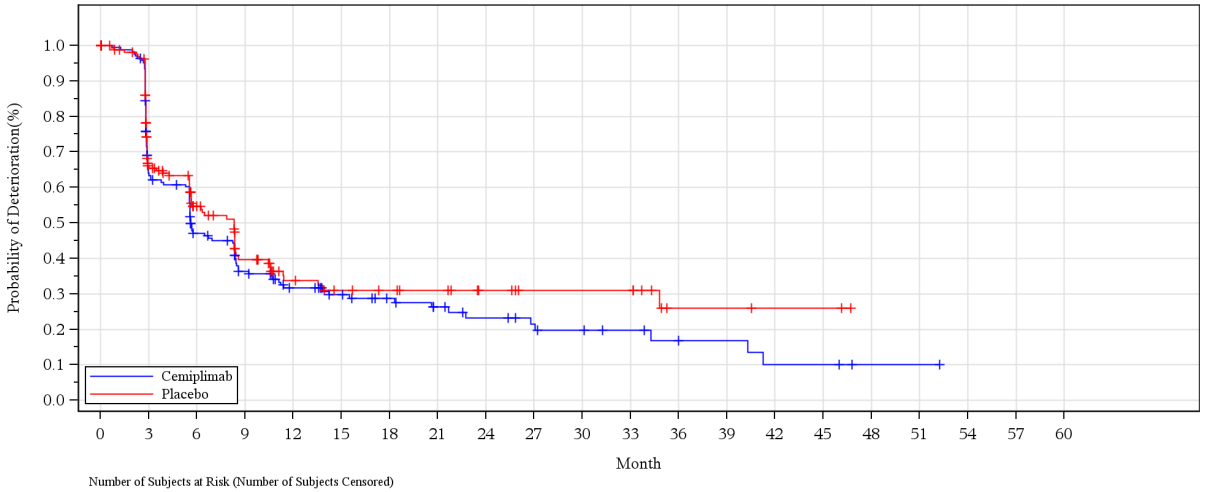
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	101 (29)	69 (35)	49 (40)	37 (46)	30 (51)	24 (56)	19 (59)	15 (61)	12 (63)	10 (64)	8 (66)	5 (68)	5 (68)	3 (68)	3 (68)	1 (70)	1 (70)	0 (71)	0 (71)	0 (71)
Placebo	189 (0)	94 (43)	64 (58)	40 (66)	26 (75)	21 (78)	19 (80)	17 (82)	13 (86)	10 (89)	10 (89)	10 (89)	3 (95)	3 (95)	2 (96)	2 (96)	0 (98)	0 (98)	0 (98)	0 (98)	0 (98)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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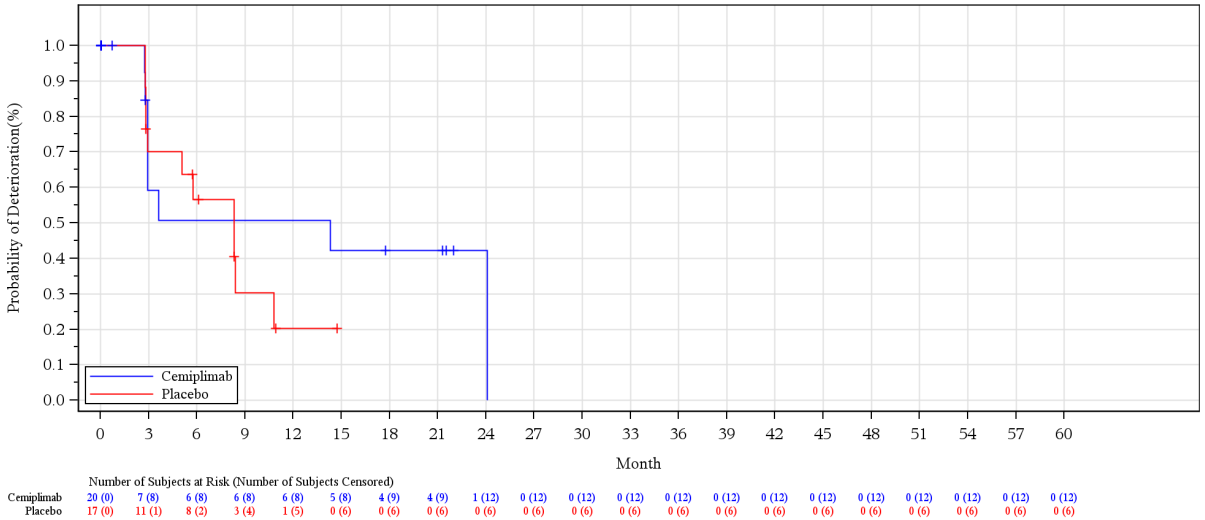
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	7 (8)	6 (8)	6 (8)	6 (8)	5 (8)	4 (9)	4 (9)	1 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)
Placebo	17 (0)	11 (1)	8 (2)	3 (4)	1 (5)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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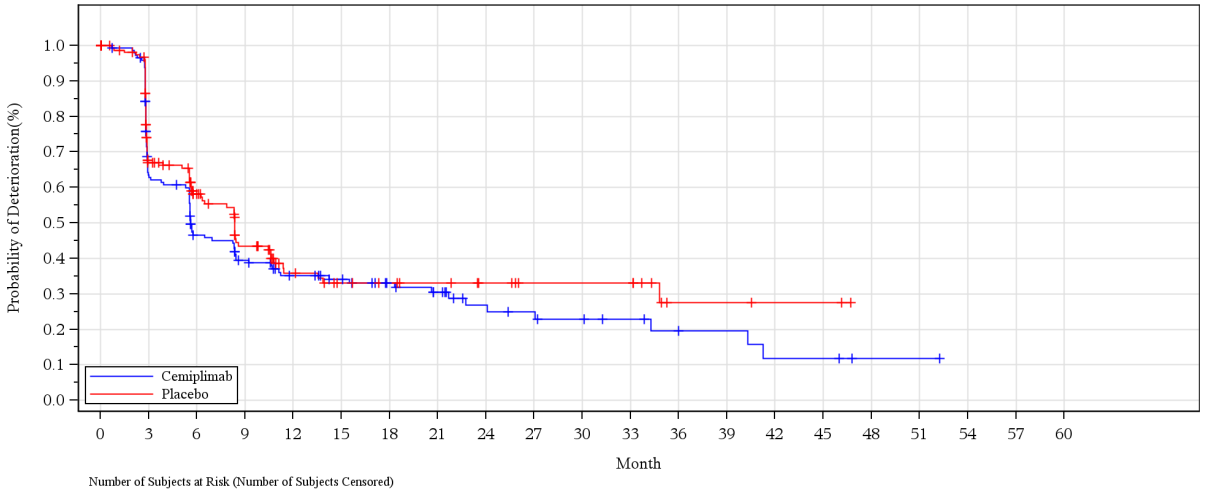
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	88 (26)	60 (31)	48 (34)	38 (39)	33 (43)	26 (49)	21 (52)	14 (57)	12 (58)	10 (59)	8 (61)	5 (63)	5 (63)	3 (63)	3 (63)	1 (65)	1 (65)	0 (66)	0 (66)	0 (66)
Placebo	177 (0)	91 (38)	65 (53)	42 (61)	26 (71)	20 (75)	18 (77)	16 (79)	13 (82)	10 (85)	10 (85)	10 (85)	3 (91)	3 (91)	2 (92)	2 (92)	0 (94)	0 (94)	0 (94)	0 (94)	0 (94)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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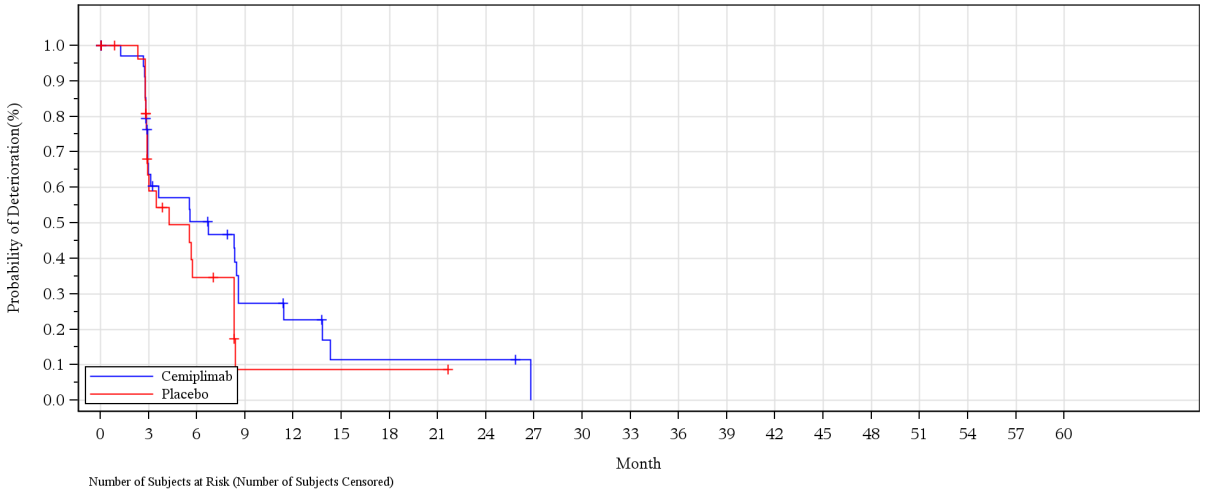
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



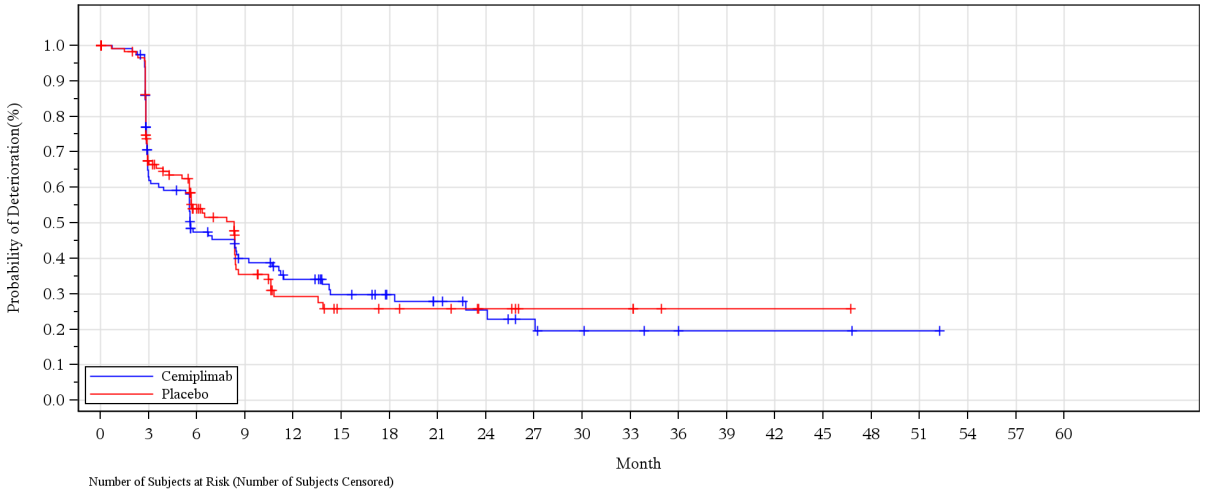
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	20 (11)	15 (12)	7 (14)	5 (15)	2 (16)	2 (16)	2 (16)	2 (16)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	29 (0)	14 (6)	7 (7)	1 (9)	1 (9)	1 (9)	1 (9)	1 (9)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



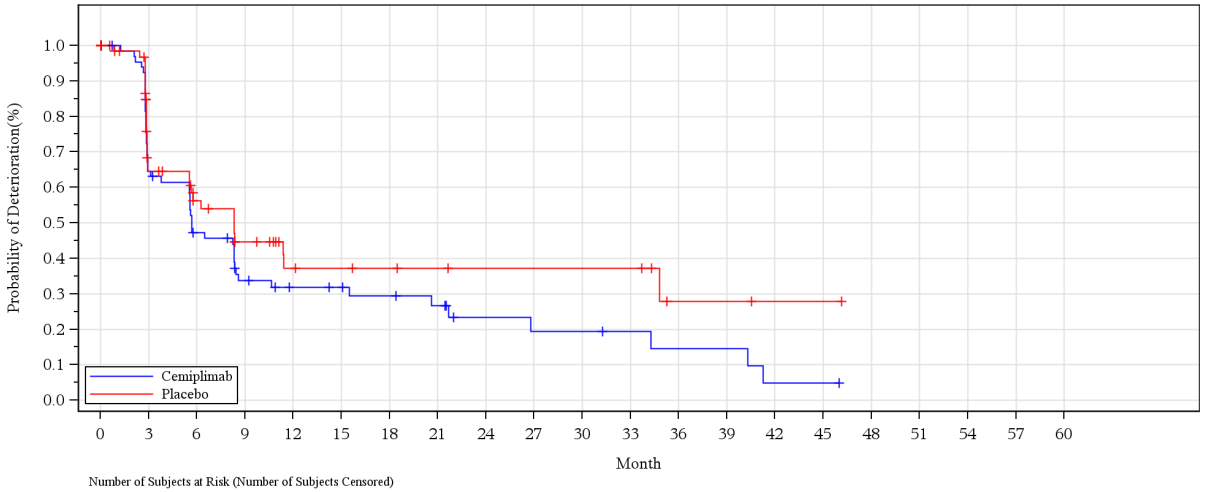
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	66 (26)	46 (30)	36 (33)	28 (36)	21 (40)	16 (45)	13 (47)	10 (49)	7 (51)	5 (52)	4 (53)	2 (55)	2 (55)	2 (55)	2 (55)	1 (56)	1 (56)	0 (57)	0 (57)	0 (57)
Placebo	131 (0)	71 (23)	47 (34)	26 (41)	17 (46)	12 (49)	11 (50)	10 (51)	7 (54)	4 (57)	4 (57)	4 (57)	1 (60)	1 (60)	1 (60)	1 (60)	0 (61)	0 (61)	0 (61)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	42 (11)	29 (13)	19 (15)	15 (18)	14 (19)	12 (20)	10 (21)	6 (24)	5 (24)	5 (24)	4 (25)	3 (25)	3 (25)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	75 (0)	34 (21)	25 (26)	17 (29)	10 (34)	9 (35)	8 (36)	7 (37)	6 (38)	6 (38)	6 (38)	6 (38)	2 (41)	2 (41)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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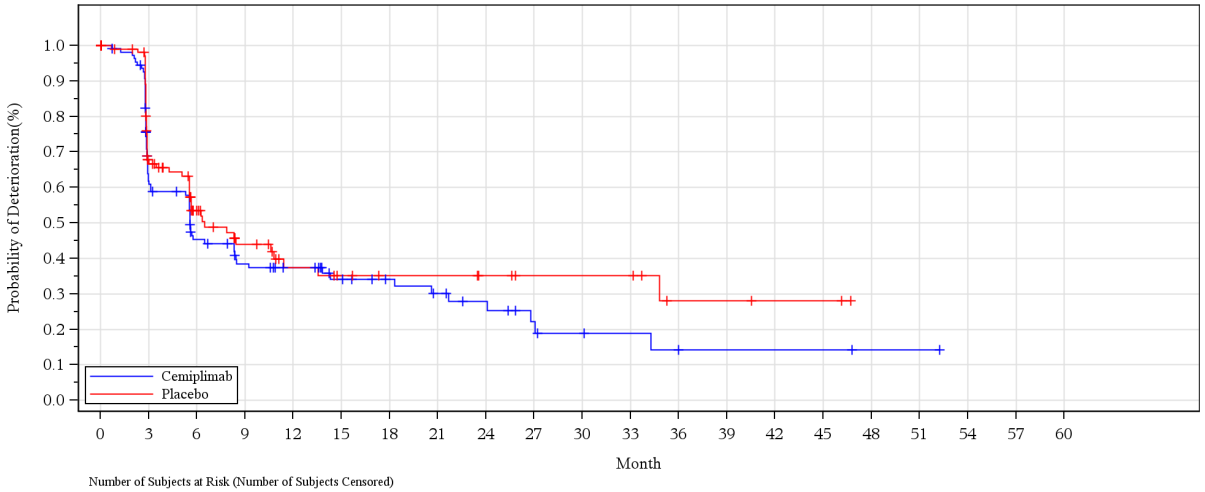
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



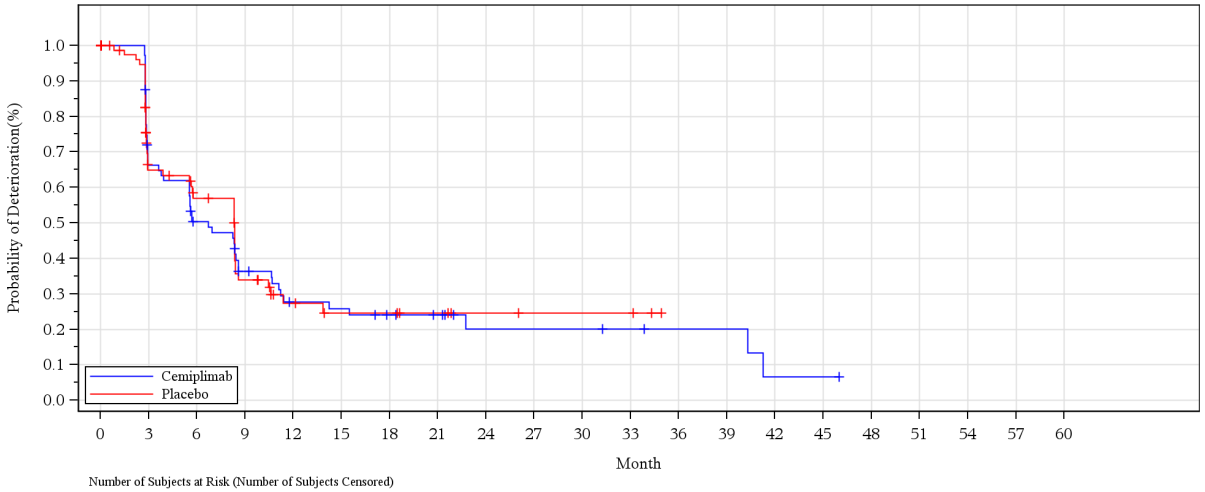
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	62 (23)	42 (27)	33 (30)	28 (34)	21 (39)	17 (43)	14 (44)	11 (46)	7 (48)	5 (49)	4 (50)	2 (51)	2 (51)	2 (51)	2 (51)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)
Placebo	117 (0)	63 (22)	38 (35)	24 (43)	16 (48)	13 (50)	11 (52)	11 (52)	9 (54)	7 (56)	7 (56)	7 (56)	3 (59)	3 (59)	2 (60)	2 (60)	0 (62)	0 (62)	0 (62)	0 (62)	0 (62)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



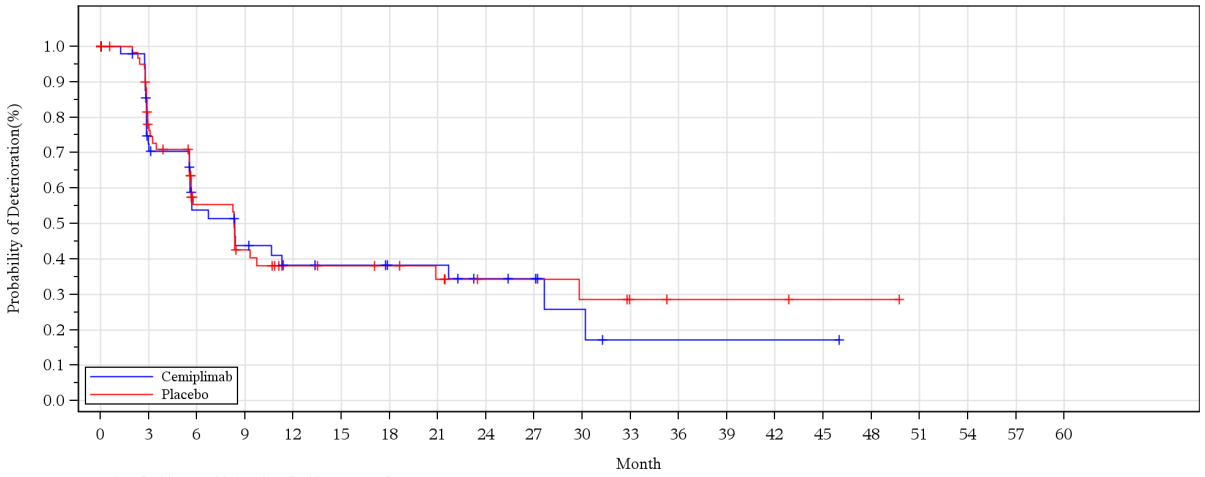
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	46 (14)	33 (16)	22 (18)	15 (20)	14 (20)	11 (22)	9 (24)	5 (27)	5 (27)	5 (27)	4 (28)	3 (29)	3 (29)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)	0 (30)
Placebo	89 (0)	42 (22)	34 (25)	19 (27)	11 (32)	8 (34)	8 (34)	6 (36)	4 (38)	3 (39)	3 (39)	3 (39)	0 (42)	0 (42)	0 (42)	0 (42)	0 (42)	0 (42)	0 (42)	0 (42)	0 (42)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



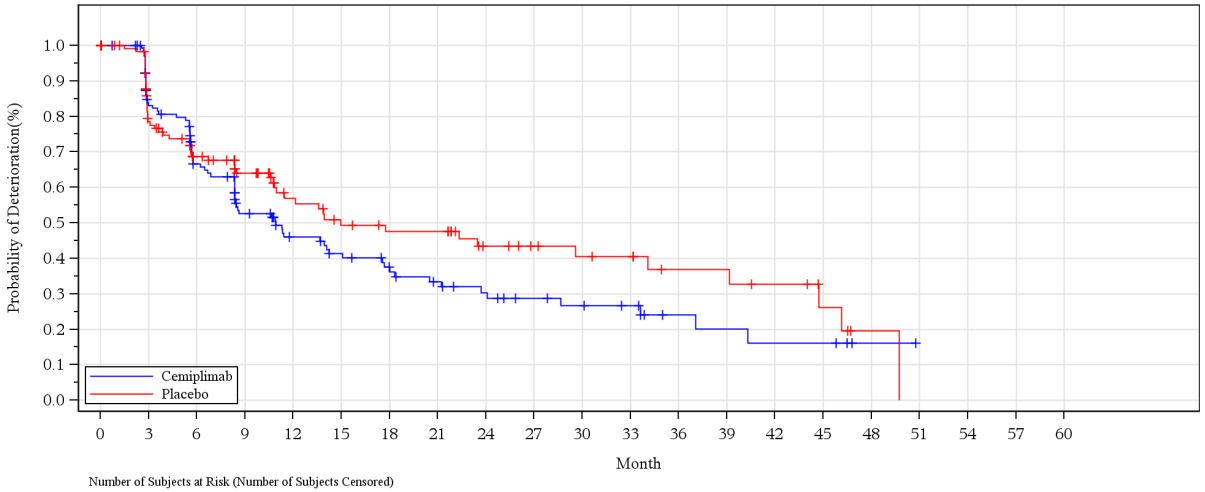
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	33 (10)	22 (13)	17 (14)	13 (16)	12 (17)	10 (19)	10 (19)	7 (21)	6 (22)	3 (24)	1 (25)	1 (25)	1 (25)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	65 (0)	44 (8)	26 (14)	19 (15)	13 (19)	12 (20)	11 (21)	9 (22)	6 (25)	6 (25)	5 (25)	3 (27)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



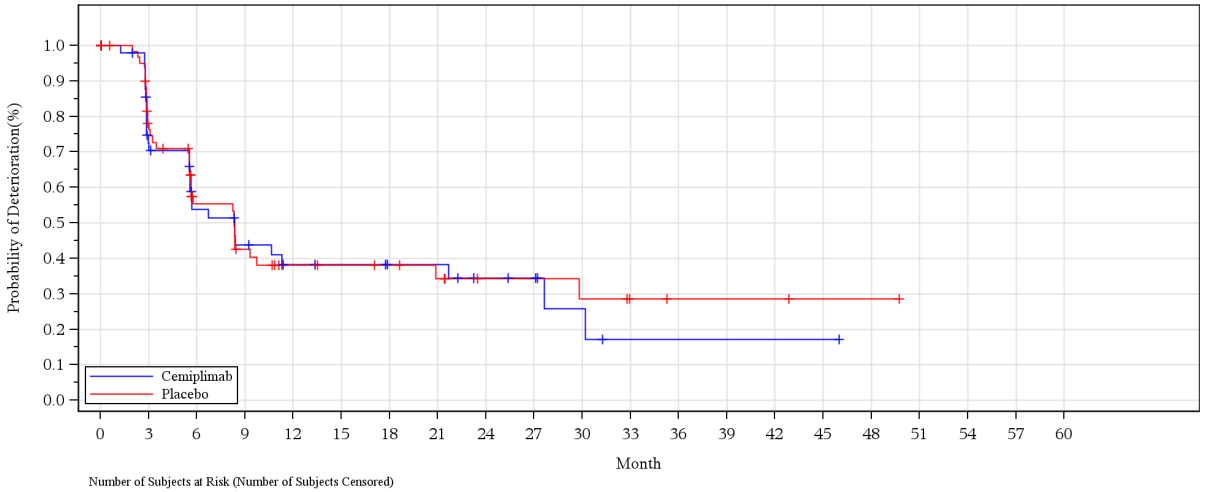
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	99 (33)	74 (39)	53 (45)	40 (52)	34 (54)	28 (57)	23 (59)	19 (61)	15 (64)	13 (65)	11 (67)	6 (71)	5 (71)	4 (71)	4 (71)	1 (74)	0 (75)	0 (75)	0 (75)	0 (75)
Placebo	141 (0)	84 (33)	65 (42)	52 (51)	38 (60)	31 (62)	28 (64)	28 (64)	19 (71)	16 (74)	14 (75)	13 (76)	9 (79)	9 (79)	7 (80)	4 (82)	1 (84)	0 (84)	0 (84)	0 (84)	0 (84)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



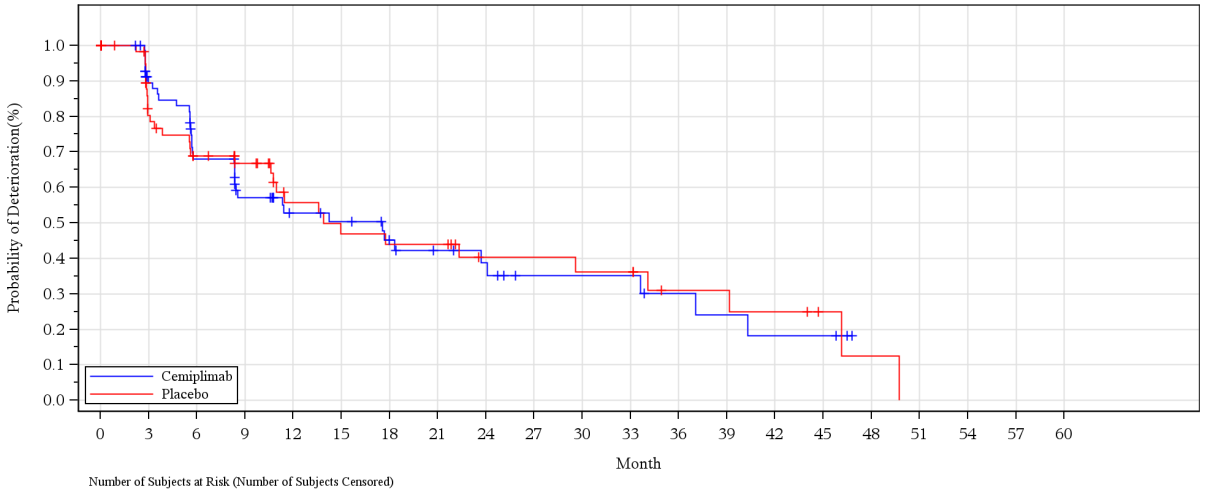
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	33 (10)	22 (13)	17 (14)	13 (16)	12 (17)	10 (19)	10 (19)	7 (21)	6 (22)	3 (24)	1 (25)	1 (25)	1 (25)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	65 (0)	44 (8)	26 (14)	19 (15)	13 (19)	12 (20)	11 (21)	9 (22)	6 (25)	6 (25)	5 (25)	3 (27)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



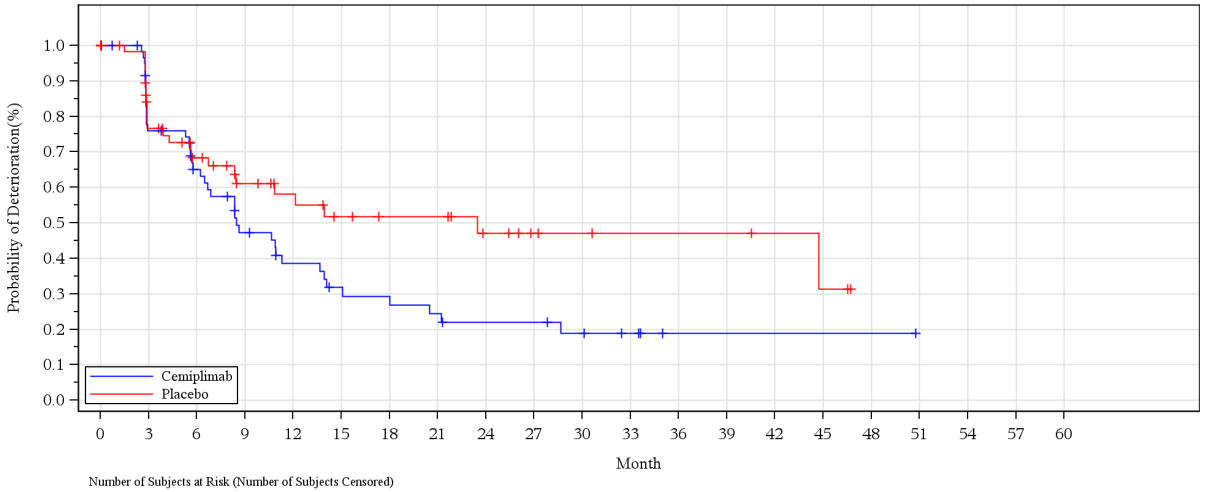
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	55 (18)	40 (20)	30 (24)	23 (29)	21 (30)	16 (33)	13 (35)	11 (36)	7 (39)	7 (39)	7 (39)	5 (40)	4 (40)	3 (40)	3 (40)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	69 (0)	43 (15)	34 (18)	29 (22)	19 (28)	16 (28)	15 (28)	15 (28)	10 (32)	10 (32)	9 (32)	9 (32)	5 (35)	5 (35)	4 (35)	2 (37)	1 (37)	0 (37)	0 (37)	0 (37)	0 (37)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	44 (15)	34 (19)	23 (21)	17 (23)	13 (24)	12 (24)	10 (24)	8 (25)	8 (25)	6 (26)	4 (28)	1 (31)	1 (31)	1 (31)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	72 (0)	41 (18)	31 (24)	23 (29)	19 (32)	15 (34)	13 (36)	13 (36)	9 (39)	6 (42)	5 (43)	4 (44)	4 (44)	4 (44)	3 (45)	2 (45)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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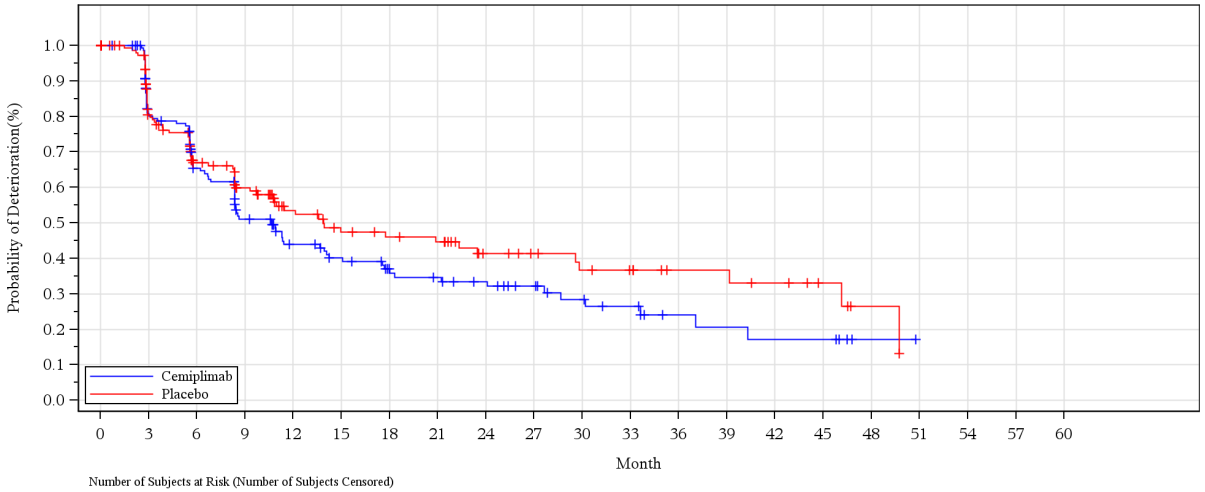
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	114 (32)	85 (40)	62 (45)	47 (52)	40 (55)	32 (60)	29 (61)	25 (64)	20 (68)	15 (71)	12 (73)	7 (77)	6 (77)	5 (77)	5 (77)	1 (81)	0 (82)	0 (82)	0 (82)	0 (82)
Placebo	174 (0)	111 (35)	80 (48)	64 (56)	45 (69)	37 (72)	34 (74)	32 (75)	22 (83)	19 (86)	16 (87)	14 (89)	10 (93)	10 (93)	8 (94)	5 (97)	2 (99)	0 (100)	0 (100)	0 (100)	0 (100)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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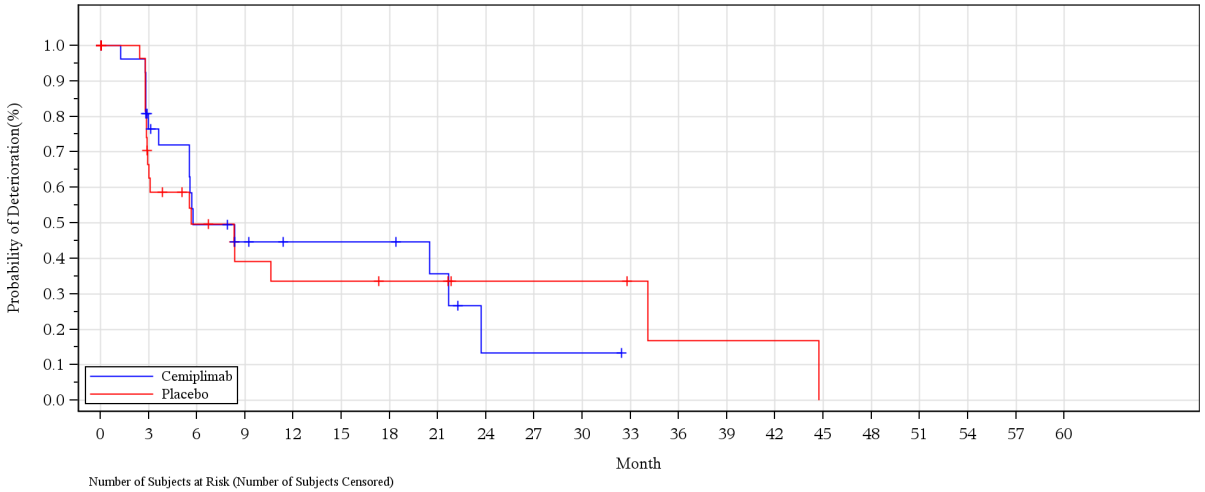
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	18 (11)	11 (12)	8 (14)	6 (16)	6 (16)	6 (16)	4 (17)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)
Placebo	32 (0)	17 (6)	11 (8)	7 (10)	6 (10)	6 (10)	5 (11)	5 (11)	3 (13)	3 (13)	3 (13)	2 (14)	1 (14)	1 (14)	1 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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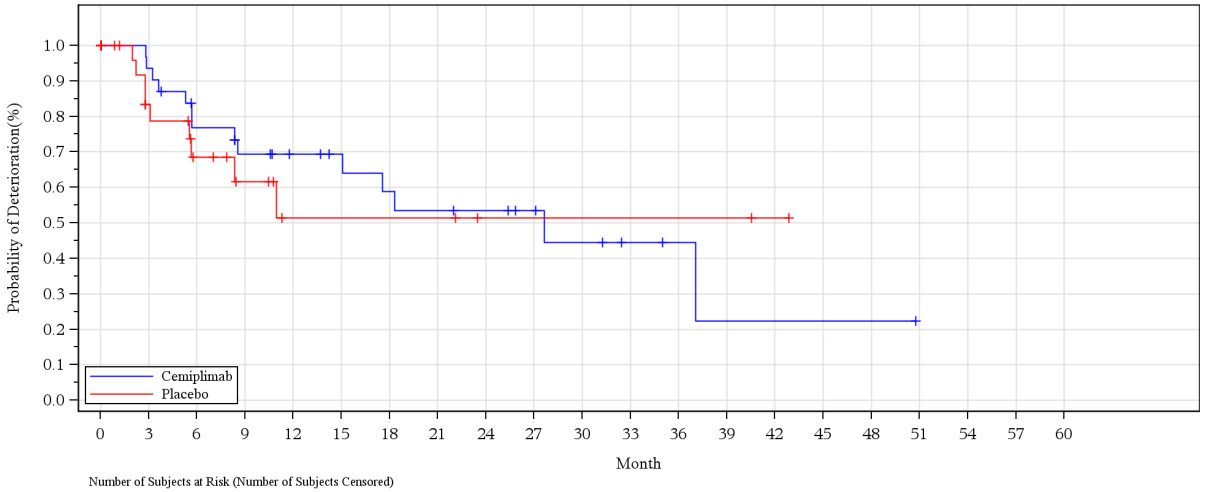
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



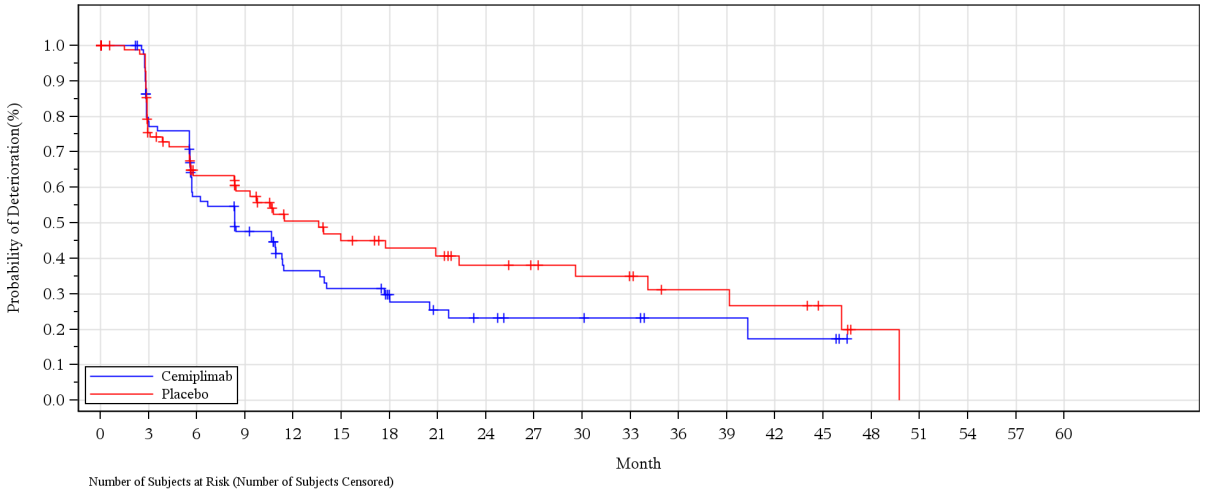
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (6)	22 (8)	18 (10)	15 (13)	13 (15)	11 (15)	10 (15)	9 (16)	7 (18)	5 (19)	3 (21)	2 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	31 (0)	18 (9)	12 (12)	8 (15)	4 (18)	4 (18)	4 (18)	4 (18)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	1 (21)	0 (22)	0 (22)	0 (22)	0 (22)	0 (22)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



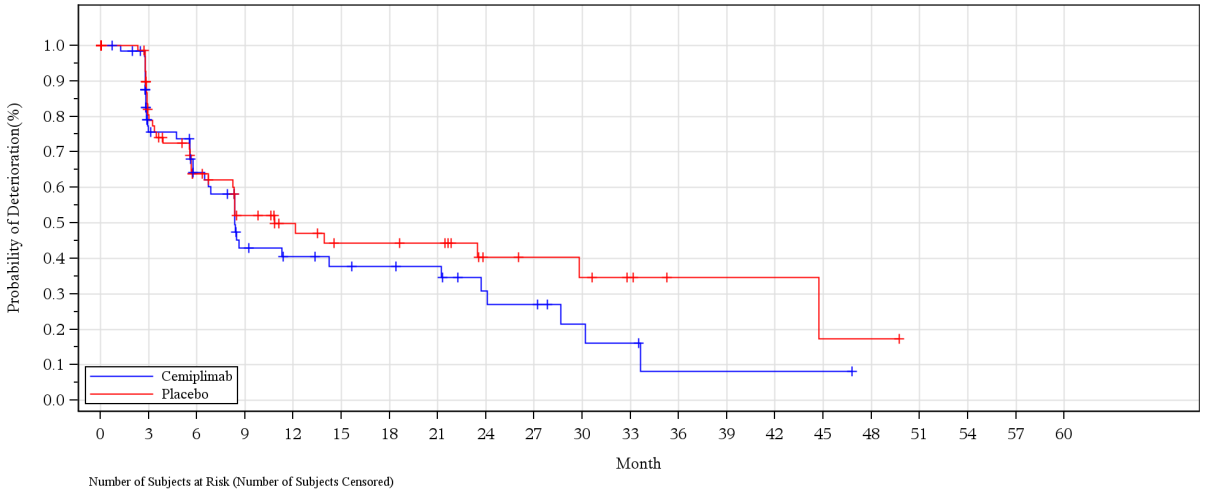
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	61 (12)	42 (15)	33 (17)	22 (21)	19 (21)	14 (25)	11 (26)	9 (27)	7 (29)	7 (29)	6 (30)	4 (32)	4 (32)	3 (32)	3 (32)	0 (35)	0 (35)	0 (35)	0 (35)	0 (35)
Placebo	90 (0)	59 (11)	44 (17)	38 (20)	28 (25)	24 (26)	20 (29)	19 (29)	15 (32)	13 (34)	11 (35)	10 (36)	7 (38)	7 (38)	6 (38)	4 (40)	1 (42)	0 (42)	0 (42)	0 (42)	0 (42)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	42 (25)	32 (29)	19 (32)	16 (34)	14 (35)	13 (36)	12 (37)	8 (39)	7 (39)	4 (41)	3 (41)	1 (42)	1 (42)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	85 (0)	51 (21)	35 (27)	25 (31)	19 (36)	15 (38)	15 (38)	14 (39)	8 (44)	7 (45)	6 (45)	4 (47)	2 (49)	2 (49)	2 (49)	1 (49)	1 (49)	0 (50)	0 (50)	0 (50)	0 (50)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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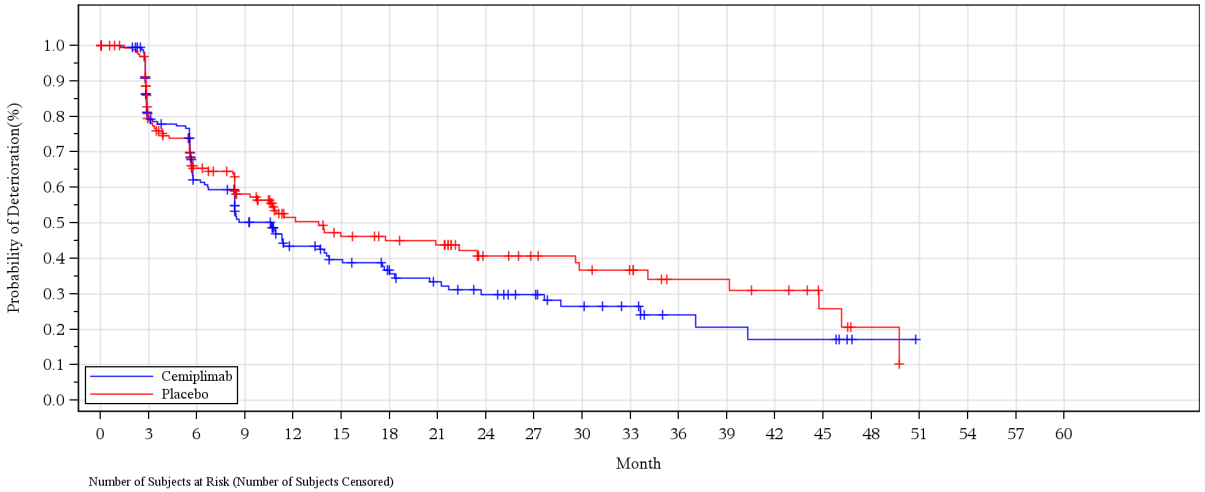
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	122 (35)	87 (44)	65 (50)	48 (59)	41 (62)	34 (66)	29 (68)	24 (70)	20 (74)	15 (77)	12 (80)	7 (84)	6 (84)	5 (84)	5 (84)	1 (88)	0 (89)	0 (89)	0 (89)	0 (89)
Placebo	189 (0)	118 (39)	86 (51)	68 (60)	49 (72)	42 (74)	38 (77)	36 (78)	24 (88)	21 (91)	18 (92)	16 (94)	11 (98)	11 (98)	9 (99)	5 (102)	2 (104)	0 (105)	0 (105)	0 (105)	0 (105)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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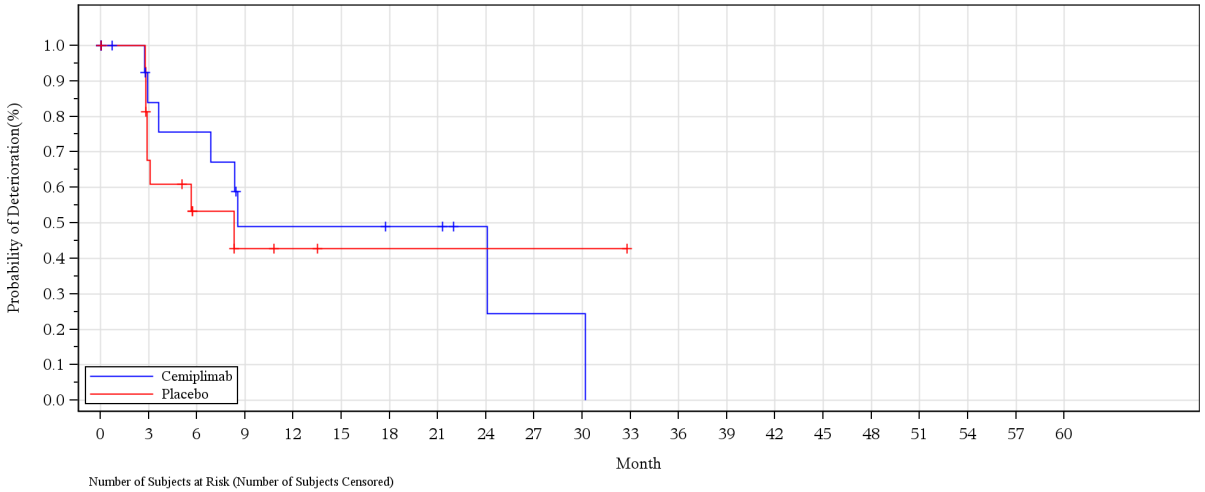
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Race: Non-white



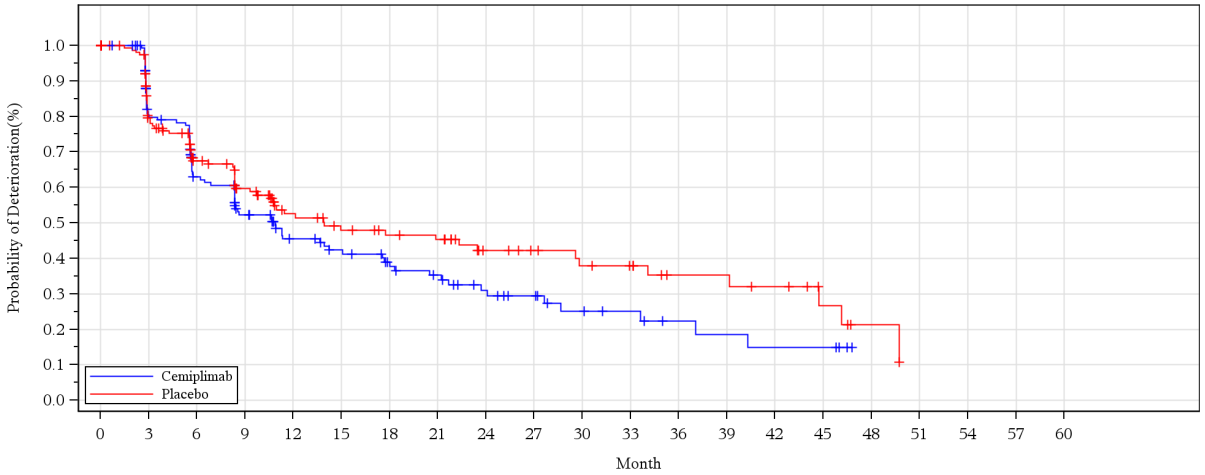
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	10 (8)	9 (8)	5 (9)	5 (9)	5 (9)	4 (10)	4 (10)	2 (12)	1 (12)	1 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)
Placebo	17 (0)	10 (2)	5 (5)	3 (6)	2 (7)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	108 (31)	79 (37)	60 (43)	45 (51)	39 (54)	32 (58)	27 (60)	20 (64)	16 (67)	11 (70)	9 (72)	6 (74)	5 (74)	4 (74)	4 (74)	0 (78)	0 (78)	0 (78)	0 (78)	0 (78)
Placebo	177 (0)	112 (35)	82 (49)	65 (57)	47 (68)	40 (71)	36 (74)	34 (75)	24 (83)	21 (86)	18 (87)	16 (89)	11 (93)	11 (93)	9 (94)	5 (97)	2 (99)	0 (100)	0 (100)	0 (100)	0 (100)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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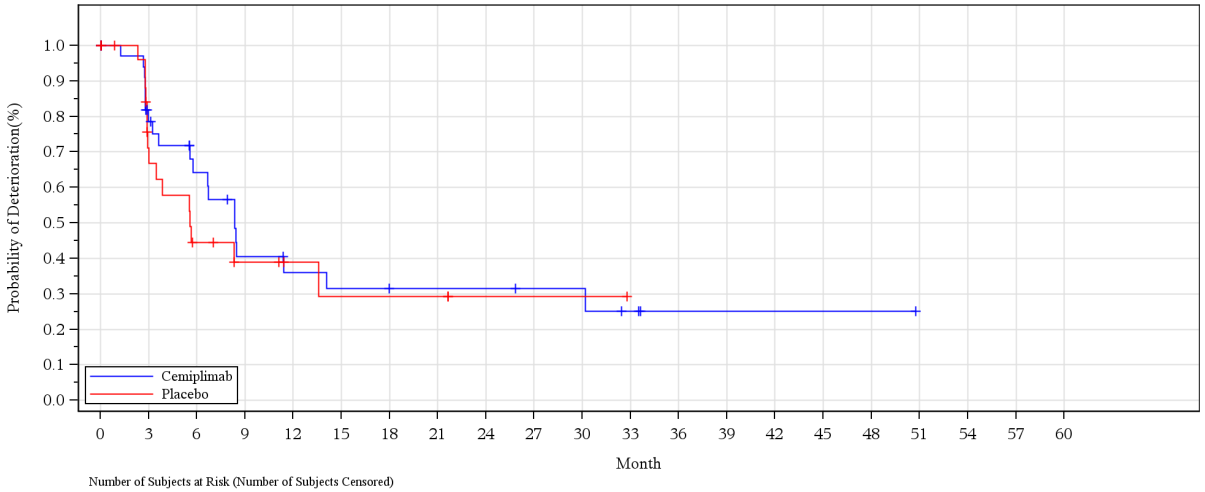
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



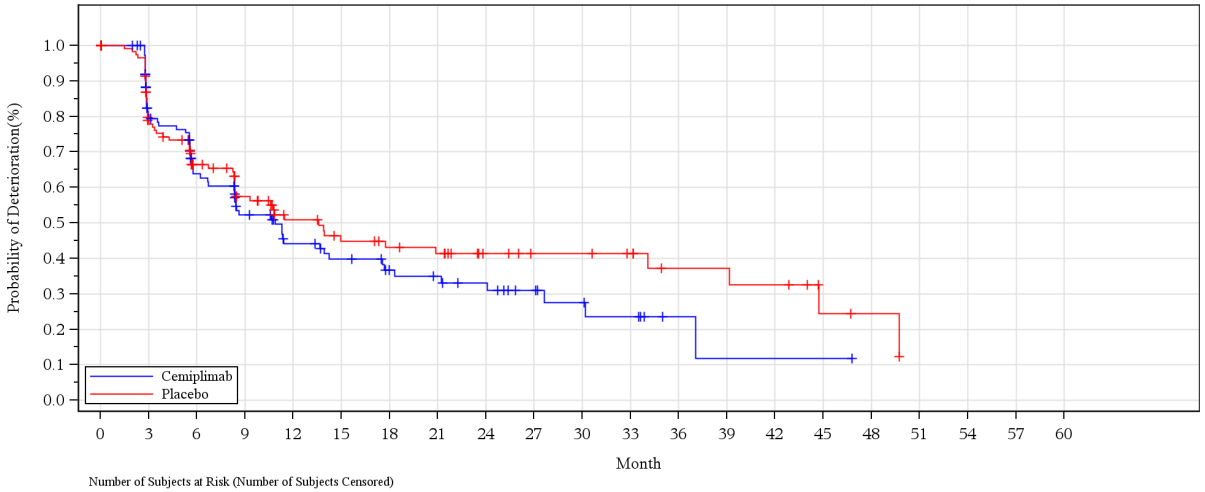
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	24 (12)	17 (15)	10 (16)	8 (17)	7 (17)	6 (18)	6 (18)	6 (18)	5 (19)	5 (19)	3 (20)	1 (22)	1 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	29 (0)	16 (6)	9 (7)	6 (9)	4 (11)	3 (11)	3 (11)	3 (11)	1 (13)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



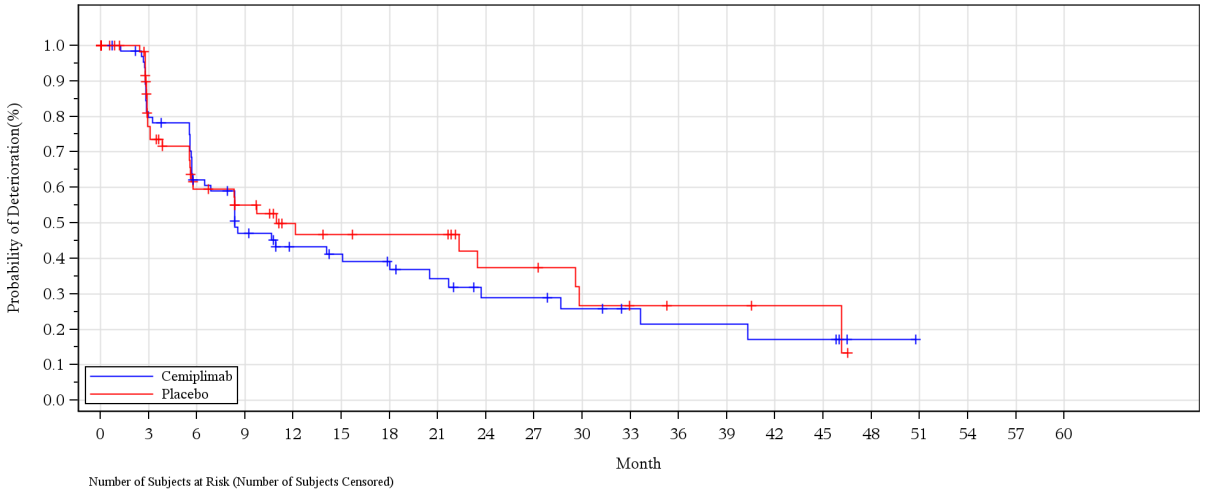
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	81 (31)	58 (38)	43 (43)	32 (48)	27 (50)	21 (54)	19 (55)	16 (57)	11 (61)	8 (63)	6 (64)	2 (68)	1 (68)	1 (68)	1 (68)	0 (69)	0 (69)	0 (69)	0 (69)	0 (69)
Placebo	131 (0)	86 (21)	63 (31)	48 (38)	35 (46)	29 (48)	26 (50)	24 (51)	17 (58)	14 (61)	14 (61)	12 (63)	8 (66)	8 (66)	7 (66)	3 (69)	2 (70)	0 (71)	0 (71)	0 (71)	0 (71)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



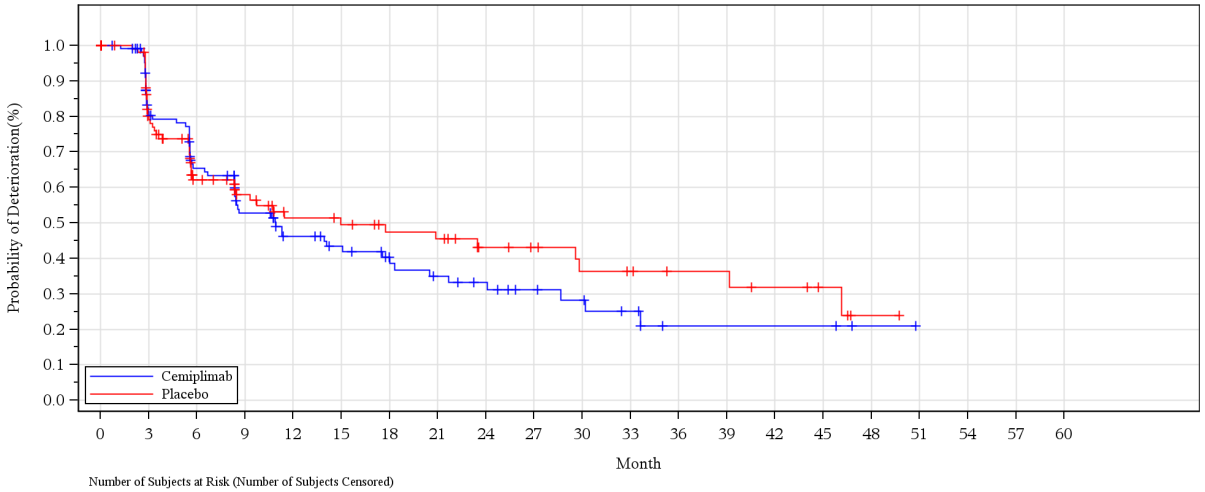
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	51 (12)	38 (14)	27 (16)	21 (20)	19 (21)	17 (22)	14 (23)	10 (25)	10 (25)	8 (26)	6 (28)	5 (28)	5 (28)	4 (28)	4 (28)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	75 (0)	42 (20)	28 (25)	23 (28)	16 (33)	14 (34)	13 (35)	13 (35)	8 (38)	8 (38)	5 (39)	4 (40)	3 (41)	3 (41)	2 (42)	2 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:16 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	79 (27)	60 (31)	44 (36)	34 (41)	29 (44)	23 (48)	19 (49)	16 (51)	12 (54)	10 (55)	7 (57)	3 (60)	3 (60)	3 (60)	1 (62)	0 (63)	0 (63)	0 (63)	0 (63)
Placebo	117 (0)	77 (20)	49 (32)	38 (40)	29 (45)	27 (46)	23 (49)	22 (49)	16 (54)	14 (56)	11 (57)	10 (58)	8 (60)	8 (60)	6 (61)	4 (63)	1 (65)	0 (66)	0 (66)	0 (66)	0 (66)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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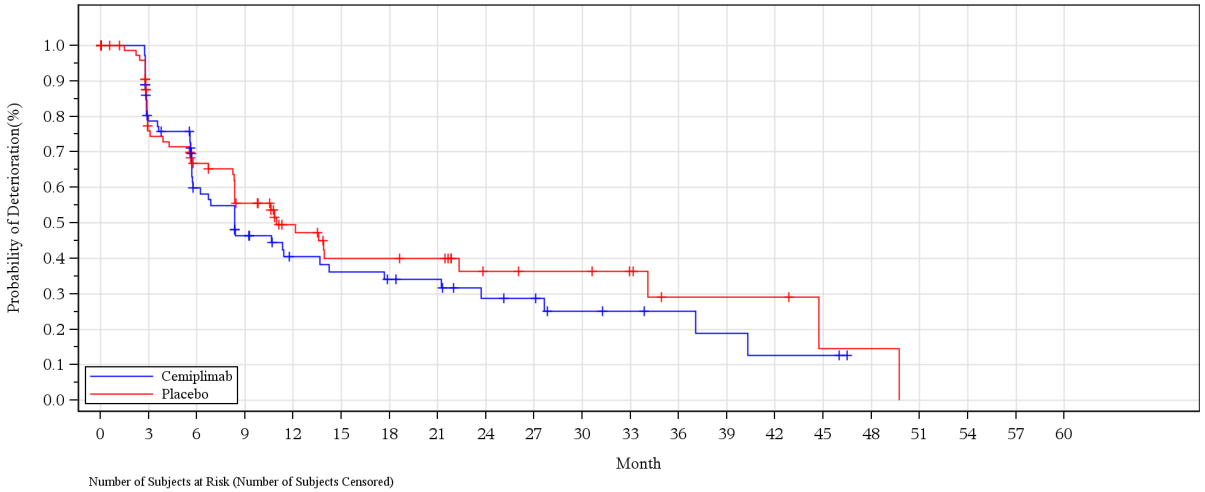
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	53 (16)	36 (21)	26 (23)	19 (27)	17 (27)	15 (28)	14 (29)	10 (31)	9 (32)	6 (34)	5 (35)	4 (36)	3 (36)	2 (36)	2 (36)	0 (38)	0 (38)	0 (38)	0 (38)	0 (38)
Placebo	89 (0)	51 (21)	42 (24)	33 (26)	22 (34)	16 (36)	16 (36)	15 (37)	9 (42)	8 (43)	8 (43)	6 (45)	3 (47)	3 (47)	3 (47)	1 (48)	1 (48)	0 (48)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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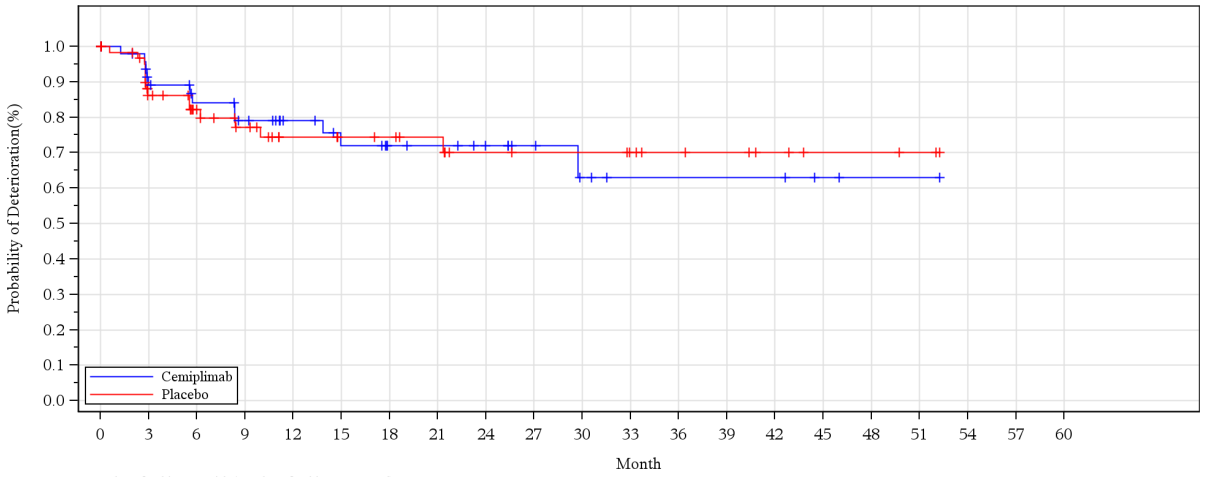
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



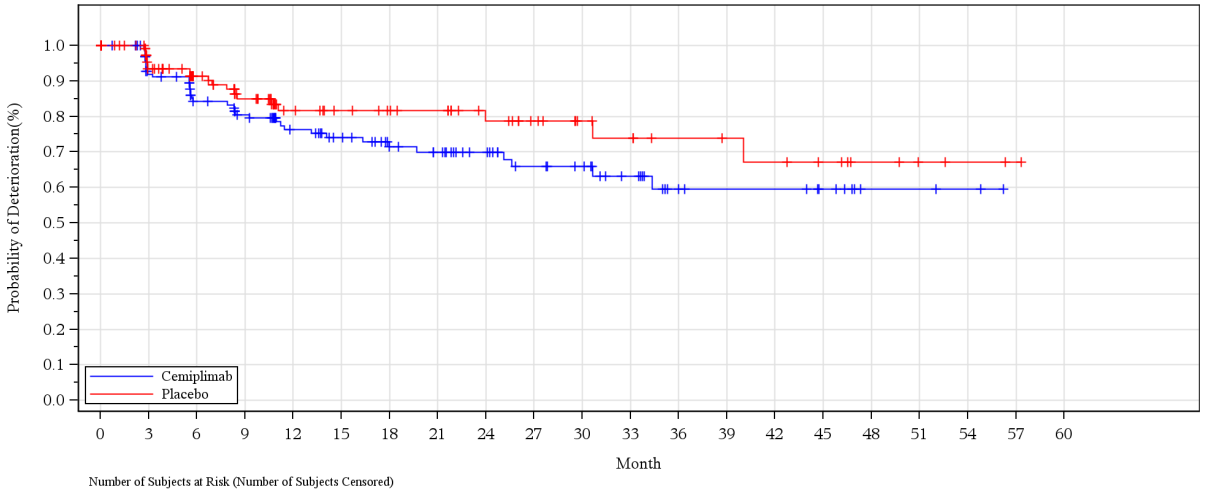
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	39 (12)	34 (15)	30 (17)	24 (23)	20 (25)	16 (29)	15 (30)	12 (33)	9 (36)	6 (38)	4 (40)	4 (40)	4 (40)	4 (40)	2 (42)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)
Placebo	65 (0)	46 (11)	36 (19)	29 (24)	22 (30)	20 (32)	19 (33)	17 (35)	13 (38)	12 (39)	12 (39)	10 (41)	8 (43)	7 (44)	5 (46)	3 (48)	3 (48)	2 (49)	0 (51)	0 (51)	0 (51)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



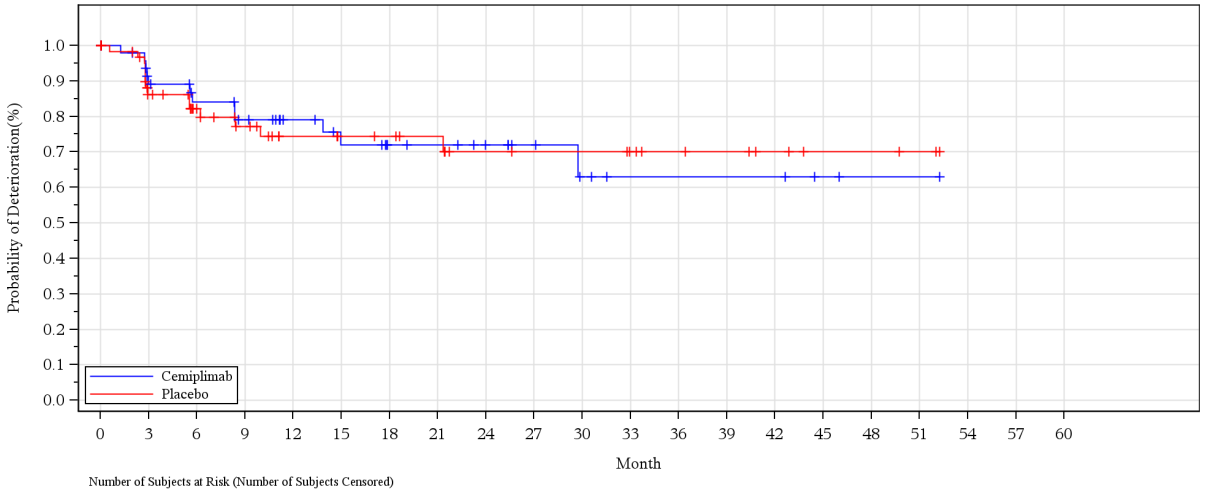
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	111 (32)	94 (40)	84 (46)	69 (57)	61 (63)	51 (71)	47 (74)	39 (82)	31 (88)	28 (91)	21 (97)	12 (105)	11 (106)	11 (106)	8 (109)	3 (114)	3 (114)	2 (115)	0 (117)	0 (117)
Placebo	141 (0)	96 (38)	77 (55)	62 (65)	44 (81)	39 (86)	36 (89)	34 (91)	27 (97)	22 (102)	17 (107)	15 (108)	12 (111)	11 (112)	10 (112)	8 (114)	5 (117)	3 (119)	2 (120)	1 (121)	0 (122)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



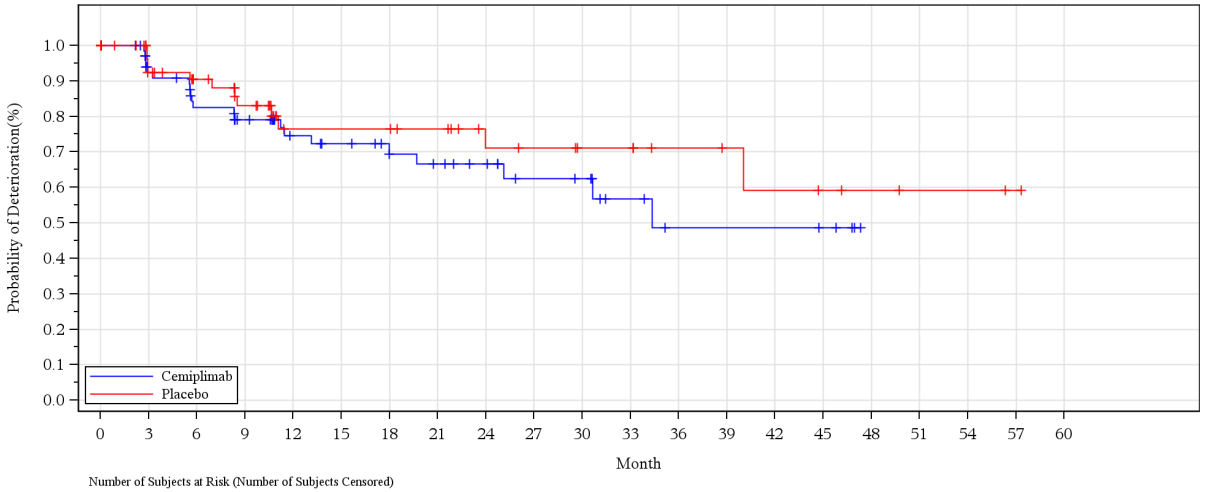
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	39 (12)	34 (15)	30 (17)	24 (23)	20 (25)	16 (29)	15 (30)	12 (33)	9 (36)	6 (38)	4 (40)	4 (40)	4 (40)	4 (40)	2 (42)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)
Placebo	65 (0)	46 (11)	36 (19)	29 (24)	22 (30)	20 (32)	19 (33)	17 (35)	13 (38)	12 (39)	12 (39)	10 (41)	8 (43)	7 (44)	5 (46)	3 (48)	3 (48)	2 (49)	0 (51)	0 (51)	0 (51)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



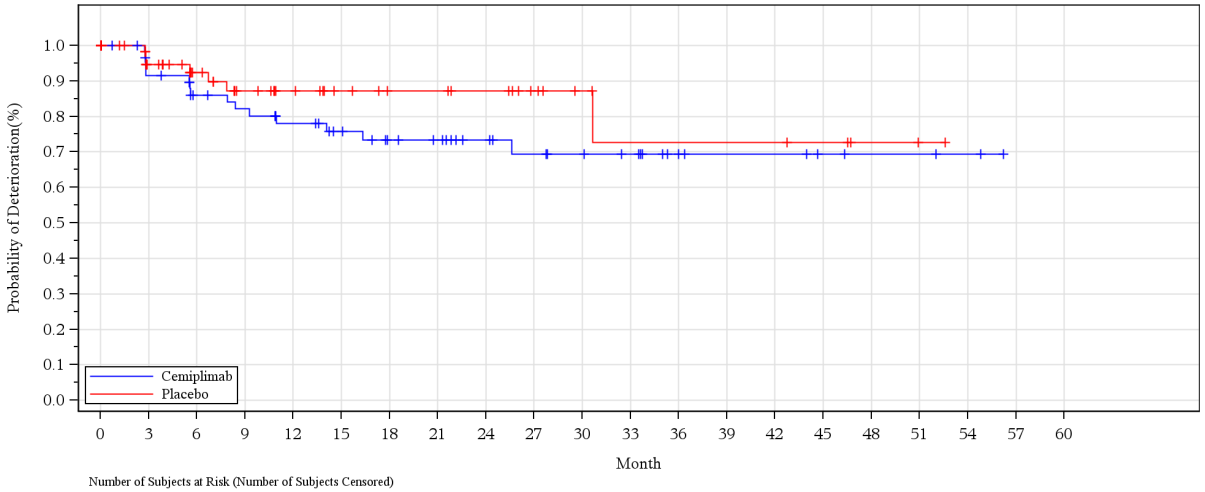
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	58 (17)	49 (20)	42 (25)	32 (33)	29 (35)	24 (39)	22 (40)	19 (43)	14 (47)	13 (48)	8 (52)	5 (54)	5 (54)	5 (54)	4 (55)	0 (59)	0 (59)	0 (59)	0 (59)	0 (59)
Placebo	69 (0)	48 (17)	40 (24)	33 (28)	20 (39)	20 (39)	20 (39)	18 (41)	13 (45)	12 (46)	10 (48)	10 (48)	7 (51)	6 (52)	5 (52)	4 (53)	3 (54)	2 (55)	2 (55)	1 (56)	0 (57)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



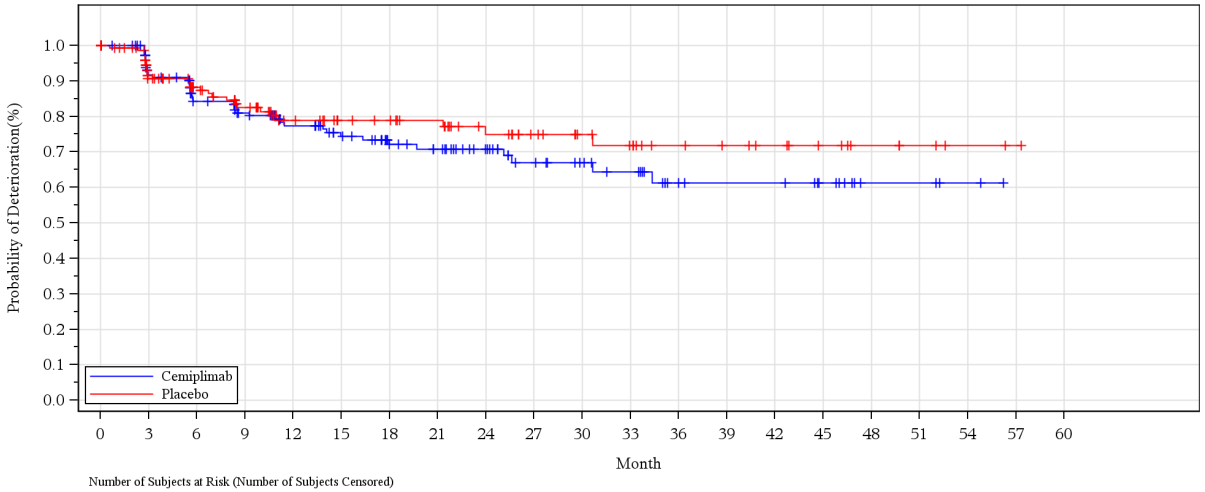
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	53 (15)	45 (20)	42 (21)	37 (24)	32 (28)	27 (32)	25 (34)	20 (39)	17 (41)	15 (43)	13 (45)	7 (51)	6 (52)	6 (52)	4 (54)	3 (55)	3 (55)	2 (56)	0 (58)	0 (58)
Placebo	72 (0)	48 (21)	37 (31)	29 (37)	24 (42)	19 (47)	16 (50)	16 (50)	14 (52)	10 (56)	7 (59)	5 (60)	5 (60)	5 (60)	5 (60)	4 (61)	2 (63)	1 (64)	0 (65)	0 (65)	0 (65)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Gender group: Male



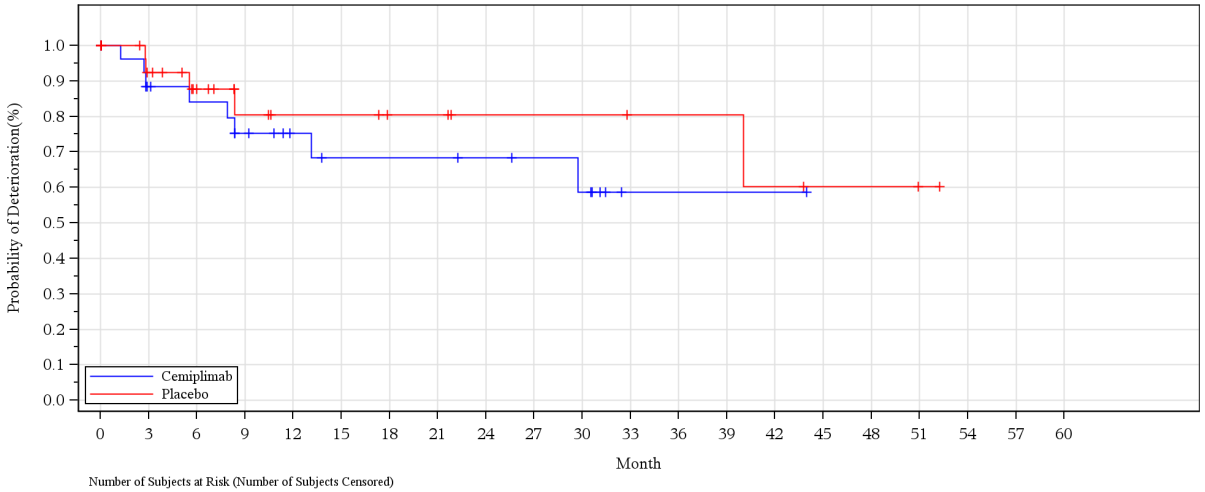
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	129 (33)	109 (43)	99 (49)	82 (62)	72 (69)	58 (81)	53 (85)	43 (95)	33 (103)	28 (108)	24 (111)	15 (119)	14 (120)	14 (120)	10 (124)	4 (130)	4 (130)	2 (132)	0 (134)	0 (134)
Placebo	174 (0)	119 (42)	96 (62)	80 (72)	57 (92)	50 (99)	48 (101)	44 (105)	35 (112)	29 (118)	24 (123)	21 (125)	16 (130)	14 (132)	12 (134)	9 (137)	6 (140)	4 (142)	2 (144)	1 (145)	0 (146)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Gender group: Female



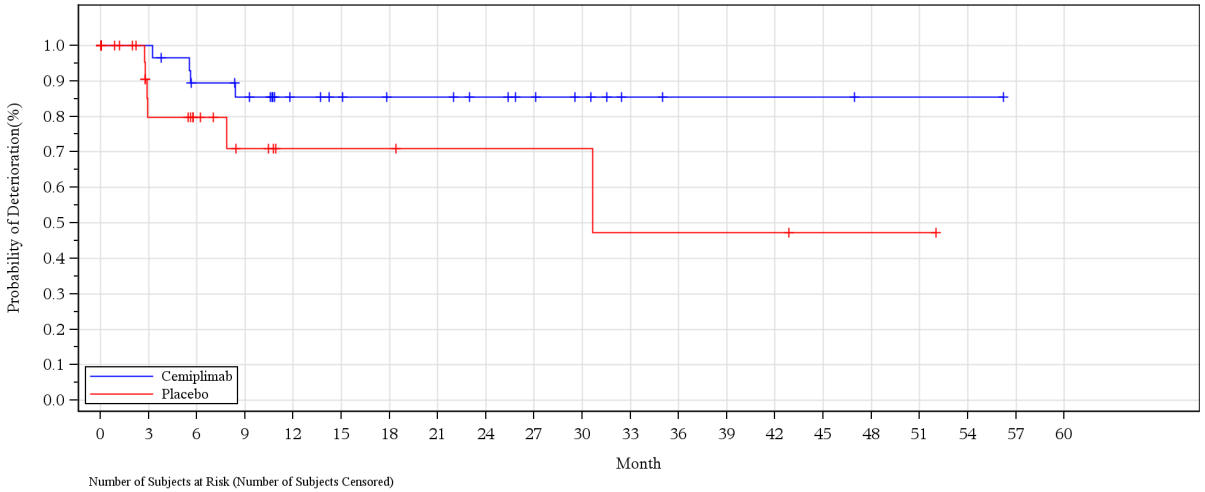
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	21 (11)	19 (12)	15 (14)	11 (18)	9 (19)	9 (19)	9 (19)	8 (20)	7 (21)	6 (21)	1 (26)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	32 (0)	23 (7)	17 (12)	11 (17)	9 (19)	9 (19)	7 (21)	7 (21)	5 (23)	5 (23)	5 (23)	4 (24)	4 (24)	4 (24)	3 (24)	2 (25)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



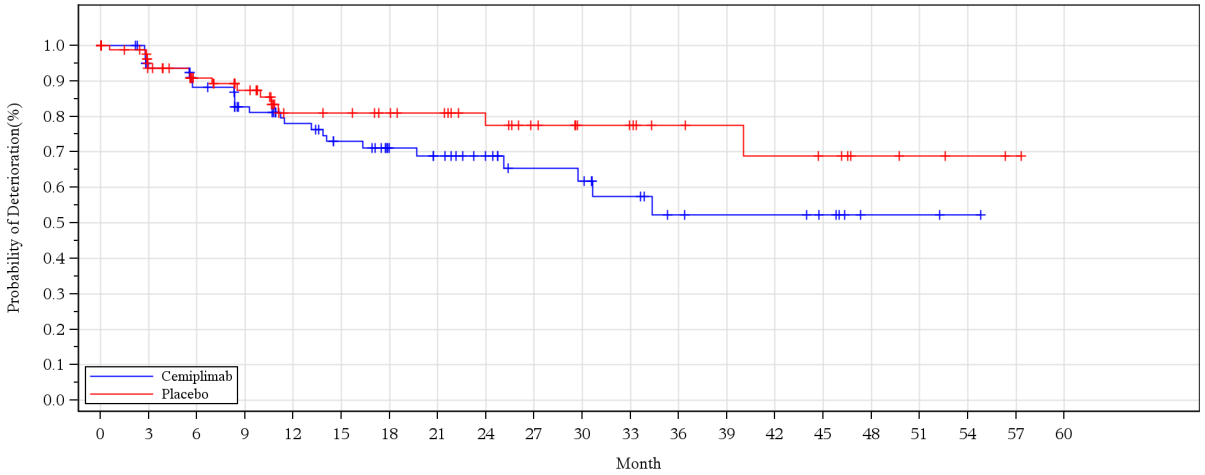
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (8)	24 (10)	22 (11)	16 (17)	14 (19)	12 (21)	12 (21)	10 (23)	8 (25)	6 (27)	3 (30)	2 (31)	2 (31)	2 (31)	2 (31)	1 (32)	1 (32)	1 (32)	0 (33)	0 (33)
Placebo	31 (0)	15 (12)	11 (16)	7 (19)	4 (22)	4 (22)	4 (22)	3 (23)	3 (23)	3 (23)	3 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)	0 (25)	0 (25)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



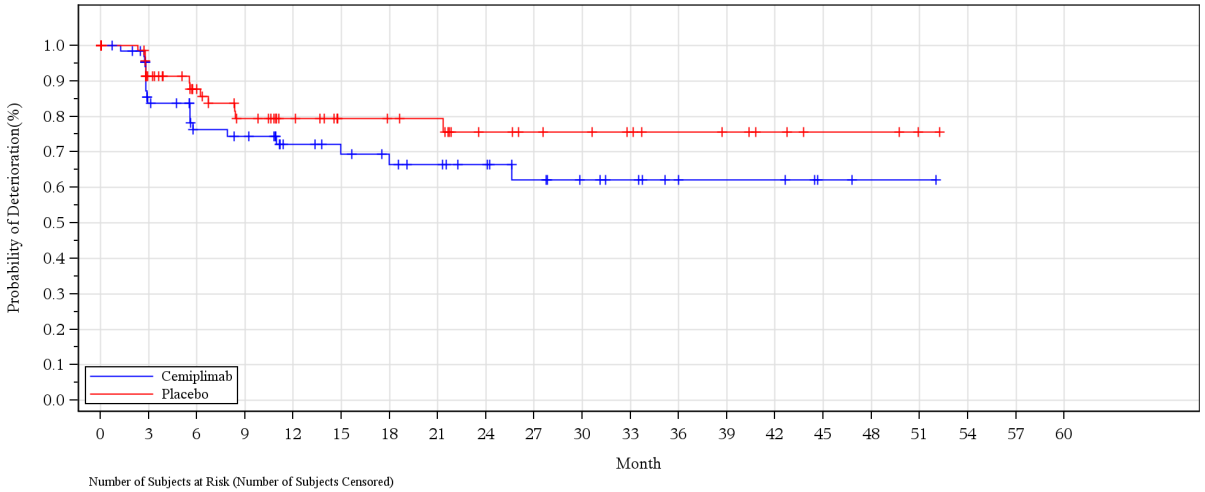
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	72 (13)	65 (16)	55 (22)	48 (26)	41 (30)	32 (38)	29 (40)	23 (46)	18 (50)	17 (50)	13 (53)	9 (56)	8 (57)	8 (57)	6 (59)	2 (63)	2 (63)	1 (64)	0 (65)	0 (65)
Placebo	90 (0)	70 (15)	57 (26)	48 (33)	33 (45)	32 (46)	29 (49)	27 (51)	22 (55)	18 (59)	14 (63)	13 (64)	10 (67)	9 (68)	8 (68)	7 (69)	4 (72)	3 (73)	2 (74)	1 (75)	0 (76)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	49 (23)	39 (29)	37 (30)	29 (37)	26 (39)	23 (41)	21 (43)	18 (46)	14 (49)	11 (52)	9 (54)	5 (58)	5 (58)	5 (58)	2 (61)	1 (62)	1 (62)	0 (63)	0 (63)	0 (63)
Placebo	85 (0)	57 (22)	45 (32)	36 (37)	29 (44)	23 (50)	22 (51)	21 (52)	15 (57)	13 (59)	12 (60)	10 (62)	8 (64)	7 (65)	5 (67)	3 (69)	3 (69)	1 (71)	0 (72)	0 (72)	0 (72)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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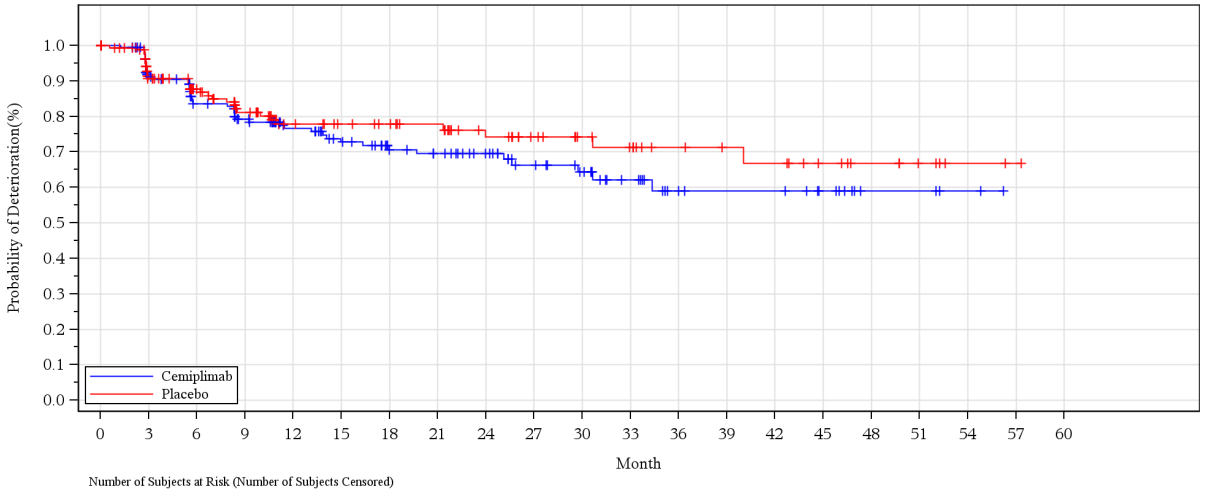
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	139 (36)	117 (47)	103 (55)	85 (70)	74 (77)	61 (88)	57 (91)	49 (99)	39 (107)	33 (112)	24 (120)	15 (128)	14 (129)	14 (129)	10 (133)	4 (139)	4 (139)	2 (141)	0 (143)	0 (143)
Placebo	189 (0)	128 (47)	103 (68)	82 (82)	60 (101)	55 (106)	52 (109)	48 (113)	37 (122)	31 (128)	26 (133)	23 (135)	18 (140)	16 (142)	15 (142)	11 (146)	8 (149)	5 (152)	2 (155)	1 (156)	0 (157)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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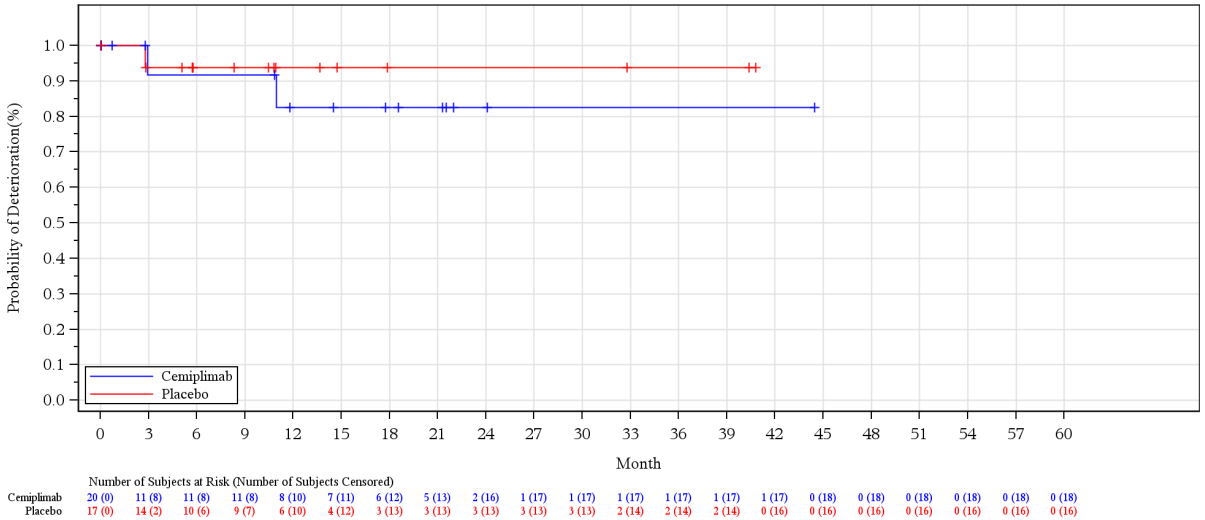
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (8)	11 (8)	11 (8)	8 (10)	7 (11)	6 (12)	5 (13)	2 (16)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	17 (0)	14 (2)	10 (6)	9 (7)	6 (10)	4 (12)	3 (13)	3 (13)	3 (13)	3 (13)	3 (13)	2 (14)	2 (14)	2 (14)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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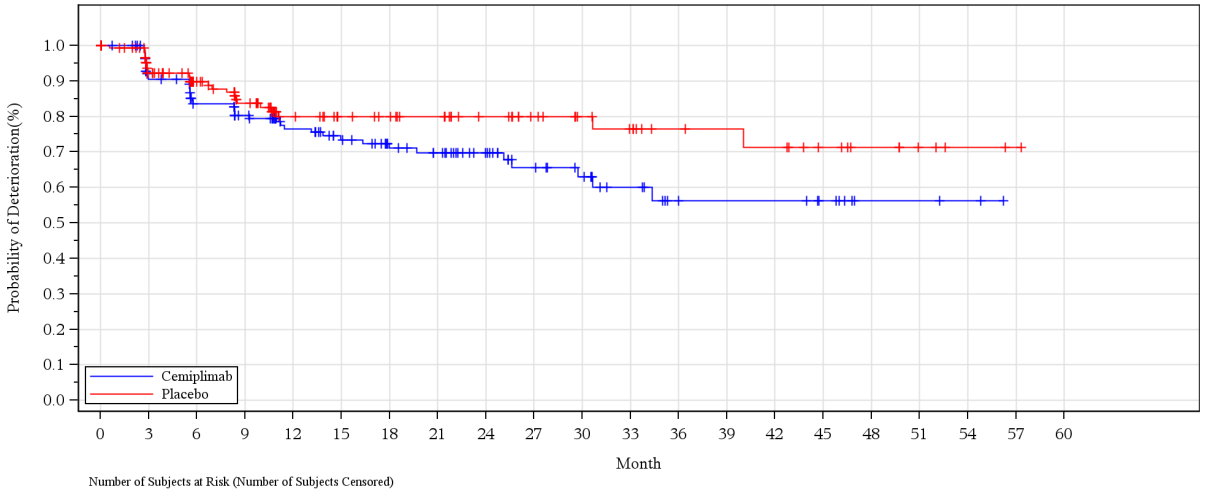
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	121 (32)	104 (40)	94 (46)	78 (58)	68 (65)	56 (75)	51 (79)	40 (90)	30 (98)	25 (102)	18 (108)	11 (114)	11 (114)	11 (114)	8 (117)	3 (122)	3 (122)	2 (123)	0 (125)	0 (125)
Placebo	177 (0)	122 (44)	96 (67)	78 (79)	56 (98)	49 (105)	46 (108)	42 (112)	35 (119)	29 (125)	24 (130)	21 (132)	16 (137)	15 (138)	14 (138)	10 (142)	7 (145)	4 (148)	2 (150)	1 (151)	0 (152)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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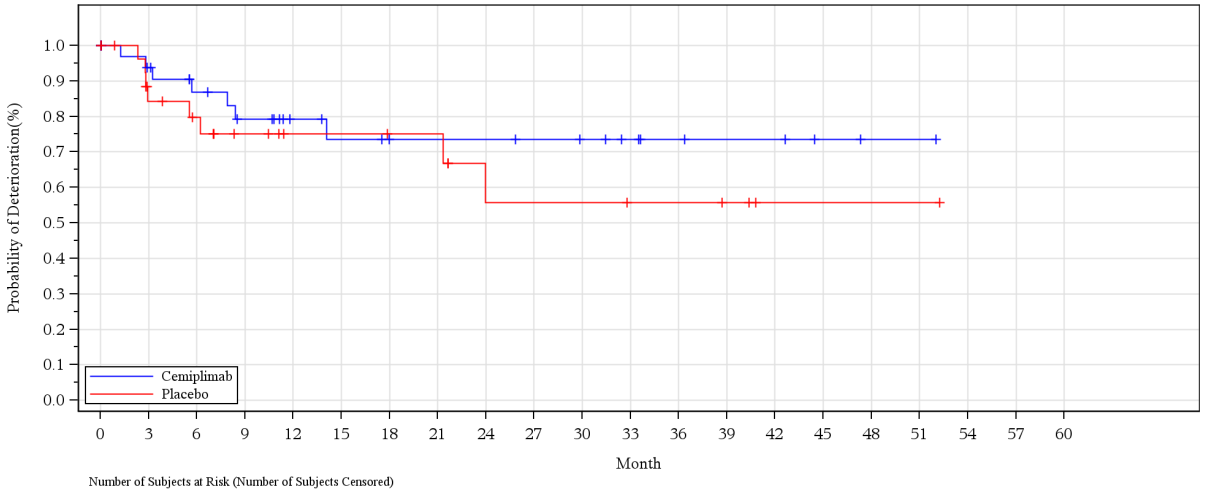
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (12)	24 (15)	20 (17)	15 (22)	13 (23)	11 (25)	11 (25)	11 (25)	10 (26)	9 (27)	7 (29)	5 (31)	4 (32)	4 (32)	2 (34)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)
Placebo	29 (0)	20 (5)	17 (7)	13 (10)	10 (13)	10 (13)	9 (14)	9 (14)	5 (16)	5 (16)	5 (16)	4 (17)	4 (17)	3 (18)	1 (20)	1 (20)	1 (20)	1 (20)	0 (21)	0 (21)	0 (21)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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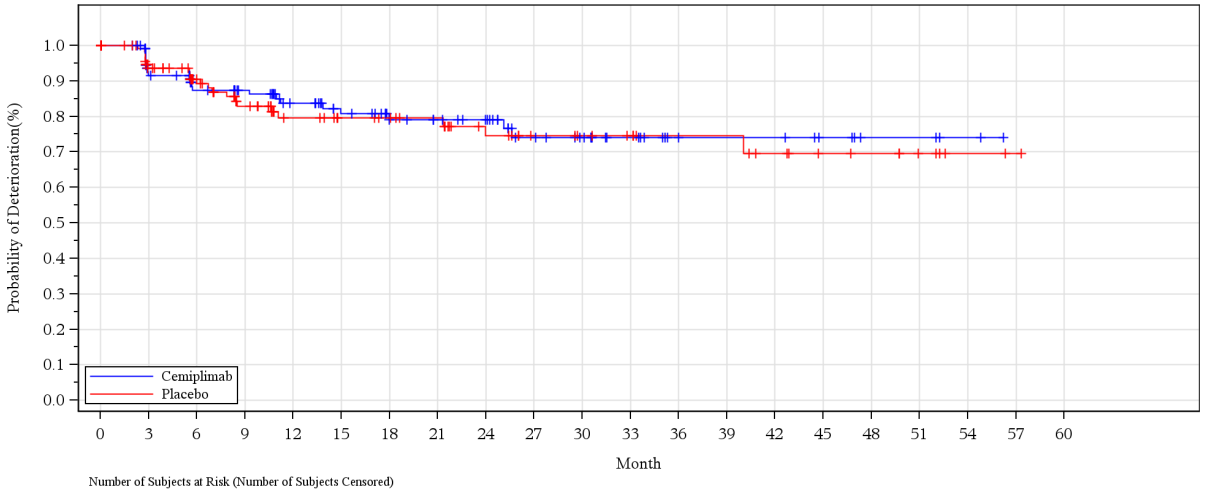
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



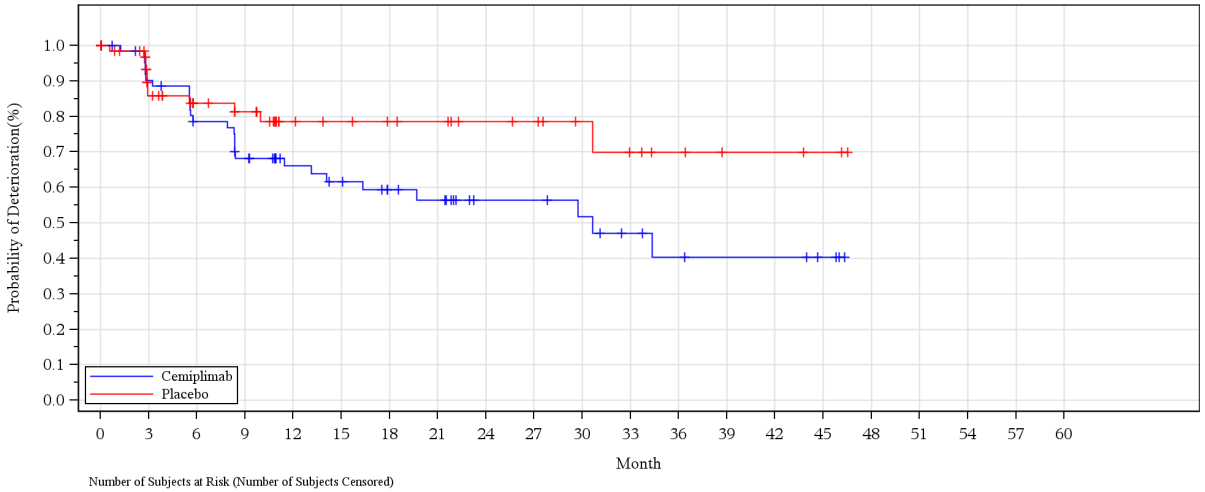
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	95 (29)	82 (38)	75 (45)	63 (54)	54 (61)	45 (69)	42 (72)	38 (76)	27 (85)	23 (89)	17 (95)	10 (102)	10 (102)	10 (102)	7 (105)	4 (108)	4 (108)	2 (110)	0 (112)	0 (112)
Placebo	131 (0)	97 (27)	77 (44)	59 (56)	45 (68)	40 (73)	38 (75)	35 (78)	27 (84)	22 (89)	20 (91)	18 (93)	15 (96)	15 (96)	12 (98)	9 (101)	8 (102)	5 (105)	2 (108)	1 (109)	0 (110)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



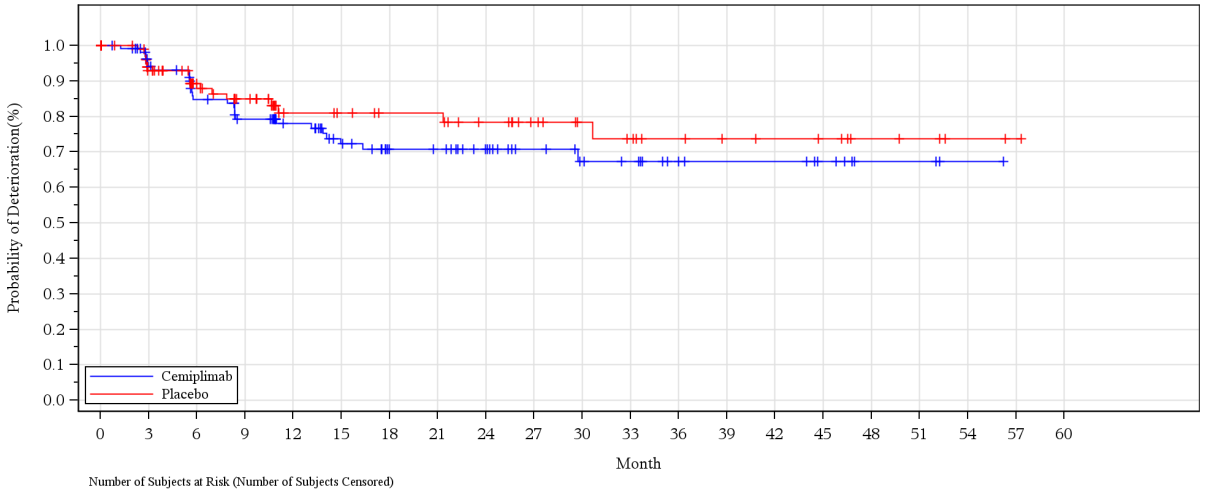
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	55 (15)	46 (17)	39 (18)	30 (26)	27 (27)	22 (31)	20 (32)	13 (39)	13 (39)	11 (40)	8 (42)	6 (43)	5 (44)	5 (44)	3 (46)	0 (49)	0 (49)	0 (49)	0 (49)	0 (49)
Placebo	75 (0)	45 (22)	36 (30)	32 (33)	21 (43)	19 (45)	17 (47)	16 (48)	13 (51)	12 (52)	9 (55)	7 (56)	5 (58)	3 (60)	3 (60)	2 (61)	0 (63)	0 (63)	0 (63)	0 (63)	0 (63)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



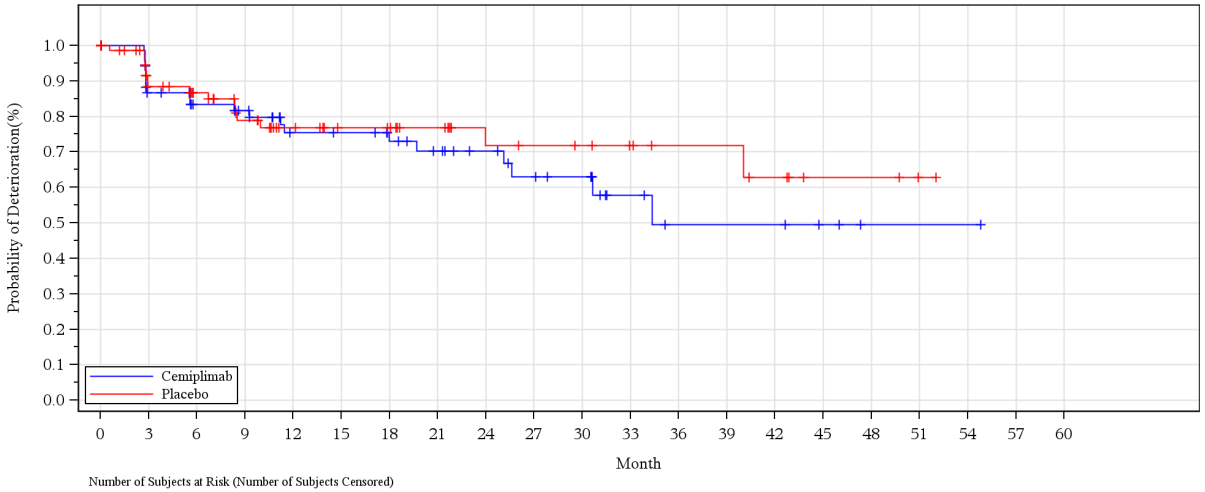
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	94 (25)	80 (30)	70 (35)	59 (45)	48 (52)	38 (61)	37 (62)	30 (69)	23 (76)	19 (79)	17 (81)	11 (87)	10 (88)	10 (88)	7 (91)	3 (95)	3 (95)	1 (97)	0 (98)	0 (98)
Placebo	117 (0)	86 (24)	65 (42)	52 (52)	36 (66)	34 (68)	31 (71)	31 (71)	26 (75)	21 (80)	17 (84)	15 (85)	12 (88)	10 (90)	9 (91)	8 (92)	5 (95)	4 (96)	2 (98)	1 (99)	0 (100)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	56 (19)	48 (25)	44 (28)	34 (35)	33 (36)	29 (39)	25 (42)	21 (46)	17 (48)	15 (50)	8 (56)	5 (58)	5 (58)	5 (58)	3 (60)	1 (62)	1 (62)	1 (62)	0 (63)	0 (63)
Placebo	89 (0)	56 (25)	48 (32)	39 (37)	30 (45)	25 (50)	24 (51)	20 (55)	14 (60)	13 (61)	12 (62)	10 (64)	8 (66)	8 (66)	6 (67)	3 (70)	3 (70)	1 (72)	0 (73)	0 (73)	0 (73)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

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Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	32 (49.2%)
Number of censored cases	n (%)	27 (48.2%)	33 (50.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	23 (41.1%)	31 (47.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.65]	5.55 [2.86, 7.06]
	Median [95% CI]	11.30 [5.65, NC]	9.33 [7.06, NC]
	Q3 [95% CI]	NYR [29.31, NC]	49.05 [38.90, NC]
	p-value[b][d]		0.558
	HR [95 % CI][c][d]		1.17 [0.69, 1.98]
	Heterogeneity p-value[e][d]		0.5843

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	23 (41.1%)	21 (32.3%)
Number of censored cases	n (%)	33 (58.9%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	29 (51.8%)	42 (64.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.89, 13.01]	5.72 [2.89, 13.44]
	Median [95% CI]	39.82 [10.64, NC]	NYR [13.44, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.648
	HR [95 % CI][c][d]		1.16 [0.62, 2.17]
	Heterogeneity p-value[e][d]		0.9267

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	30 (53.6%)	29 (44.6%)
Number of censored cases	n (%)	26 (46.4%)	36 (55.4%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	3 (5.4%)	0
No first deterioration	n (%)	19 (33.9%)	34 (52.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.71 [2.86, 5.62]	5.52 [2.86, 8.34]
	Median [95% CI]	9.79 [5.59, 22.74]	14.78 [8.34, NC]
	Q3 [95% CI]	NYR [14.06, NC]	NYR [36.40, NC]
	p-value[b][d]		0.096
	HR [95 % CI][c][d]		1.58 [0.92, 2.71]
	Heterogeneity p-value[e][d]		0.7087

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	27 (41.5%)
Number of censored cases	n (%)	27 (48.2%)	38 (58.5%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	23 (41.1%)	36 (55.4%)
Time to first deterioration (months)	Q1 [95% CI]	3.01 [2.79, 5.59]	5.59 [4.27, 10.61]
	Median [95% CI]	11.37 [5.59, NC]	20.30 [9.95, NC]
	Q3 [95% CI]	NYR [26.45, NC]	NYR [NC, NC]
	p-value[b][d]		0.264
	HR [95 % CI][c][d]		1.37 [0.79, 2.38]
	Heterogeneity p-value[e][d]		0.1724

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	33 (58.9%)	35 (53.8%)
Number of censored cases	n (%)	23 (41.1%)	30 (46.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	19 (33.9%)	28 (43.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.99 [2.79, 5.59]	2.96 [2.83, 6.11]
	Median [95% CI]	8.41 [5.59, 14.98]	10.68 [6.11, 21.45]
	Q3 [95% CI]	NYR [14.98, NC]	NYR [14.52, NC]
	p-value[b][d]		0.652
	HR [95 % CI][c][d]		1.12 [0.69, 1.83]
	Heterogeneity p-value[e][d]		0.7091

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	26 (46.4%)	37 (56.9%)
Number of censored cases	n (%)	30 (53.6%)	28 (43.1%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (46.4%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.41]	2.89 [2.79, 5.55]
	Median [95% CI]	18.30 [8.34, NC]	8.34 [5.55, 14.39]
	Q3 [95% CI]	NYR [NC, NC]	NYR [14.39, NC]
	p-value[b][d]		0.217
	HR [95 % CI][c][d]		0.72 [0.43, 1.20]
	Heterogeneity p-value[e][d]		0.0118

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	39 (69.6%)	37 (56.9%)
Number of censored cases	n (%)	17 (30.4%)	28 (43.1%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	12 (21.4%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 3.02]	2.89 [2.79, 5.55]
	Median [95% CI]	5.59 [2.99, 8.34]	8.31 [5.55, 10.61]
	Q3 [95% CI]	21.68 [8.34, NC]	NYR [8.57, NC]
	p-value[b][d]		0.747
	HR [95 % CI][c][d]		1.08 [0.67, 1.72]
	Heterogeneity p-value[e][d]		0.8019

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	32 (57.1%)	35 (53.8%)
Number of censored cases	n (%)	24 (42.9%)	30 (46.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	1 (1.5%)
No first deterioration	n (%)	19 (33.9%)	27 (41.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.99 [2.83, 5.59]	3.25 [2.86, 5.65]
	Median [95% CI]	8.34 [5.59, 27.63]	8.38 [5.65, 29.80]
	Q3 [95% CI]	NYR [21.68, NC]	NYR [20.90, NC]
	p-value[b][d]		0.940
	HR [95 % CI][c][d]		1.03 [0.63, 1.68]
	Heterogeneity p-value[e][d]		0.3353

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	14 (25.0%)	14 (21.5%)
Number of censored cases	n (%)	42 (75.0%)	51 (78.5%)
No baseline score	n (%)	4 (7.1%)	2 (3.1%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	4 (7.1%)	1 (1.5%)
No first deterioration	n (%)	34 (60.7%)	47 (72.3%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [5.59, NC]	21.32 [2.96, NC]
	Median [95% CI]	NYR [29.73, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.451
	HR [95 % CI][c][d]		1.36 [0.61, 3.01]
	Heterogeneity p-value[e][d]		0.5003

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	15 (26.8%)	19 (29.2%)
Number of censored cases	n (%)	41 (73.2%)	46 (70.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (66.1%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	11.20 [2.86, NC]	8.31 [3.02, 25.63]
	Median [95% CI]	NYR [NC, NC]	NYR [14.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.552
	HR [95 % CI][c][d]		0.80 [0.40, 1.62]
	Heterogeneity p-value[e][d]		0.3247

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	21 (32.3%)
Number of censored cases	n (%)	27 (48.2%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	22 (39.3%)	42 (64.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 8.34]	10.64 [5.72, 21.72]
	Median [95% CI]	14.98 [8.34, 30.98]	40.71 [15.93, NC]
	Q3 [95% CI]	NYR [25.59, NC]	43.56 [40.71, NC]
	p-value[b][d]		0.045
	HR [95 % CI][c][d]		1.79 [1.01, 3.20]
	Heterogeneity p-value[e][d]		0.0681

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	26 (46.4%)	29 (44.6%)
Number of censored cases	n (%)	30 (53.6%)	36 (55.4%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	4 (7.1%)	1 (1.5%)
No first deterioration	n (%)	22 (39.3%)	33 (50.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.25]	2.89 [2.79, 8.31]
	Median [95% CI]	14.46 [5.65, NC]	15.08 [8.31, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.450
	HR [95 % CI][c][d]		1.23 [0.71, 2.12]
	Heterogeneity p-value[e][d]		0.9858

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	19 (33.9%)	15 (23.1%)
Number of censored cases	n (%)	37 (66.1%)	50 (76.9%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	3 (4.6%)
No first deterioration	n (%)	32 (57.1%)	45 (69.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.92, 14.49]	10.45 [5.62, NC]
	Median [95% CI]	NYR [14.49, NC]	NYR [31.18, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.283
	HR [95 % CI][c][d]		1.47 [0.72, 2.97]
	Heterogeneity p-value[e][d]		0.7556

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	12 (21.4%)	18 (27.7%)
Number of censored cases	n (%)	44 (78.6%)	47 (72.3%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	1 (1.5%)
No first deterioration	n (%)	40 (71.4%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	22.74 [8.34, NC]	9.95 [5.59, NC]
	Median [95% CI]	NYR [NC, NC]	58.68 [30.69, NC]
	Q3 [95% CI]	NYR [NC, NC]	58.68 [NC, NC]
	p-value[b][d]		0.474
	HR [95 % CI][c][d]		0.76 [0.36, 1.62]
	Heterogeneity p-value[e][d]		0.4587

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	16 (28.6%)	22 (33.8%)
Number of censored cases	n (%)	40 (71.4%)	43 (66.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	36 (64.3%)	41 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [5.59, NC]	5.65 [2.89, 9.95]
	Median [95% CI]	NYR [25.59, NC]	NYR [9.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.426
	HR [95 % CI][c][d]		0.76 [0.39, 1.49]
	Heterogeneity p-value[e][d]		0.2514

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	76 (49.7%)	55 (39.0%)
Number of censored cases	n (%)	77 (50.3%)	86 (61.0%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	61 (39.9%)	67 (47.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.55, 8.28]	5.59 [2.89, 7.85]
	Median [95% CI]	14.59 [10.64, 35.45]	22.21 [10.81, 50.92]
	Q3 [95% CI]	41.46 [35.98, NC]	NYR [50.92, NC]
	p-value[b][d]		0.187
	HR [95 % CI][c][d]		1.26 [0.89, 1.80]
	Heterogeneity p-value[e][d]		0.5843

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	66 (43.1%)	51 (36.2%)
Number of censored cases	n (%)	87 (56.9%)	90 (63.8%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	1 (0.7%)	0
No first deterioration	n (%)	70 (45.8%)	72 (51.1%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [5.29, 10.71]	5.78 [5.55, 8.41]
	Median [95% CI]	18.00 [15.51, 33.74]	18.46 [12.12, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.745
	HR [95 % CI][c][d]		1.06 [0.73, 1.55]
	Heterogeneity p-value[e][d]		0.9267

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	88 (57.5%)	60 (42.6%)
Number of censored cases	n (%)	65 (42.5%)	81 (57.4%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	2 (1.3%)	0
No first deterioration	n (%)	47 (30.7%)	63 (44.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.96, 5.65]	5.42 [2.89, 5.75]
	Median [95% CI]	10.84 [8.31, 16.89]	13.86 [8.41, NC]
	Q3 [95% CI]	34.66 [22.18, NC]	NYR [NC, NC]
	p-value[b][d]		0.286
	HR [95 % CI][c][d]		1.20 [0.85, 1.68]
	Heterogeneity p-value[e][d]		0.7087

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	58 (37.9%)	53 (37.6%)
Number of censored cases	n (%)	95 (62.1%)	88 (62.4%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	1 (0.7%)	1 (0.7%)
No first deterioration	n (%)	78 (51.0%)	69 (48.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.41 [5.62, 12.65]	5.65 [5.55, 8.34]
	Median [95% CI]	34.37 [17.58, NC]	25.36 [10.68, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [48.82, NC]
	p-value[b][d]		0.308
	HR [95 % CI][c][d]		0.82 [0.56, 1.20]
	Heterogeneity p-value[e][d]		0.1724

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	74 (48.4%)	59 (41.8%)
Number of censored cases	n (%)	79 (51.6%)	82 (58.2%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	63 (41.2%)	63 (44.7%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [5.29, 8.48]	5.62 [2.92, 8.38]
	Median [95% CI]	16.92 [12.55, 24.94]	18.50 [10.68, 25.69]
	Q3 [95% CI]	46.03 [35.84, NC]	51.12 [26.48, NC]
	p-value[b][d]		0.759
	HR [95 % CI][c][d]		0.94 [0.66, 1.35]
	Heterogeneity p-value[e][d]		0.7091

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	79 (51.6%)	47 (33.3%)
Number of censored cases	n (%)	74 (48.4%)	94 (66.7%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	2 (1.4%)
No first deterioration	n (%)	58 (37.9%)	74 (52.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.29, 7.85]	5.75 [2.96, 9.82]
	Median [95% CI]	15.38 [9.03, 25.13]	45.83 [12.12, NC]
	Q3 [95% CI]	46.19 [31.77, NC]	NYR [NC, NC]
	p-value[b][d]		0.075
	HR [95 % CI][c][d]		1.39 [0.96, 2.01]
	Heterogeneity p-value[e][d]		0.0118

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	97 (63.4%)	74 (52.5%)
Number of censored cases	n (%)	56 (36.6%)	67 (47.5%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	40 (26.1%)	48 (34.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.92]
	Median [95% CI]	5.78 [5.55, 8.48]	8.31 [5.65, 10.61]
	Q3 [95% CI]	26.81 [14.23, 41.26]	NYR [13.86, NC]
	p-value[b][d]		0.279
	HR [95 % CI][c][d]		1.18 [0.87, 1.62]
	Heterogeneity p-value[e][d]		0.8019

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	89 (58.2%)	62 (44.0%)
Number of censored cases	n (%)	64 (41.8%)	79 (56.0%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	1 (0.7%)	1 (0.7%)
No first deterioration	n (%)	47 (30.7%)	60 (42.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.61, 6.24]	3.88 [2.89, 8.38]
	Median [95% CI]	10.91 [8.38, 14.23]	15.90 [10.97, 39.16]
	Q3 [95% CI]	33.61 [20.50, NC]	49.74 [39.16, NC]
	p-value[b][d]		0.031
	HR [95 % CI][c][d]		1.43 [1.03, 2.00]
	Heterogeneity p-value[e][d]		0.3353

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	40 (26.1%)	21 (14.9%)
Number of censored cases	n (%)	113 (73.9%)	120 (85.1%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	2 (1.3%)	1 (0.7%)
No first deterioration	n (%)	95 (62.1%)	101 (71.6%)
Time to first deterioration (months)	Q1 [95% CI]	16.53 [8.41, 30.65]	40.05 [11.07, NC]
	Median [95% CI]	57.99 [34.96, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.117
	HR [95 % CI][c][d]		1.54 [0.90, 2.65]
	Heterogeneity p-value[e][d]		0.5003

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	46 (30.1%)	34 (24.1%)
Number of censored cases	n (%)	107 (69.9%)	107 (75.9%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	91 (59.5%)	89 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [10.12, 21.22]	17.87 [5.55, 26.48]
	Median [95% CI]	45.70 [33.68, NC]	48.82 [30.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [48.82, NC]
	p-value[b][d]		0.894
	HR [95 % CI][c][d]		1.03 [0.66, 1.62]
	Heterogeneity p-value[e][d]		0.3247

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	57 (37.3%)	45 (31.9%)
Number of censored cases	n (%)	96 (62.7%)	96 (68.1%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	2 (1.3%)	0
No first deterioration	n (%)	78 (51.0%)	78 (55.3%)
Time to first deterioration (months)	Q1 [95% CI]	11.33 [8.34, 16.53]	8.34 [5.59, 10.87]
	Median [95% CI]	27.07 [21.59, 35.45]	33.61 [14.52, NC]
	Q3 [95% CI]	44.65 [35.45, NC]	NYR [NC, NC]
	p-value[b][d]		0.588
	HR [95 % CI][c][d]		0.89 [0.60, 1.34]
	Heterogeneity p-value[e][d]		0.0681

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	65 (42.5%)	50 (35.5%)
Number of censored cases	n (%)	88 (57.5%)	91 (64.5%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	1 (0.7%)	5 (3.5%)
No first deterioration	n (%)	71 (46.4%)	68 (48.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.55, 8.31]	7.85 [5.59, 8.38]
	Median [95% CI]	16.56 [10.81, NC]	23.26 [14.55, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [38.70, NC]
	p-value[b][d]		0.613
	HR [95 % CI][c][d]		1.10 [0.75, 1.62]
	Heterogeneity p-value[e][d]		0.9858

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	51 (33.3%)	32 (22.7%)
Number of censored cases	n (%)	102 (66.7%)	109 (77.3%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	4 (2.6%)	2 (1.4%)
No first deterioration	n (%)	82 (53.6%)	89 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	12.52 [5.78, 14.59]	13.60 [3.65, 45.83]
	Median [95% CI]	35.45 [21.59, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.309
	HR [95 % CI][c][d]		1.26 [0.80, 1.98]
	Heterogeneity p-value[e][d]		0.7556

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	59 (38.6%)	50 (35.5%)
Number of censored cases	n (%)	94 (61.4%)	91 (64.5%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	2 (1.3%)	2 (1.4%)
No first deterioration	n (%)	76 (49.7%)	71 (50.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.68, 11.10]	8.51 [5.59, 11.07]
	Median [95% CI]	31.77 [23.03, 45.70]	26.25 [15.90, 52.60]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [34.53, NC]
	p-value[b][d]		0.686
	HR [95 % CI][c][d]		0.92 [0.63, 1.36]
	Heterogeneity p-value[e][d]		0.4587

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	44 (28.8%)	30 (21.3%)
Number of censored cases	n (%)	109 (71.2%)	111 (78.7%)
No baseline score	n (%)	13 (8.5%)	14 (9.9%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	1 (0.7%)	0
No first deterioration	n (%)	92 (60.1%)	93 (66.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [8.34, 21.88]	21.65 [8.34, 28.81]
	Median [95% CI]	62.26 [41.46, NC]	NYR [28.81, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.588
	HR [95 % CI][c][d]		1.13 [0.70, 1.83]
	Heterogeneity p-value[e][d]		0.2514

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	32 (49.2%)
Number of censored cases	n (%)	27 (48.2%)	33 (50.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	23 (41.1%)	31 (47.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.65]	5.55 [2.86, 7.06]
	Median [95% CI]	11.30 [5.65, NC]	9.33 [7.06, NC]
	Q3 [95% CI]	NYR [29.31, NC]	49.05 [38.90, NC]
	p-value[b][d]		0.558
	HR [95 % CI][c][d]		1.17 [0.69, 1.98]
	Heterogeneity p-value[e][d]		0.3710

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	23 (41.1%)	21 (32.3%)
Number of censored cases	n (%)	33 (58.9%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	29 (51.8%)	42 (64.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.89, 13.01]	5.72 [2.89, 13.44]
	Median [95% CI]	39.82 [10.64, NC]	NYR [13.44, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.648
	HR [95 % CI][c][d]		1.16 [0.62, 2.17]
	Heterogeneity p-value[e][d]		0.8684

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	30 (53.6%)	29 (44.6%)
Number of censored cases	n (%)	26 (46.4%)	36 (55.4%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	3 (5.4%)	0
No first deterioration	n (%)	19 (33.9%)	34 (52.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.71 [2.86, 5.62]	5.52 [2.86, 8.34]
	Median [95% CI]	9.79 [5.59, 22.74]	14.78 [8.34, NC]
	Q3 [95% CI]	NYR [14.06, NC]	NYR [36.40, NC]
	p-value[b][d]		0.096
	HR [95 % CI][c][d]		1.58 [0.92, 2.71]
	Heterogeneity p-value[e][d]		0.9225

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	27 (41.5%)
Number of censored cases	n (%)	27 (48.2%)	38 (58.5%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	23 (41.1%)	36 (55.4%)
Time to first deterioration (months)	Q1 [95% CI]	3.01 [2.79, 5.59]	5.59 [4.27, 10.61]
	Median [95% CI]	11.37 [5.59, NC]	20.30 [9.95, NC]
	Q3 [95% CI]	NYR [26.45, NC]	NYR [NC, NC]
	p-value[b][d]		0.264
	HR [95 % CI][c][d]		1.37 [0.79, 2.38]
	Heterogeneity p-value[e][d]		0.2948

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	33 (58.9%)	35 (53.8%)
Number of censored cases	n (%)	23 (41.1%)	30 (46.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	19 (33.9%)	28 (43.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.99 [2.79, 5.59]	2.96 [2.83, 6.11]
	Median [95% CI]	8.41 [5.59, 14.98]	10.68 [6.11, 21.45]
	Q3 [95% CI]	NYR [14.98, NC]	NYR [14.52, NC]
	p-value[b][d]		0.652
	HR [95 % CI][c][d]		1.12 [0.69, 1.83]
	Heterogeneity p-value[e][d]		0.1345

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	26 (46.4%)	37 (56.9%)
Number of censored cases	n (%)	30 (53.6%)	28 (43.1%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (46.4%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.41]	2.89 [2.79, 5.55]
	Median [95% CI]	18.30 [8.34, NC]	8.34 [5.55, 14.39]
	Q3 [95% CI]	NYR [NC, NC]	NYR [14.39, NC]
	p-value[b][d]		0.217
	HR [95 % CI][c][d]		0.72 [0.43, 1.20]
	Heterogeneity p-value[e][d]		0.0096

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	39 (69.6%)	37 (56.9%)
Number of censored cases	n (%)	17 (30.4%)	28 (43.1%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	12 (21.4%)	26 (40.0%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 3.02]	2.89 [2.79, 5.55]
	Median [95% CI]	5.59 [2.99, 8.34]	8.31 [5.55, 10.61]
	Q3 [95% CI]	21.68 [8.34, NC]	NYR [8.57, NC]
	p-value[b][d]		0.747
	HR [95 % CI][c][d]		1.08 [0.67, 1.72]
	Heterogeneity p-value[e][d]		0.4444

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	32 (57.1%)	35 (53.8%)
Number of censored cases	n (%)	24 (42.9%)	30 (46.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	1 (1.5%)
No first deterioration	n (%)	19 (33.9%)	27 (41.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.99 [2.83, 5.59]	3.25 [2.86, 5.65]
	Median [95% CI]	8.34 [5.59, 27.63]	8.38 [5.65, 29.80]
	Q3 [95% CI]	NYR [21.68, NC]	NYR [20.90, NC]
	p-value[b][d]		0.940
	HR [95 % CI][c][d]		1.03 [0.63, 1.68]
	Heterogeneity p-value[e][d]		0.3400

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	14 (25.0%)	14 (21.5%)
Number of censored cases	n (%)	42 (75.0%)	51 (78.5%)
No baseline score	n (%)	4 (7.1%)	2 (3.1%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	4 (7.1%)	1 (1.5%)
No first deterioration	n (%)	34 (60.7%)	47 (72.3%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [5.59, NC]	21.32 [2.96, NC]
	Median [95% CI]	NYR [29.73, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.451
	HR [95 % CI][c][d]		1.36 [0.61, 3.01]
	Heterogeneity p-value[e][d]		0.7343

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	15 (26.8%)	19 (29.2%)
Number of censored cases	n (%)	41 (73.2%)	46 (70.8%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (66.1%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	11.20 [2.86, NC]	8.31 [3.02, 25.63]
	Median [95% CI]	NYR [NC, NC]	NYR [14.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.552
	HR [95 % CI][c][d]		0.80 [0.40, 1.62]
	Heterogeneity p-value[e][d]		0.5800

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	21 (32.3%)
Number of censored cases	n (%)	27 (48.2%)	44 (67.7%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	0
No first deterioration	n (%)	22 (39.3%)	42 (64.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 8.34]	10.64 [5.72, 21.72]
	Median [95% CI]	14.98 [8.34, 30.98]	40.71 [15.93, NC]
	Q3 [95% CI]	NYR [25.59, NC]	43.56 [40.71, NC]
	p-value[b][d]		0.045
	HR [95 % CI][c][d]		1.79 [1.01, 3.20]
	Heterogeneity p-value[e][d]		0.1370

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	26 (46.4%)	29 (44.6%)
Number of censored cases	n (%)	30 (53.6%)	36 (55.4%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	4 (7.1%)	1 (1.5%)
No first deterioration	n (%)	22 (39.3%)	33 (50.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.25]	2.89 [2.79, 8.31]
	Median [95% CI]	14.46 [5.65, NC]	15.08 [8.31, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.450
	HR [95 % CI][c][d]		1.23 [0.71, 2.12]
	Heterogeneity p-value[e][d]		0.6239

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	19 (33.9%)	15 (23.1%)
Number of censored cases	n (%)	37 (66.1%)	50 (76.9%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	1 (1.8%)	3 (4.6%)
No first deterioration	n (%)	32 (57.1%)	45 (69.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.92, 14.49]	10.45 [5.62, NC]
	Median [95% CI]	NYR [14.49, NC]	NYR [31.18, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.283
	HR [95 % CI][c][d]		1.47 [0.72, 2.97]
	Heterogeneity p-value[e][d]		0.6485

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	12 (21.4%)	18 (27.7%)
Number of censored cases	n (%)	44 (78.6%)	47 (72.3%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	1 (1.5%)
No first deterioration	n (%)	40 (71.4%)	44 (67.7%)
Time to first deterioration (months)	Q1 [95% CI]	22.74 [8.34, NC]	9.95 [5.59, NC]
	Median [95% CI]	NYR [NC, NC]	58.68 [30.69, NC]
	Q3 [95% CI]	NYR [NC, NC]	58.68 [NC, NC]
	p-value[b][d]		0.474
	HR [95 % CI][c][d]		0.76 [0.36, 1.62]
	Heterogeneity p-value[e][d]		0.6065

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	16 (28.6%)	22 (33.8%)
Number of censored cases	n (%)	40 (71.4%)	43 (66.2%)
No baseline score	n (%)	4 (7.1%)	1 (1.5%)
No post-baseline score	n (%)	0	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	36 (64.3%)	41 (63.1%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [5.59, NC]	5.65 [2.89, 9.95]
	Median [95% CI]	NYR [25.59, NC]	NYR [9.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.426
	HR [95 % CI][c][d]		0.76 [0.39, 1.49]
	Heterogeneity p-value[e][d]		0.4930

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	35 (43.8%)	28 (40.6%)
Number of censored cases	n (%)	45 (56.3%)	41 (59.4%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	38 (47.5%)	33 (47.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.65, 10.97]	5.55 [2.86, 8.38]
	Median [95% CI]	19.81 [13.57, 40.31]	18.60 [8.38, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [45.83, NC]
	p-value[b][d]		0.972
	HR [95 % CI][c][d]		0.99 [0.59, 1.64]
	Heterogeneity p-value[e][d]		0.3710

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	31 (38.8%)	23 (33.3%)
Number of censored cases	n (%)	49 (61.3%)	46 (66.7%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	41 (51.3%)	38 (55.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.54 [2.96, 13.90]	8.38 [5.55, 14.85]
	Median [95% CI]	18.40 [14.23, NC]	18.46 [14.85, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.428
	HR [95 % CI][c][d]		1.26 [0.72, 2.22]
	Heterogeneity p-value[e][d]		0.8684

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	40 (50.0%)	28 (40.6%)
Number of censored cases	n (%)	40 (50.0%)	41 (59.4%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	2 (2.5%)	0
No first deterioration	n (%)	31 (38.8%)	33 (47.8%)
Time to first deterioration (months)	Q1 [95% CI]	3.25 [2.83, 5.65]	5.55 [2.83, 8.34]
	Median [95% CI]	11.47 [8.28, 34.37]	19.12 [8.34, NC]
	Q3 [95% CI]	NYR [34.37, NC]	NYR [NC, NC]
	p-value[b][d]		0.447
	HR [95 % CI][c][d]		1.22 [0.74, 2.03]
	Heterogeneity p-value[e][d]		0.9225

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	29 (36.3%)	28 (40.6%)
Number of censored cases	n (%)	51 (63.8%)	41 (59.4%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	44 (55.0%)	32 (46.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.61 [5.55, 14.23]	5.59 [2.92, 8.38]
	Median [95% CI]	40.31 [17.58, NC]	22.47 [8.38, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.30, NC]
	p-value[b][d]		0.232
	HR [95 % CI][c][d]		0.72 [0.42, 1.24]
	Heterogeneity p-value[e][d]		0.2948

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	32 (40.0%)	32 (46.4%)
Number of censored cases	n (%)	48 (60.0%)	37 (53.6%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	41 (51.3%)	28 (40.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.51 [3.61, 13.77]	5.55 [2.83, 8.31]
	Median [95% CI]	35.84 [13.90, NC]	10.84 [8.31, 51.12]
	Q3 [95% CI]	NYR [40.31, NC]	51.12 [26.48, NC]
	p-value[b][d]		0.053
	HR [95 % CI][c][d]		0.60 [0.36, 1.01]
	Heterogeneity p-value[e][d]		0.1345

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	38 (47.5%)	27 (39.1%)
Number of censored cases	n (%)	42 (52.5%)	42 (60.9%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	35 (43.8%)	33 (47.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 11.24]	2.96 [2.86, 8.34]
	Median [95% CI]	17.58 [13.83, 28.65]	25.86 [8.34, NC]
	Q3 [95% CI]	46.19 [26.38, NC]	NYR [45.83, NC]
	p-value[b][d]		0.945
	HR [95 % CI][c][d]		0.98 [0.58, 1.66]
	Heterogeneity p-value[e][d]		0.0096

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	48 (60.0%)	38 (55.1%)
Number of censored cases	n (%)	32 (40.0%)	31 (44.9%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	25 (31.3%)	22 (31.9%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.83, 2.92]	2.86 [2.83, 2.89]
	Median [95% CI]	8.38 [5.52, 11.40]	5.78 [2.89, 10.61]
	Q3 [95% CI]	40.31 [13.83, NC]	NYR [10.61, NC]
	p-value[b][d]		0.932
	HR [95 % CI][c][d]		0.98 [0.63, 1.52]
	Heterogeneity p-value[e][d]		0.4444

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	43 (53.8%)	34 (49.3%)
Number of censored cases	n (%)	37 (46.3%)	35 (50.7%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	29 (36.3%)	27 (39.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [3.61, 8.34]	5.55 [2.89, 10.78]
	Median [95% CI]	14.23 [8.34, 24.08]	14.98 [10.78, 34.07]
	Q3 [95% CI]	37.06 [24.08, NC]	46.16 [29.57, NC]
	p-value[b][d]		0.588
	HR [95 % CI][c][d]		1.14 [0.71, 1.84]
	Heterogeneity p-value[e][d]		0.3400

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	22 (27.5%)	13 (18.8%)
Number of censored cases	n (%)	58 (72.5%)	56 (81.2%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	2 (2.5%)	1 (1.4%)
No first deterioration	n (%)	49 (61.3%)	47 (68.1%)
Time to first deterioration (months)	Q1 [95% CI]	17.97 [5.68, 34.37]	23.95 [8.38, NC]
	Median [95% CI]	NYR [30.65, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.188
	HR [95 % CI][c][d]		1.59 [0.79, 3.20]
	Heterogeneity p-value[e][d]		0.7343

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	22 (27.5%)	17 (24.6%)
Number of censored cases	n (%)	58 (72.5%)	52 (75.4%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	51 (63.8%)	44 (63.8%)
Time to first deterioration (months)	Q1 [95% CI]	14.59 [8.44, 33.68]	23.26 [2.92, 45.83]
	Median [95% CI]	NYR [33.68, NC]	45.83 [30.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [45.83, NC]
	p-value[b][d]		0.976
	HR [95 % CI][c][d]		1.01 [0.52, 1.94]
	Heterogeneity p-value[e][d]		0.5800

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	23 (28.8%)	22 (31.9%)
Number of censored cases	n (%)	57 (71.3%)	47 (68.1%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	49 (61.3%)	39 (56.5%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [5.68, 26.48]	9.69 [2.89, 14.52]
	Median [95% CI]	41.26 [26.48, NC]	33.61 [14.52, NC]
	Q3 [95% CI]	NYR [41.26, NC]	NYR [NC, NC]
	p-value[b][d]		0.425
	HR [95 % CI][c][d]		0.78 [0.42, 1.44]
	Heterogeneity p-value[e][d]		0.1370

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	32 (40.0%)	28 (40.6%)
Number of censored cases	n (%)	48 (60.0%)	41 (59.4%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	1 (1.3%)	1 (1.4%)
No first deterioration	n (%)	40 (50.0%)	32 (46.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.99, 8.38]	5.78 [2.92, 8.38]
	Median [95% CI]	39.82 [8.61, NC]	22.28 [8.38, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [38.70, NC]
	p-value[b][d]		0.682
	HR [95 % CI][c][d]		0.90 [0.53, 1.52]
	Heterogeneity p-value[e][d]		0.6239

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	22 (27.5%)	16 (23.2%)
Number of censored cases	n (%)	58 (72.5%)	53 (76.8%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	1 (1.3%)	2 (2.9%)
No first deterioration	n (%)	50 (62.5%)	43 (62.3%)
Time to first deterioration (months)	Q1 [95% CI]	14.59 [5.62, 24.08]	13.60 [2.89, NC]
	Median [95% CI]	NYR [24.08, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.879
	HR [95 % CI][c][d]		0.95 [0.48, 1.86]
	Heterogeneity p-value[e][d]		0.6485

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	25 (31.3%)	23 (33.3%)
Number of censored cases	n (%)	55 (68.8%)	46 (66.7%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	47 (58.8%)	38 (55.1%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [5.68, 24.74]	10.64 [5.59, 14.69]
	Median [95% CI]	NYR [24.74, NC]	28.81 [14.69, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.440
	HR [95 % CI][c][d]		0.80 [0.45, 1.42]
	Heterogeneity p-value[e][d]		0.6065

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	20 (25.0%)	15 (21.7%)
Number of censored cases	n (%)	60 (75.0%)	54 (78.3%)
No baseline score	n (%)	6 (7.5%)	8 (11.6%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	53 (66.3%)	46 (66.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [8.31, NC]	11.40 [8.34, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [28.81, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.965
	HR [95 % CI][c][d]		1.01 [0.50, 2.01]
	Heterogeneity p-value[e][d]		0.4930

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	41 (56.2%)	27 (37.5%)
Number of censored cases	n (%)	32 (43.8%)	45 (62.5%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	23 (31.5%)	34 (47.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.98]	5.59 [2.86, 8.34]
	Median [95% CI]	8.54 [6.24, 21.03]	24.44 [8.34, NC]
	Q3 [95% CI]	41.46 [21.03, NC]	NYR [50.92, NC]
	p-value[b][d]		0.072
	HR [95 % CI][c][d]		1.58 [0.95, 2.63]
	Heterogeneity p-value[e][d]		0.3710

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	35 (47.9%)	28 (38.9%)
Number of censored cases	n (%)	38 (52.1%)	44 (61.1%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	29 (39.7%)	34 (47.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.86, 8.34]	5.62 [2.89, 7.85]
	Median [95% CI]	17.68 [8.44, 33.74]	13.93 [7.85, NC]
	Q3 [95% CI]	NYR [33.74, NC]	34.83 [34.83, NC]
	p-value[b][d]		0.902
	HR [95 % CI][c][d]		1.03 [0.62, 1.72]
	Heterogeneity p-value[e][d]		0.8684

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	48 (65.8%)	32 (44.4%)
Number of censored cases	n (%)	25 (34.2%)	40 (55.6%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (21.9%)	30 (41.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.29, 6.47]	3.65 [2.83, 6.51]
	Median [95% CI]	10.84 [7.85, 16.89]	11.40 [6.51, 25.69]
	Q3 [95% CI]	25.76 [17.54, NC]	NYR [17.77, NC]
	p-value[b][d]		0.572
	HR [95 % CI][c][d]		1.14 [0.71, 1.83]
	Heterogeneity p-value[e][d]		0.9225

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	29 (39.7%)	25 (34.7%)
Number of censored cases	n (%)	44 (60.3%)	47 (65.3%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	1 (1.4%)	0
No first deterioration	n (%)	34 (46.6%)	37 (51.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [5.55, 14.46]	6.51 [5.59, 10.61]
	Median [95% CI]	25.63 [14.46, NC]	25.53 [8.38, NC]
	Q3 [95% CI]	NYR [34.37, NC]	NYR [48.82, NC]
	p-value[b][d]		0.771
	HR [95 % CI][c][d]		0.92 [0.52, 1.61]
	Heterogeneity p-value[e][d]		0.2948

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	42 (57.5%)	27 (37.5%)
Number of censored cases	n (%)	31 (42.5%)	45 (62.5%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (30.1%)	35 (48.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.86, 8.31]	6.34 [4.27, 13.47]
	Median [95% CI]	10.87 [8.34, 17.77]	18.50 [10.91, 29.73]
	Q3 [95% CI]	25.63 [17.77, NC]	29.73 [22.41, NC]
	p-value[b][d]		0.082
	HR [95 % CI][c][d]		1.56 [0.94, 2.59]
	Heterogeneity p-value[e][d]		0.1345

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	41 (56.2%)	20 (27.8%)
Number of censored cases	n (%)	32 (43.8%)	52 (72.2%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	23 (31.5%)	41 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	4.86 [2.83, 5.62]	8.41 [5.59, 12.12]
	Median [95% CI]	8.54 [5.68, 20.60]	NYR [11.37, NC]
	Q3 [95% CI]	39.49 [20.60, NC]	NYR [NC, NC]
	p-value[b][d]		0.007
	HR [95 % CI][c][d]		2.10 [1.21, 3.62]
	Heterogeneity p-value[e][d]		0.0096

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	49 (67.1%)	36 (50.0%)
Number of censored cases	n (%)	24 (32.9%)	36 (50.0%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	15 (20.5%)	26 (36.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.84 [2.79, 2.99]	2.89 [2.83, 5.65]
	Median [95% CI]	5.62 [3.12, 8.31]	8.44 [5.65, 24.44]
	Q3 [95% CI]	20.60 [8.31, NC]	34.83 [13.86, NC]
	p-value[b][d]		0.102
	HR [95 % CI][c][d]		1.46 [0.92, 2.30]
	Heterogeneity p-value[e][d]		0.4444

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	46 (63.0%)	28 (38.9%)
Number of censored cases	n (%)	27 (37.0%)	44 (61.1%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	18 (24.7%)	33 (45.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 6.67]	2.89 [2.83, 8.38]
	Median [95% CI]	8.64 [6.87, 11.30]	23.49 [8.38, NC]
	Q3 [95% CI]	20.50 [11.30, NC]	NYR [44.75, NC]
	p-value[b][d]		0.006
	HR [95 % CI][c][d]		1.96 [1.19, 3.22]
	Heterogeneity p-value[e][d]		0.3400

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	18 (24.7%)	8 (11.1%)
Number of censored cases	n (%)	55 (75.3%)	64 (88.9%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	46 (63.0%)	54 (75.0%)
Time to first deterioration (months)	Q1 [95% CI]	16.53 [7.89, 57.99]	NYR [18.43, NC]
	Median [95% CI]	57.99 [57.99, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.206
	HR [95 % CI][c][d]		1.75 [0.73, 4.19]
	Heterogeneity p-value[e][d]		0.7343

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	24 (32.9%)	17 (23.6%)
Number of censored cases	n (%)	49 (67.1%)	55 (76.4%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	40 (54.8%)	45 (62.5%)
Time to first deterioration (months)	Q1 [95% CI]	13.67 [6.87, 21.22]	13.47 [5.55, 26.48]
	Median [95% CI]	45.70 [21.22, NC]	48.82 [21.65, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [48.82, NC]
	p-value[b][d]		0.819
	HR [95 % CI][c][d]		1.08 [0.57, 2.05]
	Heterogeneity p-value[e][d]		0.5800

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	34 (46.6%)	23 (31.9%)
Number of censored cases	n (%)	39 (53.4%)	49 (68.1%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	1 (1.4%)	0
No first deterioration	n (%)	29 (39.7%)	39 (54.2%)
Time to first deterioration (months)	Q1 [95% CI]	11.33 [5.59, 14.46]	8.31 [5.55, 9.82]
	Median [95% CI]	22.18 [14.46, 29.14]	28.55 [8.44, NC]
	Q3 [95% CI]	34.37 [27.07, NC]	NYR [NC, NC]
	p-value[b][d]		0.812
	HR [95 % CI][c][d]		1.07 [0.62, 1.85]
	Heterogeneity p-value[e][d]		0.1370

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	33 (45.2%)	22 (30.6%)
Number of censored cases	n (%)	40 (54.8%)	50 (69.4%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	4 (5.6%)
No first deterioration	n (%)	31 (42.5%)	36 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.06, 8.31]	8.34 [2.92, 14.82]
	Median [95% CI]	16.53 [8.41, NC]	29.34 [14.55, NC]
	Q3 [95% CI]	NYR [31.38, NC]	NYR [34.53, NC]
	p-value[b][d]		0.431
	HR [95 % CI][c][d]		1.26 [0.71, 2.22]
	Heterogeneity p-value[e][d]		0.6239

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	29 (39.7%)	16 (22.2%)
Number of censored cases	n (%)	44 (60.3%)	56 (77.8%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	3 (4.1%)	0
No first deterioration	n (%)	32 (43.8%)	46 (63.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [5.55, 14.42]	8.38 [2.89, NC]
	Median [95% CI]	21.59 [13.86, NC]	NYR [28.85, NC]
	Q3 [95% CI]	NYR [35.45, NC]	NYR [NC, NC]
	p-value[b][d]		0.205
	HR [95 % CI][c][d]		1.50 [0.79, 2.83]
	Heterogeneity p-value[e][d]		0.6485

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	34 (46.6%)	27 (37.5%)
Number of censored cases	n (%)	39 (53.4%)	45 (62.5%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	1 (1.4%)	2 (2.8%)
No first deterioration	n (%)	29 (39.7%)	33 (45.8%)
Time to first deterioration (months)	Q1 [95% CI]	6.87 [5.29, 10.64]	8.41 [2.86, 15.90]
	Median [95% CI]	23.03 [10.64, 43.96]	22.34 [10.81, 34.53]
	Q3 [95% CI]	45.70 [38.87, NC]	34.53 [27.56, NC]
	p-value[b][d]		0.864
	HR [95 % CI][c][d]		1.05 [0.61, 1.83]
	Heterogeneity p-value[e][d]		0.6065

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	24 (32.9%)	15 (20.8%)
Number of censored cases	n (%)	49 (67.1%)	57 (79.2%)
No baseline score	n (%)	7 (9.6%)	6 (8.3%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	1 (1.4%)	0
No first deterioration	n (%)	39 (53.4%)	47 (65.3%)
Time to first deterioration (months)	Q1 [95% CI]	9.26 [5.59, 21.88]	22.21 [5.59, 29.73]
	Median [95% CI]	41.46 [21.39, NC]	32.89 [25.66, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [32.89, NC]
	p-value[b][d]		0.424
	HR [95 % CI][c][d]		1.31 [0.67, 2.55]
	Heterogeneity p-value[e][d]		0.4930

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	88 (50.6%)	71 (40.8%)
Number of censored cases	n (%)	86 (49.4%)	103 (59.2%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	71 (40.8%)	87 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.29, 7.85]	5.55 [2.89, 5.78]
	Median [95% CI]	16.33 [10.68, 34.66]	22.21 [9.33, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [49.05, NC]
	p-value[b][d]		0.422
	HR [95 % CI][c][d]		1.14 [0.83, 1.56]
	Heterogeneity p-value[e][d]		0.8286

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	76 (43.7%)	61 (35.1%)
Number of censored cases	n (%)	98 (56.3%)	113 (64.9%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	82 (47.1%)	97 (55.7%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [5.29, 8.54]	5.75 [3.84, 9.33]
	Median [95% CI]	21.22 [16.39, 39.82]	34.83 [14.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.571
	HR [95 % CI][c][d]		1.10 [0.78, 1.56]
	Heterogeneity p-value[e][d]		0.6234

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	99 (56.9%)	76 (43.7%)
Number of censored cases	n (%)	75 (43.1%)	98 (56.3%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	4 (2.3%)	0
No first deterioration	n (%)	56 (32.2%)	82 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.02, 5.65]	5.42 [2.89, 5.65]
	Median [95% CI]	11.47 [8.41, 17.54]	11.40 [9.33, NC]
	Q3 [95% CI]	35.45 [23.03, NC]	NYR [NC, NC]
	p-value[b][d]		0.284
	HR [95 % CI][c][d]		1.18 [0.87, 1.59]
	Heterogeneity p-value[e][d]		0.5367

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	73 (42.0%)	66 (37.9%)
Number of censored cases	n (%)	101 (58.0%)	108 (62.1%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	85 (48.9%)	91 (52.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.55, 10.12]	5.65 [5.55, 8.38]
	Median [95% CI]	25.63 [14.98, NC]	22.47 [11.63, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [48.82, NC]
	p-value[b][d]		0.974
	HR [95 % CI][c][d]		0.99 [0.71, 1.39]
	Heterogeneity p-value[e][d]		0.6512

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	92 (52.9%)	80 (46.0%)
Number of censored cases	n (%)	82 (47.1%)	94 (54.0%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	67 (38.5%)	77 (44.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.02, 8.31]	5.55 [2.89, 6.34]
	Median [95% CI]	13.77 [8.57, 18.99]	14.09 [9.33, 22.34]
	Q3 [95% CI]	46.03 [35.84, NC]	NYR [34.86, NC]
	p-value[b][d]		0.893
	HR [95 % CI][c][d]		0.98 [0.72, 1.33]
	Heterogeneity p-value[e][d]		0.6227

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	88 (50.6%)	72 (41.4%)
Number of censored cases	n (%)	86 (49.4%)	102 (58.6%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	71 (40.8%)	85 (48.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.55, 8.34]	5.55 [2.89, 5.75]
	Median [95% CI]	16.33 [10.81, 26.38]	19.22 [9.82, NC]
	Q3 [95% CI]	46.95 [39.49, NC]	NYR [NC, NC]
	p-value[b][d]		0.754
	HR [95 % CI][c][d]		1.05 [0.76, 1.44]
	Heterogeneity p-value[e][d]		0.7565

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	116 (66.7%)	90 (51.7%)
Number of censored cases	n (%)	58 (33.3%)	84 (48.3%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	42 (24.1%)	67 (38.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.92]
	Median [95% CI]	5.68 [5.55, 8.34]	8.38 [5.65, 10.61]
	Q3 [95% CI]	26.81 [14.23, 41.26]	NYR [34.83, NC]
	p-value[b][d]		0.180
	HR [95 % CI][c][d]		1.21 [0.91, 1.60]
	Heterogeneity p-value[e][d]		0.2844

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	103 (59.2%)	78 (44.8%)
Number of censored cases	n (%)	71 (40.8%)	96 (55.2%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	55 (31.6%)	79 (45.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.99, 5.72]	5.55 [2.92, 5.78]
	Median [95% CI]	10.87 [8.38, 13.93]	15.90 [10.97, 29.80]
	Q3 [95% CI]	37.06 [24.08, NC]	NYR [46.16, NC]
	p-value[b][d]		0.045
	HR [95 % CI][c][d]		1.36 [1.01, 1.83]
	Heterogeneity p-value[e][d]		0.2514

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	45 (25.9%)	29 (16.7%)
Number of censored cases	n (%)	129 (74.1%)	145 (83.3%)
No baseline score	n (%)	13 (7.5%)	12 (6.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	4 (2.3%)	1 (0.6%)
No first deterioration	n (%)	110 (63.2%)	127 (73.0%)
Time to first deterioration (months)	Q1 [95% CI]	16.53 [8.41, 30.65]	30.65 [10.64, NC]
	Median [95% CI]	57.99 [57.99, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.222
	HR [95 % CI][c][d]		1.34 [0.84, 2.16]
	Heterogeneity p-value[e][d]		0.8638

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	54 (31.0%)	40 (23.0%)
Number of censored cases	n (%)	120 (69.0%)	134 (77.0%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	105 (60.3%)	118 (67.8%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [10.68, 18.30]	14.75 [8.31, 45.83]
	Median [95% CI]	NYR [33.68, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.442
	HR [95 % CI][c][d]		1.17 [0.78, 1.77]
	Heterogeneity p-value[e][d]		0.0185

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	74 (42.5%)	55 (31.6%)
Number of censored cases	n (%)	100 (57.5%)	119 (68.4%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	3 (1.7%)	0
No first deterioration	n (%)	82 (47.1%)	103 (59.2%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.62, 12.52]	8.41 [6.24, 11.33]
	Median [95% CI]	25.86 [17.74, 34.37]	33.61 [21.72, NC]
	Q3 [95% CI]	NYR [35.45, NC]	NYR [43.56, NC]
	p-value[b][d]		0.388
	HR [95 % CI][c][d]		1.16 [0.81, 1.66]
	Heterogeneity p-value[e][d]		0.6869

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	74 (42.5%)	66 (37.9%)
Number of censored cases	n (%)	100 (57.5%)	108 (62.1%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	4 (2.3%)	4 (2.3%)
No first deterioration	n (%)	81 (46.6%)	88 (50.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.25, 8.31]	6.11 [2.92, 8.51]
	Median [95% CI]	16.53 [11.33, NC]	29.34 [14.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.712
	HR [95 % CI][c][d]		1.07 [0.76, 1.50]
	Heterogeneity p-value[e][d]		0.9601

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	60 (34.5%)	36 (20.7%)
Number of censored cases	n (%)	114 (65.5%)	138 (79.3%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	4 (2.3%)	2 (1.1%)
No first deterioration	n (%)	95 (54.6%)	120 (69.0%)
Time to first deterioration (months)	Q1 [95% CI]	9.07 [5.65, 14.42]	18.00 [8.31, NC]
	Median [95% CI]	37.06 [22.51, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.040
	HR [95 % CI][c][d]		1.54 [1.02, 2.34]
	Heterogeneity p-value[e][d]		0.0870

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	62 (35.6%)	55 (31.6%)
Number of censored cases	n (%)	112 (64.4%)	119 (68.4%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	96 (55.2%)	102 (58.6%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [6.87, 14.59]	10.64 [6.11, 15.15]
	Median [95% CI]	45.70 [24.74, NC]	34.53 [22.34, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [52.60, NC]
	p-value[b][d]		0.831
	HR [95 % CI][c][d]		0.96 [0.66, 1.39]
	Heterogeneity p-value[e][d]		0.1512

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	49 (28.2%)	42 (24.1%)
Number of censored cases	n (%)	125 (71.8%)	132 (75.9%)
No baseline score	n (%)	13 (7.5%)	11 (6.3%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	109 (62.6%)	116 (66.7%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [8.34, 24.74]	10.84 [5.72, 28.81]
	Median [95% CI]	62.26 [41.46, NC]	NYR [32.89, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.854
	HR [95 % CI][c][d]		0.96 [0.63, 1.46]
	Heterogeneity p-value[e][d]		0.9274

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	17 (48.6%)	16 (50.0%)
Number of censored cases	n (%)	18 (51.4%)	16 (50.0%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	1 (3.1%)
No first deterioration	n (%)	13 (37.1%)	11 (34.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.79, 5.85]	6.11 [2.79, 8.38]
	Median [95% CI]	10.84 [5.59, NC]	11.43 [6.11, 27.47]
	Q3 [95% CI]	NYR [13.80, NC]	27.47 [11.43, NC]
	p-value[b][d]		0.244
	HR [95 % CI][c][d]		1.55 [0.73, 3.29]
	Heterogeneity p-value[e][d]		0.8286

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	13 (37.1%)	11 (34.4%)
Number of censored cases	n (%)	22 (62.9%)	21 (65.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (48.6%)	17 (53.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, 18.40]	5.72 [2.79, 8.38]
	Median [95% CI]	39.82 [8.31, NC]	17.77 [6.74, NC]
	Q3 [95% CI]	39.82 [NC, NC]	NYR [17.77, NC]
	p-value[b][d]		0.799
	HR [95 % CI][c][d]		0.88 [0.38, 2.08]
	Heterogeneity p-value[e][d]		0.6234

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	19 (54.3%)	13 (40.6%)
Number of censored cases	n (%)	16 (45.7%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	1 (2.9%)	0
No first deterioration	n (%)	10 (28.6%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.73, 5.55]	5.52 [2.79, 15.21]
	Median [95% CI]	5.65 [3.29, 8.51]	17.58 [5.72, NC]
	Q3 [95% CI]	NYR [6.37, NC]	25.69 [17.58, NC]
	p-value[b][d]		0.252
	HR [95 % CI][c][d]		1.57 [0.71, 3.44]
	Heterogeneity p-value[e][d]		0.5367

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	14 (40.0%)	14 (43.8%)
Number of censored cases	n (%)	21 (60.0%)	18 (56.3%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (45.7%)	14 (43.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [2.83, 10.81]	5.65 [2.79, 8.31]
	Median [95% CI]	34.96 [8.41, NC]	13.54 [5.65, NC]
	Q3 [95% CI]	NYR [34.96, NC]	NYR [25.53, NC]
	p-value[b][d]		0.959
	HR [95 % CI][c][d]		1.02 [0.46, 2.29]
	Heterogeneity p-value[e][d]		0.6512

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	15 (42.9%)	14 (43.8%)
Number of censored cases	n (%)	20 (57.1%)	18 (56.3%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	15 (42.9%)	14 (43.8%)
Time to first deterioration (months)	Q1 [95% CI]	3.12 [2.79, 13.57]	5.62 [2.79, 10.91]
	Median [95% CI]	15.38 [5.59, NC]	11.37 [5.62, 26.48]
	Q3 [95% CI]	NYR [18.40, NC]	26.48 [11.37, NC]
	p-value[b][d]		0.456
	HR [95 % CI][c][d]		0.74 [0.34, 1.63]
	Heterogeneity p-value[e][d]		0.6227

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	17 (48.6%)	12 (37.5%)
Number of censored cases	n (%)	18 (51.4%)	20 (62.5%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	1 (3.1%)
No first deterioration	n (%)	13 (37.1%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	2.96 [2.83, 5.55]	5.59 [2.79, 13.73]
	Median [95% CI]	9.03 [3.29, NC]	15.21 [5.59, NC]
	Q3 [95% CI]	NYR [18.40, NC]	NYR [15.21, NC]
	p-value[b][d]		0.513
	HR [95 % CI][c][d]		1.32 [0.59, 2.96]
	Heterogeneity p-value[e][d]		0.7565

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	20 (57.1%)	21 (65.6%)
Number of censored cases	n (%)	15 (42.9%)	11 (34.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	10 (28.6%)	7 (21.9%)
Time to first deterioration (months)	Q1 [95% CI]	2.83 [2.79, 3.61]	2.86 [2.79, 5.09]
	Median [95% CI]	5.62 [2.92, NC]	5.78 [2.92, 8.38]
	Q3 [95% CI]	21.68 [8.31, NC]	10.61 [8.31, NC]
	p-value[b][d]		0.681
	HR [95 % CI][c][d]		0.87 [0.45, 1.69]
	Heterogeneity p-value[e][d]		0.2844

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	18 (51.4%)	19 (59.4%)
Number of censored cases	n (%)	17 (48.6%)	13 (40.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	1 (2.9%)	1 (3.1%)
No first deterioration	n (%)	11 (31.4%)	8 (25.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.65]	2.86 [2.79, 3.09]
	Median [95% CI]	5.75 [5.55, 21.68]	5.65 [2.89, 10.61]
	Q3 [95% CI]	23.72 [8.34, NC]	34.07 [8.31, NC]
	p-value[b][d]		0.747
	HR [95 % CI][c][d]		0.91 [0.45, 1.84]
	Heterogeneity p-value[e][d]		0.2514

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	9 (25.7%)	6 (18.8%)
Number of censored cases	n (%)	26 (74.3%)	26 (81.3%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	2 (5.7%)	1 (3.1%)
No first deterioration	n (%)	19 (54.3%)	21 (65.6%)
Time to first deterioration (months)	Q1 [95% CI]	13.14 [2.73, NC]	40.05 [2.83, NC]
	Median [95% CI]	34.96 [29.73, NC]	NYR [10.61, NC]
	Q3 [95% CI]	NYR [34.96, NC]	NYR [40.05, NC]
	p-value[b][d]		0.382
	HR [95 % CI][c][d]		1.61 [0.55, 4.75]
	Heterogeneity p-value[e][d]		0.8638

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	7 (20.0%)	13 (40.6%)
Number of censored cases	n (%)	28 (80.0%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	23 (65.7%)	15 (46.9%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.89, NC]	5.55 [2.83, 10.78]
	Median [95% CI]	NYR [NC, NC]	17.87 [5.55, NC]
	Q3 [95% CI]	NYR [NC, NC]	23.26 [17.87, NC]
	p-value[b][d]		0.053
	HR [95 % CI][c][d]		0.38 [0.14, 1.05]
	Heterogeneity p-value[e][d]		0.0185

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	12 (34.3%)	11 (34.4%)
Number of censored cases	n (%)	23 (65.7%)	21 (65.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	18 (51.4%)	17 (53.1%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [2.92, 25.59]	8.41 [2.79, 13.83]
	Median [95% CI]	29.73 [17.77, NC]	14.52 [8.41, NC]
	Q3 [95% CI]	33.91 [29.73, NC]	40.71 [14.52, NC]
	p-value[b][d]		0.771
	HR [95 % CI][c][d]		0.87 [0.33, 2.25]
	Heterogeneity p-value[e][d]		0.6869

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	17 (48.6%)	13 (40.6%)
Number of censored cases	n (%)	18 (51.4%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	1 (2.9%)	2 (6.3%)
No first deterioration	n (%)	12 (34.3%)	13 (40.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.79, 7.89]	5.68 [2.79, 8.31]
	Median [95% CI]	8.31 [5.59, NC]	8.31 [5.68, NC]
	Q3 [95% CI]	NYR [8.61, NC]	NYR [8.38, NC]
	p-value[b][d]		0.879
	HR [95 % CI][c][d]		1.06 [0.48, 2.32]
	Heterogeneity p-value[e][d]		0.9601

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	10 (28.6%)	11 (34.4%)
Number of censored cases	n (%)	25 (71.4%)	21 (65.6%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	1 (2.9%)	3 (9.4%)
No first deterioration	n (%)	19 (54.3%)	14 (43.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [2.83, NC]	2.86 [2.79, 10.45]
	Median [95% CI]	NYR [15.15, NC]	28.85 [3.02, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [28.85, NC]
	p-value[b][d]		0.594
	HR [95 % CI][c][d]		0.77 [0.30, 1.96]
	Heterogeneity p-value[e][d]		0.0870

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	9 (25.7%)	13 (40.6%)
Number of censored cases	n (%)	26 (74.3%)	19 (59.4%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	1 (2.9%)	2 (6.3%)
No first deterioration	n (%)	20 (57.1%)	13 (40.6%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [2.79, NC]	5.55 [2.79, 8.41]
	Median [95% CI]	43.96 [11.10, NC]	10.45 [5.55, NC]
	Q3 [95% CI]	43.96 [NC, NC]	58.68 [10.45, NC]
	p-value[b][d]		0.092
	HR [95 % CI][c][d]		0.45 [0.17, 1.18]
	Heterogeneity p-value[e][d]		0.1512

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	11 (31.4%)	10 (31.3%)
Number of censored cases	n (%)	24 (68.6%)	22 (68.8%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	1 (2.9%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	19 (54.3%)	18 (56.3%)
Time to first deterioration (months)	Q1 [95% CI]	9.03 [5.49, 20.50]	8.44 [2.89, 21.65]
	Median [95% CI]	25.59 [10.97, NC]	25.69 [8.44, NC]
	Q3 [95% CI]	NYR [25.59, NC]	NYR [21.65, NC]
	p-value[b][d]		0.984
	HR [95 % CI][c][d]		1.01 [0.35, 2.92]
	Heterogeneity p-value[e][d]		0.9274

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	11 (29.7%)	11 (35.5%)
Number of censored cases	n (%)	26 (70.3%)	20 (64.5%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (56.8%)	15 (48.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, NC]	5.78 [1.97, 8.44]
	Median [95% CI]	37.06 [14.59, NC]	49.05 [6.11, NC]
	Q3 [95% CI]	NYR [37.06, NC]	49.05 [NC, NC]
	p-value[b][d]		0.558
	HR [95 % CI][c][d]		0.78 [0.34, 1.81]
	Heterogeneity p-value[e][d]		0.2658

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	10 (27.0%)	6 (19.4%)
Number of censored cases	n (%)	27 (73.0%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	22 (59.5%)	20 (64.5%)
Time to first deterioration (months)	Q1 [95% CI]	17.58 [3.78, NC]	8.31 [1.18, NC]
	Median [95% CI]	NYR [17.58, NC]	NYR [8.31, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.811
	HR [95 % CI][c][d]		0.88 [0.31, 2.51]
	Heterogeneity p-value[e][d]		0.8655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	15 (40.5%)	11 (35.5%)
Number of censored cases	n (%)	22 (59.5%)	20 (64.5%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	16 (43.2%)	15 (48.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [3.02, 8.41]	2.89 [2.20, 10.97]
	Median [95% CI]	22.74 [8.31, NC]	36.40 [5.78, NC]
	Q3 [95% CI]	NYR [23.03, NC]	NYR [36.40, NC]
	p-value[b][d]		0.594
	HR [95 % CI][c][d]		0.80 [0.35, 1.79]
	Heterogeneity p-value[e][d]		0.3477

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	13 (35.1%)	10 (32.3%)
Number of censored cases	n (%)	24 (64.9%)	21 (67.7%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	19 (51.4%)	16 (51.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.18 [2.92, 14.98]	5.55 [2.20, 8.38]
	Median [95% CI]	NYR [8.31, NC]	NYR [5.55, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.456
	HR [95 % CI][c][d]		0.72 [0.30, 1.71]
	Heterogeneity p-value[e][d]		0.4683

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	19 (51.4%)	10 (32.3%)
Number of censored cases	n (%)	18 (48.6%)	21 (67.7%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	13 (35.1%)	16 (51.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.83, 8.38]	2.89 [2.20, 11.24]
	Median [95% CI]	14.46 [5.68, NC]	NYR [5.62, NC]
	Q3 [95% CI]	46.03 [18.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.634
	HR [95 % CI][c][d]		1.20 [0.54, 2.63]
	Heterogeneity p-value[e][d]		0.7899

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	16 (43.2%)	12 (38.7%)
Number of censored cases	n (%)	21 (56.8%)	19 (61.3%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	16 (43.2%)	14 (45.2%)
Time to first deterioration (months)	Q1 [95% CI]	6.98 [2.92, 15.38]	2.79 [2.20, 2.92]
	Median [95% CI]	27.63 [8.44, NC]	7.85 [2.79, NC]
	Q3 [95% CI]	46.95 [46.95, NC]	NYR [7.85, NC]
	p-value[b][d]		0.305
	HR [95 % CI][c][d]		0.66 [0.30, 1.43]
	Heterogeneity p-value[e][d]		0.2810

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	20 (54.1%)	12 (38.7%)
Number of censored cases	n (%)	17 (45.9%)	19 (61.3%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	12 (32.4%)	14 (45.2%)
Time to first deterioration (months)	Q1 [95% CI]	3.27 [2.79, 8.31]	2.89 [2.20, 8.31]
	Median [95% CI]	11.10 [3.78, 27.07]	8.38 [2.89, NC]
	Q3 [95% CI]	27.07 [22.74, NC]	NYR [8.38, NC]
	p-value[b][d]		0.848
	HR [95 % CI][c][d]		0.93 [0.44, 1.94]
	Heterogeneity p-value[e][d]		0.7097

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	15 (40.5%)	9 (29.0%)
Number of censored cases	n (%)	22 (59.5%)	22 (71.0%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (45.9%)	17 (54.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [3.25, 17.58]	5.60 [1.97, NC]
	Median [95% CI]	27.63 [13.01, NC]	NYR [5.65, NC]
	Q3 [95% CI]	37.06 [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.911
	HR [95 % CI][c][d]		1.05 [0.45, 2.44]
	Heterogeneity p-value[e][d]		0.7523

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	4 (10.8%)	6 (19.4%)
Number of censored cases	n (%)	33 (89.2%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	2 (5.4%)	1 (3.2%)
No first deterioration	n (%)	26 (70.3%)	19 (61.3%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [5.62, NC]	7.85 [2.76, NC]
	Median [95% CI]	NYR [NC, NC]	30.65 [7.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [30.65, NC]
	p-value[b][d]		0.062
	HR [95 % CI][c][d]		0.28 [0.07, 1.16]
	Heterogeneity p-value[e][d]		0.0564

Data cut-off as of April 07, 2025.

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.

[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.

The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.

Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	7 (18.9%)	4 (12.9%)
Number of censored cases	n (%)	30 (81.1%)	27 (87.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	25 (67.6%)	22 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	33.68 [5.65, NC]	NYR [2.89, NC]
	Median [95% CI]	NYR [33.68, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.840
	HR [95 % CI][c][d]		0.88 [0.25, 3.08]
	Heterogeneity p-value[e][d]		0.6337

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	11 (29.7%)	8 (25.8%)
Number of censored cases	n (%)	26 (70.3%)	23 (74.2%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	20 (54.1%)	18 (58.1%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [5.29, 27.07]	6.24 [1.18, NC]
	Median [95% CI]	NYR [23.16, NC]	NYR [7.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.646
	HR [95 % CI][c][d]		0.80 [0.31, 2.04]
	Heterogeneity p-value[e][d]		0.5002

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	14 (37.8%)	9 (29.0%)
Number of censored cases	n (%)	23 (62.2%)	22 (71.0%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	17 (45.9%)	17 (54.8%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.92, 8.41]	7.85 [2.20, 34.53]
	Median [95% CI]	14.98 [8.34, NC]	34.53 [7.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.808
	HR [95 % CI][c][d]		0.89 [0.37, 2.15]
	Heterogeneity p-value[e][d]		0.0627

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	9 (24.3%)	4 (12.9%)
Number of censored cases	n (%)	28 (75.7%)	27 (87.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	1 (2.7%)	0
No first deterioration	n (%)	22 (59.5%)	22 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	17.58 [5.62, NC]	NYR [2.20, NC]
	Median [95% CI]	37.06 [37.06, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.655
	HR [95 % CI][c][d]		1.32 [0.39, 4.44]
	Heterogeneity p-value[e][d]		0.5582

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	13 (35.1%)	6 (19.4%)
Number of censored cases	n (%)	24 (64.9%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	1 (3.2%)
No first deterioration	n (%)	19 (51.4%)	19 (61.3%)
Time to first deterioration (months)	Q1 [95% CI]	11.10 [3.25, 23.03]	26.25 [2.20, NC]
	Median [95% CI]	NYR [14.59, NC]	30.65 [26.25, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [30.65, NC]
	p-value[b][d]		0.497
	HR [95 % CI][c][d]		1.41 [0.52, 3.78]
	Heterogeneity p-value[e][d]		0.6070

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	11 (29.7%)	4 (12.9%)
Number of censored cases	n (%)	26 (70.3%)	27 (87.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (56.8%)	22 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	9.03 [3.25, NC]	NYR [2.79, NC]
	Median [95% CI]	NYR [21.88, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.607
	HR [95 % CI][c][d]		1.36 [0.41, 4.50]
	Heterogeneity p-value[e][d]		0.1510

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	48 (53.3%)	37 (41.1%)
Number of censored cases	n (%)	42 (46.7%)	53 (58.9%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (41.1%)	48 (53.3%)
Time to first deterioration (months)	Q1 [95% CI]	6.24 [3.12, 8.44]	2.92 [2.86, 7.06]
	Median [95% CI]	16.39 [10.68, 34.66]	24.44 [13.63, NC]
	Q3 [95% CI]	NYR [30.62, NC]	NYR [45.83, NC]
	p-value[b][d]		0.556
	HR [95 % CI][c][d]		1.13 [0.74, 1.75]
	Heterogeneity p-value[e][d]		0.2658

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	41 (45.6%)	34 (37.8%)
Number of censored cases	n (%)	49 (54.4%)	56 (62.2%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	1 (1.1%)	0
No first deterioration	n (%)	43 (47.8%)	51 (56.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.86, 8.44]	5.75 [2.92, 9.95]
	Median [95% CI]	21.68 [11.33, NC]	34.83 [10.78, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.622
	HR [95 % CI][c][d]		1.13 [0.71, 1.78]
	Heterogeneity p-value[e][d]		0.8655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	58 (64.4%)	39 (43.3%)
Number of censored cases	n (%)	32 (35.6%)	51 (56.7%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	2 (2.2%)	0
No first deterioration	n (%)	25 (27.8%)	46 (51.1%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.83, 5.59]	5.55 [2.89, 8.34]
	Median [95% CI]	9.72 [5.62, 13.86]	13.86 [8.38, NC]
	Q3 [95% CI]	34.37 [17.58, NC]	NYR [NC, NC]
	p-value[b][d]		0.092
	HR [95 % CI][c][d]		1.42 [0.94, 2.15]
	Heterogeneity p-value[e][d]		0.3477

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	39 (43.3%)	40 (44.4%)
Number of censored cases	n (%)	51 (56.7%)	50 (55.6%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	46 (51.1%)	44 (48.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.02, 10.78]	5.62 [2.92, 8.38]
	Median [95% CI]	25.30 [14.06, NC]	20.73 [9.95, NC]
	Q3 [95% CI]	NYR [40.31, NC]	NYR [34.30, NC]
	p-value[b][d]		0.505
	HR [95 % CI][c][d]		0.86 [0.55, 1.34]
	Heterogeneity p-value[e][d]		0.4683

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	51 (56.7%)	47 (52.2%)
Number of censored cases	n (%)	39 (43.3%)	43 (47.8%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	34 (37.8%)	37 (41.1%)
Time to first deterioration (months)	Q1 [95% CI]	3.22 [2.86, 5.62]	5.55 [2.89, 8.31]
	Median [95% CI]	13.40 [8.31, 21.88]	10.91 [8.38, 22.34]
	Q3 [95% CI]	NYR [24.94, NC]	51.12 [22.34, NC]
	p-value[b][d]		0.923
	HR [95 % CI][c][d]		0.98 [0.65, 1.47]
	Heterogeneity p-value[e][d]		0.7899

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	53 (58.9%)	40 (44.4%)
Number of censored cases	n (%)	37 (41.1%)	50 (55.6%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	32 (35.6%)	44 (48.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.68]	4.27 [2.86, 5.62]
	Median [95% CI]	13.63 [8.28, 18.40]	25.86 [8.31, NC]
	Q3 [95% CI]	46.19 [25.13, NC]	NYR [45.83, NC]
	p-value[b][d]		0.419
	HR [95 % CI][c][d]		1.18 [0.78, 1.79]
	Heterogeneity p-value[e][d]		0.2810

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	64 (71.1%)	54 (60.0%)
Number of censored cases	n (%)	26 (28.9%)	36 (40.0%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	21 (23.3%)	30 (33.3%)
Time to first deterioration (months)	Q1 [95% CI]	2.83 [2.79, 2.86]	2.86 [2.83, 2.89]
	Median [95% CI]	5.59 [2.92, 8.25]	5.72 [2.92, 10.68]
	Q3 [95% CI]	34.27 [10.64, NC]	34.83 [10.87, NC]
	p-value[b][d]		0.548
	HR [95 % CI][c][d]		1.12 [0.77, 1.61]
	Heterogeneity p-value[e][d]		0.7097

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	60 (66.7%)	50 (55.6%)
Number of censored cases	n (%)	30 (33.3%)	40 (44.4%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	25 (27.8%)	35 (38.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.62]	2.96 [2.86, 5.62]
	Median [95% CI]	8.44 [5.68, 11.40]	13.90 [8.38, 29.57]
	Q3 [95% CI]	25.30 [13.93, NC]	46.16 [29.57, NC]
	p-value[b][d]		0.227
	HR [95 % CI][c][d]		1.27 [0.86, 1.85]
	Heterogeneity p-value[e][d]		0.7523

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	26 (28.9%)	15 (16.7%)
Number of censored cases	n (%)	64 (71.1%)	75 (83.3%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	2 (2.2%)	1 (1.1%)
No first deterioration	n (%)	57 (63.3%)	69 (76.7%)
Time to first deterioration (months)	Q1 [95% CI]	16.33 [8.34, 30.65]	40.05 [10.64, NC]
	Median [95% CI]	NYR [30.65, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.205
	HR [95 % CI][c][d]		1.51 [0.80, 2.86]
	Heterogeneity p-value[e][d]		0.0564

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	29 (32.2%)	29 (32.2%)
Number of censored cases	n (%)	61 (67.8%)	61 (67.8%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	56 (62.2%)	56 (62.2%)
Time to first deterioration (months)	Q1 [95% CI]	12.52 [8.34, 26.41]	8.44 [2.92, 23.26]
	Median [95% CI]	NYR [30.59, NC]	45.83 [23.26, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.444
	HR [95 % CI][c][d]		0.82 [0.49, 1.37]
	Heterogeneity p-value[e][d]		0.6337

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	40 (44.4%)	28 (31.1%)
Number of censored cases	n (%)	50 (55.6%)	62 (68.9%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	1 (1.1%)	0
No first deterioration	n (%)	44 (48.9%)	57 (63.3%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.55, 12.52]	10.87 [5.72, 14.52]
	Median [95% CI]	29.73 [14.09, 41.26]	33.61 [14.52, NC]
	Q3 [95% CI]	NYR [34.27, NC]	NYR [NC, NC]
	p-value[b][d]		0.357
	HR [95 % CI][c][d]		1.26 [0.77, 2.06]
	Heterogeneity p-value[e][d]		0.5002

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	35 (38.9%)	39 (43.3%)
Number of censored cases	n (%)	55 (61.1%)	51 (56.7%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	2 (2.2%)	2 (2.2%)
No first deterioration	n (%)	48 (53.3%)	44 (48.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.99, 10.64]	5.59 [2.89, 8.38]
	Median [95% CI]	NYR [11.33, NC]	22.28 [8.51, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.193
	HR [95 % CI][c][d]		0.74 [0.46, 1.17]
	Heterogeneity p-value[e][d]		0.0627

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	31 (34.4%)	24 (26.7%)
Number of censored cases	n (%)	59 (65.6%)	66 (73.3%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	2 (2.2%)
No first deterioration	n (%)	54 (60.0%)	59 (65.6%)
Time to first deterioration (months)	Q1 [95% CI]	9.07 [5.55, 14.49]	10.91 [2.92, 45.83]
	Median [95% CI]	NYR [17.77, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.805
	HR [95 % CI][c][d]		1.07 [0.63, 1.83]
	Heterogeneity p-value[e][d]		0.5582

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	35 (38.9%)	34 (37.8%)
Number of censored cases	n (%)	55 (61.1%)	56 (62.2%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	50 (55.6%)	51 (56.7%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.62, 21.62]	8.34 [5.55, 11.07]
	Median [95% CI]	39.46 [23.23, NC]	34.53 [11.40, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [52.60, NC]
	p-value[b][d]		0.361
	HR [95 % CI][c][d]		0.80 [0.50, 1.29]
	Heterogeneity p-value[e][d]		0.6070

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	26 (28.9%)	30 (33.3%)
Number of censored cases	n (%)	64 (71.1%)	60 (66.7%)
No baseline score	n (%)	4 (4.4%)	2 (2.2%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	59 (65.6%)	55 (61.1%)
Time to first deterioration (months)	Q1 [95% CI]	14.72 [8.38, 25.79]	8.34 [3.09, 13.54]
	Median [95% CI]	62.26 [NC, NC]	NYR [13.83, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.118
	HR [95 % CI][c][d]		0.65 [0.39, 1.11]
	Heterogeneity p-value[e][d]		0.1510

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	46 (56.1%)	39 (45.9%)
Number of censored cases	n (%)	36 (43.9%)	46 (54.1%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	26 (31.7%)	35 (41.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.65]	5.59 [3.25, 8.31]
	Median [95% CI]	8.48 [5.65, 15.51]	10.81 [8.34, 38.90]
	Q3 [95% CI]	35.98 [15.51, NC]	50.92 [27.47, NC]
	p-value[b][d]		0.302
	HR [95 % CI][c][d]		1.25 [0.81, 1.93]
	Heterogeneity p-value[e][d]		0.2658

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	38 (46.3%)	32 (37.6%)
Number of censored cases	n (%)	44 (53.7%)	53 (62.4%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	34 (41.5%)	43 (50.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, 8.34]	5.65 [2.89, 8.38]
	Median [95% CI]	17.61 [10.97, 30.19]	18.00 [8.38, NC]
	Q3 [95% CI]	NYR [29.70, NC]	NYR [NC, NC]
	p-value[b][d]		0.834
	HR [95 % CI][c][d]		1.05 [0.65, 1.68]
	Heterogeneity p-value[e][d]		0.8655

Data cut-off as of April 07, 2025.

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.

[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.

The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.

Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	45 (54.9%)	39 (45.9%)
Number of censored cases	n (%)	37 (45.1%)	46 (54.1%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	2 (2.4%)	0
No first deterioration	n (%)	25 (30.5%)	36 (42.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.89, 6.47]	3.65 [2.83, 5.62]
	Median [95% CI]	9.79 [6.74, 16.53]	14.78 [6.34, 25.69]
	Q3 [95% CI]	35.45 [16.53, NC]	NYR [25.69, NC]
	p-value[b][d]		0.539
	HR [95 % CI][c][d]		1.14 [0.74, 1.76]
	Heterogeneity p-value[e][d]		0.3477

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	35 (42.7%)	30 (35.3%)
Number of censored cases	n (%)	47 (57.3%)	55 (64.7%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	36 (43.9%)	45 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.28 [2.86, 10.81]	6.70 [5.59, 10.61]
	Median [95% CI]	17.18 [11.27, NC]	27.47 [10.61, NC]
	Q3 [95% CI]	NYR [34.37, NC]	NYR [48.82, NC]
	p-value[b][d]		0.435
	HR [95 % CI][c][d]		1.21 [0.74, 1.98]
	Heterogeneity p-value[e][d]		0.4683

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	37 (45.1%)	37 (43.5%)
Number of censored cases	n (%)	45 (54.9%)	48 (56.5%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	35 (42.7%)	38 (44.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [3.12, 10.32]	5.78 [2.86, 8.87]
	Median [95% CI]	16.53 [10.71, 31.77]	14.09 [10.18, 29.73]
	Q3 [95% CI]	NYR [25.63, NC]	34.86 [25.69, NC]
	p-value[b][d]		0.477
	HR [95 % CI][c][d]		0.84 [0.53, 1.34]
	Heterogeneity p-value[e][d]		0.7899

Data cut-off as of April 07, 2025.

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.

[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.

The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.

Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	36 (43.9%)	32 (37.6%)
Number of censored cases	n (%)	46 (56.1%)	53 (62.4%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	36 (43.9%)	42 (49.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.96, 8.44]	8.34 [3.48, 11.30]
	Median [95% CI]	16.53 [8.48, 39.49]	17.77 [11.30, NC]
	Q3 [95% CI]	NYR [31.77, NC]	NYR [21.45, NC]
	p-value[b][d]		0.717
	HR [95 % CI][c][d]		1.09 [0.68, 1.76]
	Heterogeneity p-value[e][d]		0.2810

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	52 (63.4%)	45 (52.9%)
Number of censored cases	n (%)	30 (36.6%)	40 (47.1%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	19 (23.2%)	30 (35.3%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.79, 5.55]	2.92 [2.79, 5.65]
	Median [95% CI]	5.78 [5.55, 8.44]	8.38 [6.11, 10.61]
	Q3 [95% CI]	15.51 [8.48, NC]	NYR [10.81, NC]
	p-value[b][d]		0.288
	HR [95 % CI][c][d]		1.24 [0.82, 1.85]
	Heterogeneity p-value[e][d]		0.7097

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	46 (56.1%)	38 (44.7%)
Number of censored cases	n (%)	36 (43.9%)	47 (55.3%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	2 (2.4%)	2 (2.4%)
No first deterioration	n (%)	24 (29.3%)	35 (41.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 6.47]	3.88 [2.89, 6.70]
	Median [95% CI]	8.48 [6.74, 14.23]	13.93 [8.31, 44.75]
	Q3 [95% CI]	28.68 [14.23, NC]	44.75 [29.80, NC]
	p-value[b][d]		0.200
	HR [95 % CI][c][d]		1.32 [0.86, 2.04]
	Heterogeneity p-value[e][d]		0.7523

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	24 (29.3%)	14 (16.5%)
Number of censored cases	n (%)	58 (70.7%)	71 (83.5%)
No baseline score	n (%)	9 (11.0%)	10 (11.8%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	2 (2.4%)	0
No first deterioration	n (%)	46 (56.1%)	60 (70.6%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [2.92, 25.63]	NYR [6.70, NC]
	Median [95% CI]	57.99 [17.97, NC]	NYR [NC, NC]
	Q3 [95% CI]	57.99 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.068
	HR [95 % CI][c][d]		1.83 [0.95, 3.54]
	Heterogeneity p-value[e][d]		0.0564

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	25 (30.5%)	20 (23.5%)
Number of censored cases	n (%)	57 (69.5%)	65 (76.5%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	47 (57.3%)	55 (64.7%)
Time to first deterioration (months)	Q1 [95% CI]	13.83 [6.87, 21.22]	17.87 [5.65, 26.48]
	Median [95% CI]	45.70 [21.22, NC]	48.82 [25.63, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [48.82, NC]
	p-value[b][d]		0.573
	HR [95 % CI][c][d]		1.18 [0.66, 2.14]
	Heterogeneity p-value[e][d]		0.6337

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	35 (42.7%)	30 (35.3%)
Number of censored cases	n (%)	47 (57.3%)	55 (64.7%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	36 (43.9%)	45 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.61 [5.59, 14.46]	8.31 [3.88, 9.82]
	Median [95% CI]	21.59 [14.46, 33.91]	22.14 [10.64, 43.56]
	Q3 [95% CI]	35.45 [25.59, NC]	43.56 [40.71, NC]
	p-value[b][d]		0.721
	HR [95 % CI][c][d]		1.09 [0.67, 1.78]
	Heterogeneity p-value[e][d]		0.5002

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	42 (51.2%)	31 (36.5%)
Number of censored cases	n (%)	40 (48.8%)	54 (63.5%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	2 (2.4%)	4 (4.7%)
No first deterioration	n (%)	28 (34.1%)	40 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.89, 6.24]	6.70 [2.96, 8.54]
	Median [95% CI]	8.48 [6.41, 14.98]	16.89 [8.54, NC]
	Q3 [95% CI]	31.38 [14.72, NC]	NYR [38.70, NC]
	p-value[b][d]		0.054
	HR [95 % CI][c][d]		1.58 [0.99, 2.52]
	Heterogeneity p-value[e][d]		0.0627

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	30 (36.6%)	19 (22.4%)
Number of censored cases	n (%)	52 (63.4%)	66 (77.6%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	4 (4.9%)	3 (3.5%)
No first deterioration	n (%)	38 (46.3%)	53 (62.4%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [3.12, 14.23]	10.45 [3.65, NC]
	Median [95% CI]	21.59 [14.23, 35.45]	NYR [28.85, NC]
	Q3 [95% CI]	NYR [33.74, NC]	NYR [NC, NC]
	p-value[b][d]		0.067
	HR [95 % CI][c][d]		1.71 [0.96, 3.05]
	Heterogeneity p-value[e][d]		0.5582

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	23 (28.0%)	28 (32.9%)
Number of censored cases	n (%)	59 (72.0%)	57 (67.1%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	2 (2.4%)	2 (2.4%)
No first deterioration	n (%)	47 (57.3%)	45 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	10.58 [5.68, 23.33]	8.61 [5.59, 21.75]
	Median [95% CI]	45.70 [23.33, NC]	27.56 [21.75, NC]
	Q3 [95% CI]	NYR [45.70, NC]	58.68 [NC, NC]
	p-value[b][d]		0.453
	HR [95 % CI][c][d]		0.81 [0.46, 1.42]
	Heterogeneity p-value[e][d]		0.6070

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	23 (28.0%)	18 (21.2%)
Number of censored cases	n (%)	59 (72.0%)	67 (78.8%)
No baseline score	n (%)	9 (11.0%)	9 (10.6%)
No post-baseline score	n (%)	1 (1.2%)	1 (1.2%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	48 (58.5%)	57 (67.1%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [2.99, 21.39]	25.66 [5.65, 32.89]
	Median [95% CI]	NYR [21.39, NC]	NYR [25.69, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.417
	HR [95 % CI][c][d]		1.29 [0.69, 2.40]
	Heterogeneity p-value[e][d]		0.1510

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	99 (52.4%)	78 (41.3%)
Number of censored cases	n (%)	90 (47.6%)	111 (58.7%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	75 (39.7%)	90 (47.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.78, 5.98]	5.55 [2.89, 6.11]
	Median [95% CI]	14.23 [10.64, 25.30]	22.21 [9.33, 49.05]
	Q3 [95% CI]	NYR [35.98, NC]	NYR [49.05, NC]
	p-value[b][d]		0.374
	HR [95 % CI][c][d]		1.14 [0.85, 1.55]
	Heterogeneity p-value[e][d]		0.5795

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	82 (43.4%)	63 (33.3%)
Number of censored cases	n (%)	107 (56.6%)	126 (66.7%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	1 (0.5%)	0
No first deterioration	n (%)	91 (48.1%)	106 (56.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [3.94, 8.34]	6.74 [5.55, 9.33]
	Median [95% CI]	21.68 [16.53, 39.82]	34.83 [14.85, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.495
	HR [95 % CI][c][d]		1.12 [0.81, 1.57]
	Heterogeneity p-value[e][d]		0.4155

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	108 (57.1%)	80 (42.3%)
Number of censored cases	n (%)	81 (42.9%)	109 (57.7%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	5 (2.6%)	0
No first deterioration	n (%)	61 (32.3%)	89 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.99, 5.59]	5.55 [2.92, 5.72]
	Median [95% CI]	10.64 [8.34, 14.23]	14.39 [9.69, 36.40]
	Q3 [95% CI]	35.45 [23.03, NC]	NYR [NC, NC]
	p-value[b][d]		0.152
	HR [95 % CI][c][d]		1.24 [0.92, 1.67]
	Heterogeneity p-value[e][d]		0.6821

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	84 (44.4%)	73 (38.6%)
Number of censored cases	n (%)	105 (55.6%)	116 (61.4%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	1 (0.5%)	1 (0.5%)
No first deterioration	n (%)	89 (47.1%)	95 (50.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.55, 8.41]	5.65 [5.55, 8.31]
	Median [95% CI]	24.94 [14.23, 34.96]	22.47 [11.43, 48.82]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.971
	HR [95 % CI][c][d]		0.99 [0.72, 1.37]
	Heterogeneity p-value[e][d]		0.2340

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	99 (52.4%)	85 (45.0%)
Number of censored cases	n (%)	90 (47.6%)	104 (55.0%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	75 (39.7%)	83 (43.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [3.12, 8.31]	5.55 [2.89, 6.34]
	Median [95% CI]	13.86 [10.71, 18.40]	13.93 [9.72, 22.21]
	Q3 [95% CI]	46.03 [35.84, NC]	NYR [26.48, NC]
	p-value[b][d]		0.873
	HR [95 % CI][c][d]		0.97 [0.72, 1.31]
	Heterogeneity p-value[e][d]		0.9107

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	98 (51.9%)	76 (40.2%)
Number of censored cases	n (%)	91 (48.1%)	113 (59.8%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	0	2 (1.1%)
No first deterioration	n (%)	76 (40.2%)	91 (48.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [4.44, 6.24]	5.55 [2.89, 5.62]
	Median [95% CI]	15.38 [10.48, 25.13]	17.77 [9.82, NC]
	Q3 [95% CI]	46.95 [39.49, NC]	NYR [NC, NC]
	p-value[b][d]		0.623
	HR [95 % CI][c][d]		1.08 [0.79, 1.46]
	Heterogeneity p-value[e][d]		0.8085

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	126 (66.7%)	99 (52.4%)
Number of censored cases	n (%)	63 (33.3%)	90 (47.6%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	1 (0.5%)	1 (0.5%)
No first deterioration	n (%)	47 (24.9%)	69 (36.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 2.92]
	Median [95% CI]	5.65 [5.55, 8.31]	8.34 [5.65, 10.45]
	Q3 [95% CI]	22.74 [11.40, 41.26]	NYR [13.86, NC]
	p-value[b][d]		0.308
	HR [95 % CI][c][d]		1.15 [0.87, 1.51]
	Heterogeneity p-value[e][d]		0.7298

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	111 (58.7%)	88 (46.6%)
Number of censored cases	n (%)	78 (41.3%)	101 (53.4%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	2 (1.1%)	1 (0.5%)
No first deterioration	n (%)	61 (32.3%)	80 (42.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.99, 5.68]	3.88 [2.92, 5.65]
	Median [95% CI]	10.64 [8.34, 13.67]	14.85 [10.61, 29.80]
	Q3 [95% CI]	37.06 [21.68, NC]	49.74 [39.16, NC]
	p-value[b][d]		0.093
	HR [95 % CI][c][d]		1.28 [0.96, 1.70]
	Heterogeneity p-value[e][d]		0.7873

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	52 (27.5%)	33 (17.5%)
Number of censored cases	n (%)	137 (72.5%)	156 (82.5%)
No baseline score	n (%)	13 (6.9%)	16 (8.5%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	6 (3.2%)	1 (0.5%)
No first deterioration	n (%)	116 (61.4%)	134 (70.9%)
Time to first deterioration (months)	Q1 [95% CI]	14.98 [8.34, 25.63]	30.65 [9.95, NC]
	Median [95% CI]	57.99 [34.96, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.146
	HR [95 % CI][c][d]		1.39 [0.89, 2.17]
	Heterogeneity p-value[e][d]		0.7516

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	58 (30.7%)	50 (26.5%)
Number of censored cases	n (%)	131 (69.3%)	139 (73.5%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	116 (61.4%)	119 (63.0%)
Time to first deterioration (months)	Q1 [95% CI]	13.83 [8.48, 18.30]	9.95 [5.55, 23.26]
	Median [95% CI]	NYR [34.37, NC]	48.82 [30.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.751
	HR [95 % CI][c][d]		0.94 [0.64, 1.38]
	Heterogeneity p-value[e][d]		0.9730

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	79 (41.8%)	61 (32.3%)
Number of censored cases	n (%)	110 (58.2%)	128 (67.7%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	3 (1.6%)	0
No first deterioration	n (%)	92 (48.7%)	108 (57.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.61 [5.65, 13.63]	8.41 [5.72, 10.64]
	Median [95% CI]	25.86 [21.42, 34.27]	33.61 [17.97, NC]
	Q3 [95% CI]	NYR [35.45, NC]	NYR [43.56, NC]
	p-value[b][d]		0.672
	HR [95 % CI][c][d]		1.08 [0.76, 1.51]
	Heterogeneity p-value[e][d]		0.4031

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	83 (43.9%)	71 (37.6%)
Number of censored cases	n (%)	106 (56.1%)	118 (62.4%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	5 (2.6%)	4 (2.1%)
No first deterioration	n (%)	86 (45.5%)	94 (49.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.29, 8.28]	5.68 [2.96, 8.38]
	Median [95% CI]	14.98 [10.81, NC]	23.26 [14.55, 38.70]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.827
	HR [95 % CI][c][d]		1.04 [0.75, 1.44]
	Heterogeneity p-value[e][d]		0.5904

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	66 (34.9%)	41 (21.7%)
Number of censored cases	n (%)	123 (65.1%)	148 (78.3%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	3 (1.6%)	5 (2.6%)
No first deterioration	n (%)	105 (55.6%)	123 (65.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.38 [5.62, 14.23]	13.60 [5.62, 45.83]
	Median [95% CI]	37.06 [22.51, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.088
	HR [95 % CI][c][d]		1.41 [0.95, 2.10]
	Heterogeneity p-value[e][d]		0.3113

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	67 (35.4%)	62 (32.8%)
Number of censored cases	n (%)	122 (64.6%)	127 (67.2%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	1 (0.5%)	3 (1.6%)
No first deterioration	n (%)	106 (56.1%)	104 (55.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [8.28, 14.59]	8.61 [5.72, 11.40]
	Median [95% CI]	39.46 [23.46, NC]	30.65 [22.34, 58.68]
	Q3 [95% CI]	NYR [NC, NC]	58.68 [52.60, NC]
	p-value[b][d]		0.535
	HR [95 % CI][c][d]		0.89 [0.63, 1.27]
	Heterogeneity p-value[e][d]		0.4572

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	57 (30.2%)	47 (24.9%)
Number of censored cases	n (%)	132 (69.8%)	142 (75.1%)
No baseline score	n (%)	13 (6.9%)	15 (7.9%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.6%)
No deterioration possible	n (%)	1 (0.5%)	0
No first deterioration	n (%)	116 (61.4%)	122 (64.6%)
Time to first deterioration (months)	Q1 [95% CI]	10.91 [8.31, 21.39]	10.84 [8.31, 22.21]
	Median [95% CI]	62.26 [41.46, NC]	NYR [29.73, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.770
	HR [95 % CI][c][d]		0.94 [0.63, 1.39]
	Heterogeneity p-value[e][d]		0.7359

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	6 (30.0%)	9 (52.9%)
Number of censored cases	n (%)	14 (70.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	9 (45.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.79, NC]	5.78 [2.79, 8.41]
	Median [95% CI]	NYR [5.59, NC]	10.81 [5.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [10.81, NC]
	p-value[b][d]		0.982
	HR [95 % CI][c][d]		1.01 [0.33, 3.12]
	Heterogeneity p-value[e][d]		0.5795

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	7 (35.0%)	9 (52.9%)
Number of censored cases	n (%)	13 (65.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [2.92, NC]	2.86 [2.79, 8.41]
	Median [95% CI]	30.19 [8.54, NC]	8.41 [2.83, NC]
	Q3 [95% CI]	30.19 [NC, NC]	NYR [8.41, NC]
	p-value[b][d]		0.867
	HR [95 % CI][c][d]		0.90 [0.29, 2.81]
	Heterogeneity p-value[e][d]		0.4155

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	10 (50.0%)	9 (52.9%)
Number of censored cases	n (%)	10 (50.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	5 (25.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.76, 14.75]	2.86 [2.79, 5.78]
	Median [95% CI]	17.54 [2.92, NC]	17.77 [2.83, NC]
	Q3 [95% CI]	30.19 [17.54, NC]	NYR [17.77, NC]
	p-value[b][d]		0.981
	HR [95 % CI][c][d]		0.98 [0.34, 2.83]
	Heterogeneity p-value[e][d]		0.6821

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	3 (15.0%)	7 (41.2%)
Number of censored cases	n (%)	17 (85.0%)	10 (58.8%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	12 (60.0%)	10 (58.8%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.76, NC]	5.65 [2.79, NC]
	Median [95% CI]	NYR [2.92, NC]	NYR [5.59, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.216
	HR [95 % CI][c][d]		0.36 [0.07, 1.89]
	Heterogeneity p-value[e][d]		0.2340

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	8 (40.0%)	9 (52.9%)
Number of censored cases	n (%)	12 (60.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	7 (35.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.76, 18.23]	5.62 [2.79, 13.50]
	Median [95% CI]	24.08 [2.79, NC]	13.50 [2.83, NC]
	Q3 [95% CI]	NYR [18.23, NC]	34.86 [13.50, NC]
	p-value[b][d]		0.722
	HR [95 % CI][c][d]		1.23 [0.37, 4.08]
	Heterogeneity p-value[e][d]		0.9107

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	7 (35.0%)	8 (47.1%)
Number of censored cases	n (%)	13 (65.0%)	9 (52.9%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	9 (52.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.76, 14.32]	8.34 [2.79, 13.73]
	Median [95% CI]	14.32 [2.92, NC]	13.73 [5.78, NC]
	Q3 [95% CI]	NYR [14.32, NC]	19.22 [13.73, NC]
	p-value[b][d]		0.892
	HR [95 % CI][c][d]		0.92 [0.27, 3.15]
	Heterogeneity p-value[e][d]		0.8085

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	10 (50.0%)	12 (70.6%)
Number of censored cases	n (%)	10 (50.0%)	5 (29.4%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	5 (25.0%)	5 (29.4%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.76, 3.61]	2.92 [2.79, 8.31]
	Median [95% CI]	8.54 [2.79, NC]	8.31 [2.83, 10.81]
	Q3 [95% CI]	NYR [8.54, NC]	10.81 [8.31, NC]
	p-value[b][d]		0.612
	HR [95 % CI][c][d]		0.78 [0.27, 2.19]
	Heterogeneity p-value[e][d]		0.7298

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	10 (50.0%)	9 (52.9%)
Number of censored cases	n (%)	10 (50.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	1 (5.9%)
No first deterioration	n (%)	5 (25.0%)	7 (41.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.76, 8.54]	2.89 [2.79, 8.31]
	Median [95% CI]	8.54 [3.61, NC]	8.31 [2.89, NC]
	Q3 [95% CI]	30.19 [8.54, NC]	NYR [8.31, NC]
	p-value[b][d]		0.541
	HR [95 % CI][c][d]		0.70 [0.22, 2.19]
	Heterogeneity p-value[e][d]		0.7873

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	2 (10.0%)	2 (11.8%)
Number of censored cases	n (%)	18 (90.0%)	15 (88.2%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	1 (5.9%)
No first deterioration	n (%)	13 (65.0%)	14 (82.4%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.92, NC]	NYR [2.79, NC]
	Median [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.834
	HR [95 % CI][c][d]		1.26 [0.15, 10.48]
	Heterogeneity p-value[e][d]		0.7516

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	3 (15.0%)	3 (17.6%)
Number of censored cases	n (%)	17 (85.0%)	14 (82.4%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	12 (60.0%)	14 (82.4%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.76, NC]	17.87 [2.79, NC]
	Median [95% CI]	NYR [11.40, NC]	NYR [17.87, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.704
	HR [95 % CI][c][d]		0.70 [0.11, 4.50]
	Heterogeneity p-value[e][d]		0.9730

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	7 (35.0%)	5 (29.4%)
Number of censored cases	n (%)	13 (65.0%)	12 (70.6%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	12 (70.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.59, 14.49]	11.63 [2.79, NC]
	Median [95% CI]	14.49 [5.68, NC]	22.14 [11.63, NC]
	Q3 [95% CI]	NYR [14.49, NC]	NYR [22.14, NC]
	p-value[b][d]		0.093
	HR [95 % CI][c][d]		4.64 [0.72, 29.98]
	Heterogeneity p-value[e][d]		0.4031

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	8 (40.0%)	8 (47.1%)
Number of censored cases	n (%)	12 (60.0%)	9 (52.9%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	2 (11.8%)
No first deterioration	n (%)	7 (35.0%)	7 (41.2%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.76, 6.37]	5.78 [2.83, 14.82]
	Median [95% CI]	8.44 [2.83, NC]	14.82 [5.55, NC]
	Q3 [95% CI]	NYR [8.44, NC]	NYR [14.82, NC]
	p-value[b][d]		0.373
	HR [95 % CI][c][d]		1.96 [0.47, 8.17]
	Heterogeneity p-value[e][d]		0.5904

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	4 (20.0%)	6 (35.3%)
Number of censored cases	n (%)	16 (80.0%)	11 (64.7%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	2 (10.0%)	0
No first deterioration	n (%)	9 (45.0%)	11 (64.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.49 [10.97, NC]	10.45 [2.79, 31.18]
	Median [95% CI]	NYR [13.63, NC]	31.18 [10.45, NC]
	Q3 [95% CI]	NYR [24.08, NC]	NYR [18.00, NC]
	p-value[b][d]		0.479
	HR [95 % CI][c][d]		0.54 [0.10, 2.89]
	Heterogeneity p-value[e][d]		0.3113

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	4 (20.0%)	6 (35.3%)
Number of censored cases	n (%)	16 (80.0%)	11 (64.7%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	1 (5.0%)	0
No first deterioration	n (%)	10 (50.0%)	11 (64.7%)
Time to first deterioration (months)	Q1 [95% CI]	6.87 [0.72, NC]	6.24 [2.79, NC]
	Median [95% CI]	NYR [5.68, NC]	NYR [6.24, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.968
	HR [95 % CI][c][d]		1.03 [0.26, 4.01]
	Heterogeneity p-value[e][d]		0.4572

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	3 (15.0%)	5 (29.4%)
Number of censored cases	n (%)	17 (85.0%)	12 (70.6%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	12 (60.0%)	12 (70.6%)
Time to first deterioration (months)	Q1 [95% CI]	NYR [2.92, NC]	25.69 [2.79, NC]
	Median [95% CI]	NYR [9.03, NC]	NYR [5.72, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [25.69, NC]
	p-value[b][d]		0.763
	HR [95 % CI][c][d]		0.76 [0.12, 4.62]
	Heterogeneity p-value[e][d]		0.7359

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	84 (50.6%)	72 (40.7%)
Number of censored cases	n (%)	82 (49.4%)	105 (59.3%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	67 (40.4%)	86 (48.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.71, 6.24]	5.55 [2.89, 6.70]
	Median [95% CI]	15.51 [8.54, 35.45]	23.26 [12.12, 49.05]
	Q3 [95% CI]	NYR [35.98, NC]	NYR [49.05, NC]
	p-value[b][d]		0.266
	HR [95 % CI][c][d]		1.19 [0.87, 1.64]
	Heterogeneity p-value[e][d]		0.3920

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	69 (41.6%)	56 (31.6%)
Number of censored cases	n (%)	97 (58.4%)	121 (68.4%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	81 (48.8%)	102 (57.6%)
Time to first deterioration (months)	Q1 [95% CI]	7.85 [5.59, 10.97]	8.31 [5.62, 9.95]
	Median [95% CI]	27.63 [17.58, 39.82]	NYR [18.04, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.398
	HR [95 % CI][c][d]		1.17 [0.82, 1.66]
	Heterogeneity p-value[e][d]		0.2028

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	89 (53.6%)	73 (41.2%)
Number of censored cases	n (%)	77 (46.4%)	104 (58.8%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	4 (2.4%)	0
No first deterioration	n (%)	58 (34.9%)	85 (48.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.65]	5.55 [2.92, 7.85]
	Median [95% CI]	13.86 [8.44, 18.00]	16.89 [10.61, NC]
	Q3 [95% CI]	35.98 [25.89, NC]	NYR [NC, NC]
	p-value[b][d]		0.179
	HR [95 % CI][c][d]		1.24 [0.90, 1.69]
	Heterogeneity p-value[e][d]		0.9928

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	66 (39.8%)	69 (39.0%)
Number of censored cases	n (%)	100 (60.2%)	108 (61.0%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	84 (50.6%)	88 (49.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.29, 10.12]	5.65 [5.55, 7.85]
	Median [95% CI]	27.93 [17.58, NC]	22.47 [10.68, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [48.82, NC]
	p-value[b][d]		0.539
	HR [95 % CI][c][d]		0.90 [0.64, 1.26]
	Heterogeneity p-value[e][d]		0.3440

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	88 (53.0%)	78 (44.1%)
Number of censored cases	n (%)	78 (47.0%)	99 (55.9%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	63 (38.0%)	79 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.78]	5.62 [2.89, 8.38]
	Median [95% CI]	13.86 [10.71, 21.88]	14.29 [10.68, 22.41]
	Q3 [95% CI]	46.03 [35.84, NC]	NYR [29.73, NC]
	p-value[b][d]		0.662
	HR [95 % CI][c][d]		1.07 [0.79, 1.45]
	Heterogeneity p-value[e][d]		0.1101

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	85 (51.2%)	71 (40.1%)
Number of censored cases	n (%)	81 (48.8%)	106 (59.9%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	66 (39.8%)	86 (48.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [5.29, 7.85]	5.55 [2.89, 5.75]
	Median [95% CI]	16.53 [10.48, 25.63]	17.77 [9.82, NC]
	Q3 [95% CI]	46.19 [39.49, NC]	NYR [NC, NC]
	p-value[b][d]		0.668
	HR [95 % CI][c][d]		1.07 [0.78, 1.47]
	Heterogeneity p-value[e][d]		0.6623

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	109 (65.7%)	90 (50.8%)
Number of censored cases	n (%)	57 (34.3%)	87 (49.2%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	41 (24.7%)	67 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.89 [2.83, 2.96]
	Median [95% CI]	5.62 [5.55, 8.31]	8.38 [6.34, 10.81]
	Q3 [95% CI]	27.07 [17.51, NC]	NYR [24.44, NC]
	p-value[b][d]		0.111
	HR [95 % CI][c][d]		1.25 [0.94, 1.66]
	Heterogeneity p-value[e][d]		0.1330

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	98 (59.0%)	79 (44.6%)
Number of censored cases	n (%)	68 (41.0%)	98 (55.4%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	1 (0.6%)	1 (0.6%)
No first deterioration	n (%)	52 (31.3%)	78 (44.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.99, 5.68]	5.55 [2.92, 6.70]
	Median [95% CI]	10.87 [8.34, 14.23]	17.74 [10.84, 34.07]
	Q3 [95% CI]	33.61 [21.68, NC]	49.74 [44.75, NC]
	p-value[b][d]		0.036
	HR [95 % CI][c][d]		1.38 [1.02, 1.86]
	Heterogeneity p-value[e][d]		0.1137

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	45 (27.1%)	26 (14.7%)
Number of censored cases	n (%)	121 (72.9%)	151 (85.3%)
No baseline score	n (%)	13 (7.8%)	16 (9.0%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	3 (1.8%)	2 (1.1%)
No first deterioration	n (%)	103 (62.0%)	129 (72.9%)
Time to first deterioration (months)	Q1 [95% CI]	16.33 [8.34, 25.63]	40.05 [11.07, NC]
	Median [95% CI]	NYR [34.37, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.035
	HR [95 % CI][c][d]		1.68 [1.03, 2.73]
	Heterogeneity p-value[e][d]		0.1158

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	51 (30.7%)	47 (26.6%)
Number of censored cases	n (%)	115 (69.3%)	130 (73.4%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	100 (60.2%)	111 (62.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [10.12, 21.22]	9.95 [5.55, 25.56]
	Median [95% CI]	NYR [33.68, NC]	48.82 [30.75, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.741
	HR [95 % CI][c][d]		0.93 [0.63, 1.39]
	Heterogeneity p-value[e][d]		0.7481

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	70 (42.2%)	52 (29.4%)
Number of censored cases	n (%)	96 (57.8%)	125 (70.6%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	2 (1.2%)	0
No first deterioration	n (%)	79 (47.6%)	106 (59.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.54 [5.65, 13.63]	8.44 [6.34, 13.83]
	Median [95% CI]	26.48 [19.81, 34.37]	43.56 [21.72, NC]
	Q3 [95% CI]	NYR [35.45, NC]	NYR [NC, NC]
	p-value[b][d]		0.229
	HR [95 % CI][c][d]		1.25 [0.87, 1.79]
	Heterogeneity p-value[e][d]		0.2724

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	67 (40.4%)	64 (36.2%)
Number of censored cases	n (%)	99 (59.6%)	113 (63.8%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	4 (2.4%)	5 (2.8%)
No first deterioration	n (%)	80 (48.2%)	89 (50.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.09, 6.47]	6.70 [3.25, 8.51]
	Median [95% CI]	31.38 [12.55, NC]	23.26 [14.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.790
	HR [95 % CI][c][d]		1.05 [0.74, 1.48]
	Heterogeneity p-value[e][d]		0.8210

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	54 (32.5%)	37 (20.9%)
Number of censored cases	n (%)	112 (67.5%)	140 (79.1%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	4 (2.4%)	5 (2.8%)
No first deterioration	n (%)	93 (56.0%)	116 (65.5%)
Time to first deterioration (months)	Q1 [95% CI]	12.52 [8.28, 16.53]	15.70 [5.62, NC]
	Median [95% CI]	NYR [24.08, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.108
	HR [95 % CI][c][d]		1.41 [0.92, 2.15]
	Heterogeneity p-value[e][d]		0.6004

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	60 (36.1%)	59 (33.3%)
Number of censored cases	n (%)	106 (63.9%)	118 (66.7%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	1 (0.6%)	2 (1.1%)
No first deterioration	n (%)	90 (54.2%)	97 (54.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.68, 14.49]	8.61 [5.59, 11.07]
	Median [95% CI]	39.46 [23.23, NC]	28.81 [21.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [52.60, NC]
	p-value[b][d]		0.535
	HR [95 % CI][c][d]		0.89 [0.62, 1.28]
	Heterogeneity p-value[e][d]		0.9624

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	48 (28.9%)	40 (22.6%)
Number of censored cases	n (%)	118 (71.1%)	137 (77.4%)
No baseline score	n (%)	13 (7.8%)	15 (8.5%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	1 (0.6%)	0
No first deterioration	n (%)	102 (61.4%)	118 (66.7%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [8.34, 21.88]	18.79 [8.31, 29.73]
	Median [95% CI]	62.26 [41.46, NC]	NYR [32.89, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.889
	HR [95 % CI][c][d]		1.02 [0.67, 1.56]
	Heterogeneity p-value[e][d]		0.3502

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	21 (48.8%)	15 (51.7%)
Number of censored cases	n (%)	22 (51.2%)	14 (48.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	1 (3.4%)
No first deterioration	n (%)	17 (39.5%)	12 (41.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.75 [2.83, 8.48]	4.27 [2.79, 7.06]
	Median [95% CI]	13.80 [6.67, 34.66]	8.31 [5.59, NC]
	Q3 [95% CI]	NYR [21.03, NC]	NYR [8.41, NC]
	p-value[b][d]		0.765
	HR [95 % CI][c][d]		0.90 [0.46, 1.76]
	Heterogeneity p-value[e][d]		0.3920

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	20 (46.5%)	16 (55.2%)
Number of censored cases	n (%)	23 (53.5%)	13 (44.8%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	18 (41.9%)	12 (41.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.34]	2.96 [2.79, 5.55]
	Median [95% CI]	13.90 [8.31, NC]	8.31 [3.48, 18.00]
	Q3 [95% CI]	NYR [17.58, NC]	NYR [8.31, NC]
	p-value[b][d]		0.452
	HR [95 % CI][c][d]		0.77 [0.39, 1.51]
	Heterogeneity p-value[e][d]		0.2028

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	29 (67.4%)	16 (55.2%)
Number of censored cases	n (%)	14 (32.6%)	13 (44.8%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	1 (2.3%)	0
No first deterioration	n (%)	8 (18.6%)	12 (41.4%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.92, 5.59]	2.89 [2.79, 5.52]
	Median [95% CI]	6.37 [5.55, 8.48]	5.59 [3.48, NC]
	Q3 [95% CI]	13.83 [8.34, 34.66]	NYR [5.65, NC]
	p-value[b][d]		0.709
	HR [95 % CI][c][d]		1.13 [0.60, 2.13]
	Heterogeneity p-value[e][d]		0.9928

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	21 (48.8%)	11 (37.9%)
Number of censored cases	n (%)	22 (51.2%)	18 (62.1%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (39.5%)	17 (58.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.28 [3.12, 10.68]	8.31 [4.27, 13.54]
	Median [95% CI]	11.37 [8.41, 34.96]	20.73 [8.31, NC]
	Q3 [95% CI]	NYR [12.65, NC]	NYR [20.73, NC]
	p-value[b][d]		0.438
	HR [95 % CI][c][d]		1.35 [0.63, 2.85]
	Heterogeneity p-value[e][d]		0.3440

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	19 (44.2%)	16 (55.2%)
Number of censored cases	n (%)	24 (55.8%)	13 (44.8%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	19 (44.2%)	12 (41.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [2.92, 8.57]	2.96 [2.79, 5.65]
	Median [95% CI]	13.90 [8.44, NC]	8.31 [5.52, 14.52]
	Q3 [95% CI]	NYR [18.23, NC]	34.86 [8.34, NC]
	p-value[b][d]		0.050
	HR [95 % CI][c][d]		0.49 [0.24, 1.02]
	Heterogeneity p-value[e][d]		0.1101

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	20 (46.5%)	13 (44.8%)
Number of censored cases	n (%)	23 (53.5%)	16 (55.2%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	1 (3.4%)
No first deterioration	n (%)	18 (41.9%)	14 (48.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 9.03]	3.48 [2.79, 13.73]
	Median [95% CI]	13.90 [6.74, NC]	15.21 [5.55, NC]
	Q3 [95% CI]	NYR [26.38, NC]	NYR [15.21, NC]
	p-value[b][d]		0.935
	HR [95 % CI][c][d]		1.03 [0.50, 2.09]
	Heterogeneity p-value[e][d]		0.6623

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	27 (62.8%)	21 (72.4%)
Number of censored cases	n (%)	16 (37.2%)	8 (27.6%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	11 (25.6%)	7 (24.1%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.79, 5.55]	2.86 [2.79, 3.02]
	Median [95% CI]	8.31 [3.12, 8.61]	4.27 [2.89, 8.31]
	Q3 [95% CI]	13.83 [8.34, NC]	8.31 [5.55, NC]
	p-value[b][d]		0.319
	HR [95 % CI][c][d]		0.74 [0.40, 1.34]
	Heterogeneity p-value[e][d]		0.1330

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	23 (53.5%)	18 (62.1%)
Number of censored cases	n (%)	20 (46.5%)	11 (37.9%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	1 (2.3%)	1 (3.4%)
No first deterioration	n (%)	14 (32.6%)	9 (31.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.79, 6.74]	2.89 [2.79, 3.84]
	Median [95% CI]	8.38 [5.75, 30.19]	5.59 [2.96, 13.60]
	Q3 [95% CI]	38.87 [8.48, NC]	14.85 [8.31, NC]
	p-value[b][d]		0.623
	HR [95 % CI][c][d]		0.86 [0.46, 1.61]
	Heterogeneity p-value[e][d]		0.1137

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	9 (20.9%)	9 (31.0%)
Number of censored cases	n (%)	34 (79.1%)	20 (69.0%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	3 (7.0%)	0
No first deterioration	n (%)	26 (60.5%)	19 (65.5%)
Time to first deterioration (months)	Q1 [95% CI]	34.96 [5.68, 57.99]	10.61 [2.79, NC]
	Median [95% CI]	57.99 [34.96, NC]	NYR [10.61, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.337
	HR [95 % CI][c][d]		0.62 [0.24, 1.65]
	Heterogeneity p-value[e][d]		0.1158

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	10 (23.3%)	6 (20.7%)
Number of censored cases	n (%)	33 (76.7%)	23 (79.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	28 (65.1%)	22 (75.9%)
Time to first deterioration (months)	Q1 [95% CI]	18.30 [5.49, NC]	17.87 [2.86, NC]
	Median [95% CI]	45.70 [18.30, NC]	NYR [17.87, NC]
	Q3 [95% CI]	NYR [45.70, NC]	NYR [NC, NC]
	p-value[b][d]		0.873
	HR [95 % CI][c][d]		1.09 [0.39, 3.03]
	Heterogeneity p-value[e][d]		0.7481

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	16 (37.2%)	14 (48.3%)
Number of censored cases	n (%)	27 (62.8%)	15 (51.7%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	1 (2.3%)	0
No first deterioration	n (%)	21 (48.8%)	14 (48.3%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [2.92, 21.42]	8.31 [2.79, 10.64]
	Median [95% CI]	22.14 [14.09, NC]	11.63 [8.31, NC]
	Q3 [95% CI]	NYR [25.86, NC]	40.71 [13.83, NC]
	p-value[b][d]		0.342
	HR [95 % CI][c][d]		0.69 [0.32, 1.48]
	Heterogeneity p-value[e][d]		0.2724

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	24 (55.8%)	15 (51.7%)
Number of censored cases	n (%)	19 (44.2%)	14 (48.3%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	1 (2.3%)	1 (3.4%)
No first deterioration	n (%)	13 (30.2%)	12 (41.4%)
Time to first deterioration (months)	Q1 [95% CI]	6.24 [2.92, 8.34]	3.02 [2.79, 8.31]
	Median [95% CI]	8.48 [8.28, 11.30]	8.31 [3.02, NC]
	Q3 [95% CI]	14.72 [10.64, NC]	38.70 [8.54, NC]
	p-value[b][d]		0.823
	HR [95 % CI][c][d]		1.08 [0.54, 2.17]
	Heterogeneity p-value[e][d]		0.8210

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	16 (37.2%)	10 (34.5%)
Number of censored cases	n (%)	27 (62.8%)	19 (65.5%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	1 (2.3%)	0
No first deterioration	n (%)	21 (48.8%)	18 (62.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 10.68]	8.31 [2.79, 18.00]
	Median [95% CI]	26.71 [5.65, NC]	31.18 [10.45, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [31.18, NC]
	p-value[b][d]		0.864
	HR [95 % CI][c][d]		1.09 [0.49, 2.42]
	Heterogeneity p-value[e][d]		0.6004

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	11 (25.6%)	9 (31.0%)
Number of censored cases	n (%)	32 (74.4%)	20 (69.0%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	1 (2.3%)	1 (3.4%)
No first deterioration	n (%)	26 (60.5%)	18 (62.1%)
Time to first deterioration (months)	Q1 [95% CI]	13.60 [5.52, 45.70]	8.31 [2.79, NC]
	Median [95% CI]	45.70 [23.46, NC]	58.68 [8.31, NC]
	Q3 [95% CI]	NYR [45.70, NC]	58.68 [NC, NC]
	p-value[b][d]		0.419
	HR [95 % CI][c][d]		0.67 [0.25, 1.78]
	Heterogeneity p-value[e][d]		0.9624

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	12 (27.9%)	12 (41.4%)
Number of censored cases	n (%)	31 (72.1%)	17 (58.6%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	1 (2.3%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (60.5%)	16 (55.2%)
Time to first deterioration (months)	Q1 [95% CI]	9.03 [5.49, 25.79]	5.72 [2.89, 13.83]
	Median [95% CI]	NYR [10.61, NC]	21.65 [10.84, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [21.65, NC]
	p-value[b][d]		0.205
	HR [95 % CI][c][d]		0.58 [0.24, 1.36]
	Heterogeneity p-value[e][d]		0.3502

Data cut-off as of April 07, 2025.

Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.

[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.

[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.

The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.

Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	61 (45.9%)	60 (45.8%)
Number of censored cases	n (%)	72 (54.1%)	71 (54.2%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	60 (45.1%)	62 (47.3%)
Time to first deterioration (months)	Q1 [95% CI]	6.24 [5.59, 8.38]	5.59 [2.86, 7.06]
	Median [95% CI]	29.31 [10.97, 35.98]	23.26 [8.44, 49.05]
	Q3 [95% CI]	NYR [35.98, NC]	50.92 [45.83, NC]
	p-value[b][d]		0.631
	HR [95 % CI][c][d]		0.91 [0.63, 1.31]
	Heterogeneity p-value[e][d]		0.0832

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	45 (33.8%)	42 (32.1%)
Number of censored cases	n (%)	88 (66.2%)	89 (67.9%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	1 (0.8%)	0
No first deterioration	n (%)	75 (56.4%)	80 (61.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 14.23]	5.78 [4.27, 13.93]
	Median [95% CI]	NYR [17.68, NC]	NYR [18.04, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.782
	HR [95 % CI][c][d]		0.94 [0.61, 1.44]
	Heterogeneity p-value[e][d]		0.7226

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	72 (54.1%)	61 (46.6%)
Number of censored cases	n (%)	61 (45.9%)	70 (53.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	2 (1.5%)	0
No first deterioration	n (%)	47 (35.3%)	61 (46.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.02, 6.37]	5.52 [2.86, 5.72]
	Median [95% CI]	13.83 [8.48, 21.22]	14.39 [8.38, 36.40]
	Q3 [95% CI]	35.45 [25.89, NC]	NYR [NC, NC]
	p-value[b][d]		0.695
	HR [95 % CI][c][d]		1.07 [0.76, 1.52]
	Heterogeneity p-value[e][d]		0.2070

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	51 (38.3%)	49 (37.4%)
Number of censored cases	n (%)	82 (61.7%)	82 (62.6%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	1 (0.8%)	0
No first deterioration	n (%)	69 (51.9%)	73 (55.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.41 [5.59, 11.30]	6.70 [5.59, 8.38]
	Median [95% CI]	26.45 [16.53, NC]	48.82 [13.54, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.947
	HR [95 % CI][c][d]		0.98 [0.66, 1.47]
	Heterogeneity p-value[e][d]		0.7794

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	63 (47.4%)	60 (45.8%)
Number of censored cases	n (%)	70 (52.6%)	71 (54.2%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	58 (43.6%)	62 (47.3%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [3.12, 8.48]	5.55 [2.89, 8.51]
	Median [95% CI]	18.17 [13.40, 31.77]	18.50 [10.84, 34.86]
	Q3 [95% CI]	NYR [35.84, NC]	NYR [34.86, NC]
	p-value[b][d]		0.489
	HR [95 % CI][c][d]		0.88 [0.61, 1.26]
	Heterogeneity p-value[e][d]		0.8258

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	60 (45.1%)	51 (38.9%)
Number of censored cases	n (%)	73 (54.9%)	80 (61.1%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	61 (45.9%)	71 (54.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [5.55, 8.34]	5.59 [2.89, 8.34]
	Median [95% CI]	25.13 [13.01, 31.77]	45.83 [11.37, NC]
	Q3 [95% CI]	NYR [46.95, NC]	NYR [NC, NC]
	p-value[b][d]		0.765
	HR [95 % CI][c][d]		1.05 [0.72, 1.55]
	Heterogeneity p-value[e][d]		0.7588

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	83 (62.4%)	77 (58.8%)
Number of censored cases	n (%)	50 (37.6%)	54 (41.2%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	1 (0.8%)	0
No first deterioration	n (%)	37 (27.8%)	45 (34.4%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.83, 2.92]	2.86 [2.83, 3.02]
	Median [95% CI]	5.62 [5.55, 8.48]	8.34 [5.65, 8.61]
	Q3 [95% CI]	24.08 [13.83, NC]	NYR [10.87, NC]
	p-value[b][d]		0.956
	HR [95 % CI][c][d]		0.99 [0.72, 1.36]
	Heterogeneity p-value[e][d]		0.2367

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	75 (56.4%)	65 (49.6%)
Number of censored cases	n (%)	58 (43.6%)	66 (50.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	2 (1.5%)	1 (0.8%)
No first deterioration	n (%)	44 (33.1%)	56 (42.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.92, 5.68]	3.88 [2.89, 6.70]
	Median [95% CI]	10.94 [8.34, 14.23]	14.85 [9.33, 39.16]
	Q3 [95% CI]	37.06 [21.22, NC]	49.74 [39.16, NC]
	p-value[b][d]		0.203
	HR [95 % CI][c][d]		1.25 [0.89, 1.77]
	Heterogeneity p-value[e][d]		0.9992

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	25 (18.8%)	22 (16.8%)
Number of censored cases	n (%)	108 (81.2%)	109 (83.2%)
No baseline score	n (%)	11 (8.3%)	9 (6.9%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	3 (2.3%)	1 (0.8%)
No first deterioration	n (%)	93 (69.9%)	98 (74.8%)
Time to first deterioration (months)	Q1 [95% CI]	34.96 [13.86, NC]	40.05 [10.64, NC]
	Median [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.720
	HR [95 % CI][c][d]		1.12 [0.63, 1.99]
	Heterogeneity p-value[e][d]		0.2103

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	40 (30.1%)	32 (24.4%)
Number of censored cases	n (%)	93 (69.9%)	99 (75.6%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	81 (60.9%)	90 (68.7%)
Time to first deterioration (months)	Q1 [95% CI]	13.67 [8.44, 21.22]	23.26 [8.31, 45.83]
	Median [95% CI]	45.70 [30.59, NC]	48.82 [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.383
	HR [95 % CI][c][d]		1.23 [0.76, 1.98]
	Heterogeneity p-value[e][d]		0.1115

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	50 (37.6%)	44 (33.6%)
Number of censored cases	n (%)	83 (62.4%)	87 (66.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	2 (1.5%)	0
No first deterioration	n (%)	69 (51.9%)	78 (59.5%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.75, 14.23]	9.82 [8.31, 13.83]
	Median [95% CI]	25.86 [17.74, NC]	33.61 [17.97, NC]
	Q3 [95% CI]	NYR [35.45, NC]	NYR [40.71, NC]
	p-value[b][d]		0.695
	HR [95 % CI][c][d]		1.08 [0.72, 1.64]
	Heterogeneity p-value[e][d]		0.9662

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	60 (45.1%)	51 (38.9%)
Number of censored cases	n (%)	73 (54.9%)	80 (61.1%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	4 (3.0%)	5 (3.8%)
No first deterioration	n (%)	57 (42.9%)	66 (50.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.29, 8.31]	5.62 [2.89, 8.34]
	Median [95% CI]	14.23 [8.48, 31.38]	29.34 [15.08, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.381
	HR [95 % CI][c][d]		1.18 [0.81, 1.73]
	Heterogeneity p-value[e][d]		0.3357

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	46 (34.6%)	27 (20.6%)
Number of censored cases	n (%)	87 (65.4%)	104 (79.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	1 (0.8%)	2 (1.5%)
No first deterioration	n (%)	74 (55.6%)	93 (71.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [5.62, 14.52]	28.85 [8.31, NC]
	Median [95% CI]	37.06 [21.22, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.041
	HR [95 % CI][c][d]		1.65 [1.02, 2.67]
	Heterogeneity p-value[e][d]		0.1298

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	43 (32.3%)	44 (33.6%)
Number of censored cases	n (%)	90 (67.7%)	87 (66.4%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	0	1 (0.8%)
No first deterioration	n (%)	78 (58.6%)	77 (58.8%)
Time to first deterioration (months)	Q1 [95% CI]	10.87 [8.31, 22.74]	8.41 [5.59, 11.40]
	Median [95% CI]	45.70 [25.13, NC]	58.68 [21.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [58.68, NC]
	p-value[b][d]		0.540
	HR [95 % CI][c][d]		0.87 [0.57, 1.35]
	Heterogeneity p-value[e][d]		0.8995

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	37 (27.8%)	35 (26.7%)
Number of censored cases	n (%)	96 (72.2%)	96 (73.3%)
No baseline score	n (%)	11 (8.3%)	8 (6.1%)
No post-baseline score	n (%)	1 (0.8%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	84 (63.2%)	87 (66.4%)
Time to first deterioration (months)	Q1 [95% CI]	14.92 [8.48, 25.59]	8.44 [5.72, 28.81]
	Median [95% CI]	62.26 [41.46, NC]	NYR [29.73, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.467
	HR [95 % CI][c][d]		0.83 [0.52, 1.34]
	Heterogeneity p-value[e][d]		0.6387

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	44 (57.9%)	27 (36.0%)
Number of censored cases	n (%)	32 (42.1%)	48 (64.0%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	24 (31.6%)	36 (48.0%)
Time to first deterioration (months)	Q1 [95% CI]	3.07 [2.83, 5.59]	5.55 [2.89, 6.28]
	Median [95% CI]	10.74 [5.62, 17.77]	18.33 [6.28, NC]
	Q3 [95% CI]	40.31 [18.20, NC]	NYR [27.47, NC]
	p-value[b][d]		0.031
	HR [95 % CI][c][d]		1.70 [1.04, 2.79]
	Heterogeneity p-value[e][d]		0.0832

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	44 (57.9%)	30 (40.0%)
Number of censored cases	n (%)	32 (42.1%)	45 (60.0%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	24 (31.6%)	34 (45.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.34]	5.65 [2.89, 8.38]
	Median [95% CI]	15.51 [8.44, 21.68]	12.12 [8.38, 34.83]
	Q3 [95% CI]	39.82 [21.68, NC]	34.83 [17.77, NC]
	p-value[b][d]		0.747
	HR [95 % CI][c][d]		1.09 [0.67, 1.77]
	Heterogeneity p-value[e][d]		0.7226

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	46 (60.5%)	28 (37.3%)
Number of censored cases	n (%)	30 (39.5%)	47 (62.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	3 (3.9%)	0
No first deterioration	n (%)	19 (25.0%)	36 (48.0%)
Time to first deterioration (months)	Q1 [95% CI]	3.25 [2.79, 5.59]	5.55 [2.89, 5.78]
	Median [95% CI]	8.31 [5.59, 11.47]	11.40 [5.78, NC]
	Q3 [95% CI]	25.76 [14.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.051
	HR [95 % CI][c][d]		1.62 [0.99, 2.66]
	Heterogeneity p-value[e][d]		0.2070

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	36 (47.4%)	31 (41.3%)
Number of censored cases	n (%)	40 (52.6%)	44 (58.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	32 (42.1%)	32 (42.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 8.31]	5.55 [2.89, 6.74]
	Median [95% CI]	17.18 [8.31, NC]	20.30 [6.74, 25.53]
	Q3 [95% CI]	NYR [40.31, NC]	34.30 [22.47, NC]
	p-value[b][d]		0.693
	HR [95 % CI][c][d]		0.90 [0.54, 1.49]
	Heterogeneity p-value[e][d]		0.7794

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	44 (57.9%)	34 (45.3%)
Number of censored cases	n (%)	32 (42.1%)	41 (54.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	24 (31.6%)	29 (38.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.68]	5.62 [2.86, 8.31]
	Median [95% CI]	8.54 [5.78, 15.38]	8.61 [6.11, 14.55]
	Q3 [95% CI]	40.31 [15.38, NC]	22.34 [14.29, NC]
	p-value[b][d]		0.963
	HR [95 % CI][c][d]		0.99 [0.62, 1.57]
	Heterogeneity p-value[e][d]		0.8258

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	45 (59.2%)	33 (44.0%)
Number of censored cases	n (%)	31 (40.8%)	42 (56.0%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	2 (2.7%)
No first deterioration	n (%)	23 (30.3%)	29 (38.7%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.83, 5.62]	5.55 [2.86, 5.75]
	Median [95% CI]	8.54 [5.62, 16.33]	8.61 [5.75, 13.73]
	Q3 [95% CI]	40.31 [17.54, NC]	NYR [12.12, NC]
	p-value[b][d]		0.873
	HR [95 % CI][c][d]		0.96 [0.60, 1.54]
	Heterogeneity p-value[e][d]		0.7588

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	53 (69.7%)	34 (45.3%)
Number of censored cases	n (%)	23 (30.3%)	41 (54.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	15 (19.7%)	29 (38.7%)
Time to first deterioration (months)	Q1 [95% CI]	2.84 [2.79, 2.92]	2.89 [2.79, 5.55]
	Median [95% CI]	5.68 [3.78, 8.34]	8.31 [5.55, 11.40]
	Q3 [95% CI]	21.68 [8.44, 41.26]	NYR [11.37, NC]
	p-value[b][d]		0.171
	HR [95 % CI][c][d]		1.34 [0.86, 2.08]
	Heterogeneity p-value[e][d]		0.2367

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	46 (60.5%)	32 (42.7%)
Number of censored cases	n (%)	30 (39.5%)	43 (57.3%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	22 (28.9%)	31 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 5.72]	3.09 [2.86, 5.65]
	Median [95% CI]	8.54 [6.47, 18.00]	12.12 [5.65, 29.80]
	Q3 [95% CI]	33.61 [18.00, NC]	46.16 [29.57, NC]
	p-value[b][d]		0.500
	HR [95 % CI][c][d]		1.18 [0.75, 1.87]
	Heterogeneity p-value[e][d]		0.9992

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	29 (38.2%)	13 (17.3%)
Number of censored cases	n (%)	47 (61.8%)	62 (82.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	3 (3.9%)	1 (1.3%)
No first deterioration	n (%)	36 (47.4%)	50 (66.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.55, 14.09]	30.65 [2.92, NC]
	Median [95% CI]	30.65 [16.33, NC]	NYR [30.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.061
	HR [95 % CI][c][d]		1.92 [0.96, 3.83]
	Heterogeneity p-value[e][d]		0.2103

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	21 (27.6%)	21 (28.0%)
Number of censored cases	n (%)	55 (72.4%)	54 (72.0%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	47 (61.8%)	43 (57.3%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [6.87, 40.31]	6.11 [2.92, 17.87]
	Median [95% CI]	NYR [34.37, NC]	30.75 [13.47, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.113
	HR [95 % CI][c][d]		0.60 [0.32, 1.14]
	Heterogeneity p-value[e][d]		0.1115

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	36 (47.4%)	22 (29.3%)
Number of censored cases	n (%)	40 (52.6%)	53 (70.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	31 (40.8%)	42 (56.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.89, 14.06]	5.55 [2.86, 11.37]
	Median [95% CI]	26.48 [14.09, 34.27]	NYR [9.69, NC]
	Q3 [95% CI]	41.26 [33.91, NC]	NYR [NC, NC]
	p-value[b][d]		0.495
	HR [95 % CI][c][d]		1.21 [0.70, 2.09]
	Heterogeneity p-value[e][d]		0.9662

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	31 (40.8%)	28 (37.3%)
Number of censored cases	n (%)	45 (59.2%)	47 (62.7%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	1 (1.3%)	1 (1.3%)
No first deterioration	n (%)	36 (47.4%)	35 (46.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.83, 8.25]	6.11 [2.89, 8.51]
	Median [95% CI]	39.82 [8.31, NC]	14.59 [8.51, 38.70]
	Q3 [95% CI]	NYR [NC, NC]	38.70 [15.70, NC]
	p-value[b][d]		0.355
	HR [95 % CI][c][d]		0.78 [0.45, 1.35]
	Heterogeneity p-value[e][d]		0.3357

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	24 (31.6%)	20 (26.7%)
Number of censored cases	n (%)	52 (68.4%)	55 (73.3%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	4 (5.3%)	3 (4.0%)
No first deterioration	n (%)	40 (52.6%)	41 (54.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.38 [2.99, 20.60]	5.59 [2.86, 15.70]
	Median [95% CI]	NYR [20.60, NC]	NYR [10.91, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.759
	HR [95 % CI][c][d]		0.91 [0.48, 1.70]
	Heterogeneity p-value[e][d]		0.1298

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	28 (36.8%)	24 (32.0%)
Number of censored cases	n (%)	48 (63.2%)	51 (68.0%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	2 (2.6%)	2 (2.7%)
No first deterioration	n (%)	38 (50.0%)	38 (50.7%)
Time to first deterioration (months)	Q1 [95% CI]	7.85 [5.55, 14.32]	8.61 [2.89, 18.53]
	Median [95% CI]	39.46 [17.87, NC]	27.56 [18.53, NC]
	Q3 [95% CI]	NYR [43.96, NC]	52.60 [30.65, NC]
	p-value[b][d]		0.670
	HR [95 % CI][c][d]		0.88 [0.50, 1.56]
	Heterogeneity p-value[e][d]		0.8995

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	23 (30.3%)	17 (22.7%)
Number of censored cases	n (%)	53 (69.7%)	58 (77.3%)
No baseline score	n (%)	6 (7.9%)	7 (9.3%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	1 (1.3%)	0
No first deterioration	n (%)	44 (57.9%)	47 (62.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.62, 21.39]	18.79 [3.09, 25.66]
	Median [95% CI]	NYR [21.39, NC]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.707
	HR [95 % CI][c][d]		1.14 [0.58, 2.22]
	Heterogeneity p-value[e][d]		0.6387

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	61 (48.8%)	49 (41.9%)
Number of censored cases	n (%)	64 (51.2%)	68 (58.1%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	54 (43.2%)	58 (49.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.99, 5.65]	5.09 [2.89, 6.11]
	Median [95% CI]	13.83 [8.44, 35.45]	24.44 [8.41, NC]
	Q3 [95% CI]	NYR [35.45, NC]	NYR [45.83, NC]
	p-value[b][d]		0.459
	HR [95 % CI][c][d]		1.15 [0.79, 1.70]
	Heterogeneity p-value[e][d]		0.9153

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	49 (39.2%)	40 (34.2%)
Number of censored cases	n (%)	76 (60.8%)	77 (65.8%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	66 (52.8%)	67 (57.3%)
Time to first deterioration (months)	Q1 [95% CI]	8.31 [3.29, 17.58]	5.75 [3.48, 9.33]
	Median [95% CI]	30.19 [17.68, NC]	34.83 [14.72, NC]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [NC, NC]
	p-value[b][d]		0.971
	HR [95 % CI][c][d]		1.00 [0.65, 1.52]
	Heterogeneity p-value[e][d]		0.5356

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	74 (59.2%)	45 (38.5%)
Number of censored cases	n (%)	51 (40.8%)	72 (61.5%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	41 (32.8%)	62 (53.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.92, 5.59]	5.55 [2.89, 7.85]
	Median [95% CI]	10.64 [8.28, 16.89]	17.77 [8.41, NC]
	Q3 [95% CI]	30.19 [21.52, NC]	NYR [NC, NC]
	p-value[b][d]		0.085
	HR [95 % CI][c][d]		1.39 [0.95, 2.03]
	Heterogeneity p-value[e][d]		0.2414

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	50 (40.0%)	42 (35.9%)
Number of censored cases	n (%)	75 (60.0%)	75 (64.1%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	65 (52.0%)	64 (54.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.28 [5.55, 10.78]	5.65 [5.55, 8.34]
	Median [95% CI]	25.30 [14.46, NC]	25.36 [11.43, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.878
	HR [95 % CI][c][d]		1.03 [0.68, 1.57]
	Heterogeneity p-value[e][d]		0.6120

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	66 (52.8%)	53 (45.3%)
Number of censored cases	n (%)	59 (47.2%)	64 (54.7%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	49 (39.2%)	53 (45.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.96, 8.31]	5.55 [2.86, 5.78]
	Median [95% CI]	13.57 [8.51, 18.23]	10.91 [8.41, 22.41]
	Q3 [95% CI]	NYR [22.47, NC]	NYR [51.12, NC]
	p-value[b][d]		0.870
	HR [95 % CI][c][d]		1.03 [0.71, 1.50]
	Heterogeneity p-value[e][d]		0.4483

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	57 (45.6%)	46 (39.3%)
Number of censored cases	n (%)	68 (54.4%)	71 (60.7%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	58 (46.4%)	60 (51.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.12, 5.68]	5.55 [2.89, 8.34]
	Median [95% CI]	17.54 [10.48, 46.95]	25.86 [8.41, NC]
	Q3 [95% CI]	NYR [39.49, NC]	NYR [45.83, NC]
	p-value[b][d]		0.915
	HR [95 % CI][c][d]		1.02 [0.68, 1.52]
	Heterogeneity p-value[e][d]		0.8752

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	79 (63.2%)	62 (53.0%)
Number of censored cases	n (%)	46 (36.8%)	55 (47.0%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	1 (0.9%)
No first deterioration	n (%)	36 (28.8%)	44 (37.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 2.92]	2.89 [2.83, 3.48]
	Median [95% CI]	5.62 [5.29, 8.44]	6.51 [5.55, 10.87]
	Q3 [95% CI]	26.81 [17.51, NC]	NYR [13.54, NC]
	p-value[b][d]		0.389
	HR [95 % CI][c][d]		1.16 [0.83, 1.64]
	Heterogeneity p-value[e][d]		0.9832

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	71 (56.8%)	55 (47.0%)
Number of censored cases	n (%)	54 (43.2%)	62 (53.0%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	1 (0.8%)	1 (0.9%)
No first deterioration	n (%)	43 (34.4%)	51 (43.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.99, 5.78]	3.48 [2.89, 5.65]
	Median [95% CI]	10.87 [8.38, 17.58]	14.98 [8.44, 29.80]
	Q3 [95% CI]	33.61 [21.68, NC]	NYR [29.80, NC]
	p-value[b][d]		0.195
	HR [95 % CI][c][d]		1.27 [0.88, 1.82]
	Heterogeneity p-value[e][d]		0.9929

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	30 (24.0%)	19 (16.2%)
Number of censored cases	n (%)	95 (76.0%)	98 (83.8%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	1 (0.8%)	2 (1.7%)
No first deterioration	n (%)	84 (67.2%)	86 (73.5%)
Time to first deterioration (months)	Q1 [95% CI]	16.33 [8.34, 57.99]	30.65 [10.64, NC]
	Median [95% CI]	57.99 [57.99, NC]	NYR [NC, NC]
	Q3 [95% CI]	NYR [57.99, NC]	NYR [NC, NC]
	p-value[b][d]		0.549
	HR [95 % CI][c][d]		1.20 [0.67, 2.16]
	Heterogeneity p-value[e][d]		0.7185

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	34 (27.2%)	27 (23.1%)
Number of censored cases	n (%)	91 (72.8%)	90 (76.9%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	81 (64.8%)	80 (68.4%)
Time to first deterioration (months)	Q1 [95% CI]	14.06 [8.34, 33.68]	13.37 [5.65, 45.83]
	Median [95% CI]	NYR [34.37, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.955
	HR [95 % CI][c][d]		0.98 [0.59, 1.63]
	Heterogeneity p-value[e][d]		0.7758

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	49 (39.2%)	35 (29.9%)
Number of censored cases	n (%)	76 (60.8%)	82 (70.1%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	3 (2.4%)	0
No first deterioration	n (%)	63 (50.4%)	72 (61.5%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [8.34, 17.74]	8.54 [7.85, 17.97]
	Median [95% CI]	26.48 [21.59, 34.27]	40.71 [22.14, NC]
	Q3 [95% CI]	35.45 [34.27, NC]	NYR [43.56, NC]
	p-value[b][d]		0.408
	HR [95 % CI][c][d]		1.21 [0.77, 1.92]
	Heterogeneity p-value[e][d]		0.8161

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	55 (44.0%)	51 (43.6%)
Number of censored cases	n (%)	70 (56.0%)	66 (56.4%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	2 (1.6%)	2 (1.7%)
No first deterioration	n (%)	58 (46.4%)	54 (46.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.09, 6.24]	5.62 [2.89, 8.31]
	Median [95% CI]	16.33 [8.41, NC]	15.70 [8.51, 38.70]
	Q3 [95% CI]	NYR [39.82, NC]	NYR [38.70, NC]
	p-value[b][d]		0.784
	HR [95 % CI][c][d]		0.95 [0.64, 1.40]
	Heterogeneity p-value[e][d]		0.3237

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	40 (32.0%)	27 (23.1%)
Number of censored cases	n (%)	85 (68.0%)	90 (76.9%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	2 (1.6%)	2 (1.7%)
No first deterioration	n (%)	73 (58.4%)	78 (66.7%)
Time to first deterioration (months)	Q1 [95% CI]	10.97 [5.59, 17.77]	10.91 [5.55, 45.83]
	Median [95% CI]	NYR [24.08, NC]	NYR [45.83, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.442
	HR [95 % CI][c][d]		1.21 [0.74, 1.99]
	Heterogeneity p-value[e][d]		0.4950

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	43 (34.4%)	41 (35.0%)
Number of censored cases	n (%)	82 (65.6%)	76 (65.0%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	1 (0.8%)	1 (0.9%)
No first deterioration	n (%)	71 (56.8%)	65 (55.6%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.68, 15.54]	10.45 [5.72, 14.69]
	Median [95% CI]	43.96 [23.03, NC]	28.81 [18.53, 58.68]
	Q3 [95% CI]	NYR [NC, NC]	58.68 [52.60, NC]
	p-value[b][d]		0.364
	HR [95 % CI][c][d]		0.81 [0.52, 1.27]
	Heterogeneity p-value[e][d]		0.8779

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	36 (28.8%)	34 (29.1%)
Number of censored cases	n (%)	89 (71.2%)	83 (70.9%)
No baseline score	n (%)	8 (6.4%)	8 (6.8%)
No post-baseline score	n (%)	2 (1.6%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	79 (63.2%)	73 (62.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.68, 21.88]	8.34 [3.88, 18.79]
	Median [95% CI]	NYR [25.79, NC]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.365
	HR [95 % CI][c][d]		0.80 [0.49, 1.29]
	Heterogeneity p-value[e][d]		0.3773

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Global health status/QoL (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	44 (52.4%)	38 (42.7%)
Number of censored cases	n (%)	40 (47.6%)	51 (57.3%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	30 (35.7%)	40 (44.9%)
Time to first deterioration (months)	Q1 [95% CI]	6.24 [5.55, 8.44]	5.62 [2.86, 8.31]
	Median [95% CI]	15.51 [10.64, 37.06]	18.33 [8.34, NC]
	Q3 [95% CI]	41.46 [34.66, NC]	49.05 [27.47, NC]
	p-value[b][d]		0.682
	HR [95 % CI][c][d]		1.10 [0.70, 1.74]
	Heterogeneity p-value[e][d]		0.9153

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Physical Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	40 (47.6%)	32 (36.0%)
Number of censored cases	n (%)	44 (52.4%)	57 (64.0%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	33 (39.3%)	47 (52.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, 8.44]	6.74 [2.89, 9.95]
	Median [95% CI]	15.51 [10.71, NC]	18.46 [12.12, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.367
	HR [95 % CI][c][d]		1.25 [0.77, 2.01]
	Heterogeneity p-value[e][d]		0.5356

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Role Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	44 (52.4%)	44 (49.4%)
Number of censored cases	n (%)	40 (47.6%)	45 (50.6%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	5 (6.0%)	0
No first deterioration	n (%)	25 (29.8%)	35 (39.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.89, 6.74]	2.92 [2.83, 5.72]
	Median [95% CI]	11.20 [8.28, 21.22]	10.97 [5.78, 19.12]
	Q3 [95% CI]	NYR [21.22, NC]	36.40 [19.12, NC]
	p-value[b][d]		0.836
	HR [95 % CI][c][d]		1.05 [0.68, 1.62]
	Heterogeneity p-value[e][d]		0.2414

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Emotional Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	37 (44.0%)	38 (42.7%)
Number of censored cases	n (%)	47 (56.0%)	51 (57.3%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	36 (42.9%)	41 (46.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 8.61]	5.62 [2.96, 8.38]
	Median [95% CI]	25.63 [10.64, NC]	20.73 [8.41, 48.82]
	Q3 [95% CI]	NYR [40.31, NC]	NYR [34.30, NC]
	p-value[b][d]		0.910
	HR [95 % CI][c][d]		0.97 [0.61, 1.56]
	Heterogeneity p-value[e][d]		0.6120

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	41 (48.8%)	41 (46.1%)
Number of censored cases	n (%)	43 (51.2%)	48 (53.9%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	33 (39.3%)	38 (42.7%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.89, 8.48]	5.78 [2.89, 8.38]
	Median [95% CI]	16.53 [10.71, 40.31]	14.09 [10.68, 25.69]
	Q3 [95% CI]	46.03 [35.84, NC]	34.86 [22.34, NC]
	p-value[b][d]		0.417
	HR [95 % CI][c][d]		0.83 [0.53, 1.30]
	Heterogeneity p-value[e][d]		0.4483

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Social Functioning (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	48 (57.1%)	38 (42.7%)
Number of censored cases	n (%)	36 (42.9%)	51 (57.3%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	26 (31.0%)	40 (44.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.92, 8.34]	2.99 [2.86, 5.62]
	Median [95% CI]	14.23 [8.41, 25.63]	15.21 [8.31, NC]
	Q3 [95% CI]	40.31 [25.63, NC]	NYR [25.40, NC]
	p-value[b][d]		0.970
	HR [95 % CI][c][d]		1.01 [0.64, 1.59]
	Heterogeneity p-value[e][d]		0.8752

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Fatigue (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	57 (67.9%)	49 (55.1%)
Number of censored cases	n (%)	27 (32.1%)	40 (44.9%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	16 (19.0%)	30 (33.7%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.83, 3.78]	2.86 [2.79, 3.88]
	Median [95% CI]	6.74 [5.55, 8.44]	8.38 [5.65, 8.61]
	Q3 [95% CI]	15.51 [8.61, NC]	NYR [10.45, NC]
	p-value[b][d]		0.640
	HR [95 % CI][c][d]		1.10 [0.73, 1.64]
	Heterogeneity p-value[e][d]		0.9832

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Pain (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	50 (59.5%)	42 (47.2%)
Number of censored cases	n (%)	34 (40.5%)	47 (52.8%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	1 (1.2%)	1 (1.1%)
No first deterioration	n (%)	23 (27.4%)	36 (40.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 5.72]	3.48 [2.86, 8.31]
	Median [95% CI]	8.41 [6.24, 13.67]	13.60 [8.38, 44.75]
	Q3 [95% CI]	37.06 [14.23, NC]	44.75 [34.07, NC]
	p-value[b][d]		0.240
	HR [95 % CI][c][d]		1.29 [0.84, 1.98]
	Heterogeneity p-value[e][d]		0.9929

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Financial Difficulties (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	24 (28.6%)	16 (18.0%)
Number of censored cases	n (%)	60 (71.4%)	73 (82.0%)
No baseline score	n (%)	9 (10.7%)	8 (9.0%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	5 (6.0%)	0
No first deterioration	n (%)	45 (53.6%)	62 (69.7%)
Time to first deterioration (months)	Q1 [95% CI]	16.53 [5.59, 30.65]	40.05 [8.38, NC]
	Median [95% CI]	NYR [30.65, NC]	NYR [40.05, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.180
	HR [95 % CI][c][d]		1.56 [0.82, 2.98]
	Heterogeneity p-value[e][d]		0.7185

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Nausea/Vomiting (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	27 (32.1%)	26 (29.2%)
Number of censored cases	n (%)	57 (67.9%)	63 (70.8%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	47 (56.0%)	53 (59.6%)
Time to first deterioration (months)	Q1 [95% CI]	13.67 [8.34, 21.22]	8.41 [3.09, 23.26]
	Median [95% CI]	NYR [26.41, NC]	48.82 [21.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [48.82, NC]
	p-value[b][d]		0.516
	HR [95 % CI][c][d]		0.83 [0.47, 1.45]
	Heterogeneity p-value[e][d]		0.7758

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Dyspnoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	37 (44.0%)	31 (34.8%)
Number of censored cases	n (%)	47 (56.0%)	58 (65.2%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	37 (44.0%)	48 (53.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.68 [2.96, 11.20]	8.31 [2.89, 10.64]
	Median [95% CI]	22.14 [12.52, NC]	21.72 [11.63, NC]
	Q3 [95% CI]	NYR [41.26, NC]	NYR [NC, NC]
	p-value[b][d]		0.572
	HR [95 % CI][c][d]		1.15 [0.71, 1.88]
	Heterogeneity p-value[e][d]		0.8161

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Insomnia (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	36 (42.9%)	28 (31.5%)
Number of censored cases	n (%)	48 (57.1%)	61 (68.5%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	3 (3.6%)	4 (4.5%)
No first deterioration	n (%)	35 (41.7%)	47 (52.8%)
Time to first deterioration (months)	Q1 [95% CI]	6.37 [2.92, 8.38]	8.34 [2.96, 14.59]
	Median [95% CI]	14.98 [8.61, NC]	34.53 [14.59, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [34.53, NC]
	p-value[b][d]		0.286
	HR [95 % CI][c][d]		1.32 [0.79, 2.19]
	Heterogeneity p-value[e][d]		0.3237

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Appetite Loss (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	30 (35.7%)	20 (22.5%)
Number of censored cases	n (%)	54 (64.3%)	69 (77.5%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	3 (3.6%)	3 (3.4%)
No first deterioration	n (%)	41 (48.8%)	56 (62.9%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 14.23]	13.60 [2.89, NC]
	Median [95% CI]	37.06 [14.59, NC]	NYR [31.18, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.098
	HR [95 % CI][c][d]		1.64 [0.91, 2.94]
	Heterogeneity p-value[e][d]		0.4950

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Constipation (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	28 (33.3%)	27 (30.3%)
Number of censored cases	n (%)	56 (66.7%)	62 (69.7%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	1 (1.2%)	2 (2.2%)
No first deterioration	n (%)	45 (53.6%)	50 (56.2%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.65, 23.33]	8.31 [2.89, 21.82]
	Median [95% CI]	39.46 [23.33, NC]	NYR [21.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.655
	HR [95 % CI][c][d]		0.88 [0.52, 1.51]
	Heterogeneity p-value[e][d]		0.8779

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.10.1.1 Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Diarrhoea (Deterioration threshold = 10)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	24 (28.6%)	18 (20.2%)
Number of censored cases	n (%)	60 (71.4%)	71 (79.8%)
No baseline score	n (%)	9 (10.7%)	7 (7.9%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	1 (1.2%)	0
No first deterioration	n (%)	49 (58.3%)	61 (68.5%)
Time to first deterioration (months)	Q1 [95% CI]	14.23 [8.34, 41.46]	21.65 [8.34, NC]
	Median [95% CI]	62.26 [41.46, NC]	NYR [29.73, NC]
	Q3 [95% CI]	62.26 [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.946
	HR [95 % CI][c][d]		1.02 [0.54, 1.92]
	Heterogeneity p-value[e][d]		0.3773

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Health Status; HR: Hazard Ration; QoL: Quality of Life; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	32 (49.2%)
Number of censored participants, n (%)	27 (48.2%)	33 (50.8%)
Proportionality Test p-value[a][b]	0.9638	
Hazard ratio(interaction)	0.983 (0.478, 2.022)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	23 (41.1%)	21 (32.3%)
Number of censored participants, n (%)	33 (58.9%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.6912	
Hazard ratio(interaction)	0.846 (0.371, 1.929)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	30 (53.6%)	29 (44.6%)
Number of censored participants, n (%)	26 (46.4%)	36 (55.4%)
Proportionality Test p-value[a][b]	0.4370	
Hazard ratio(interaction)	0.741 (0.348, 1.577)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	27 (41.5%)
Number of censored participants, n (%)	27 (48.2%)	38 (58.5%)
Proportionality Test p-value[a][b]	0.1817	
Hazard ratio(interaction)	1.764 (0.767, 4.055)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	33 (58.9%)	35 (53.8%)
Number of censored participants, n (%)	23 (41.1%)	30 (46.2%)
Proportionality Test p-value[a][b]	0.4212	
Hazard ratio(interaction)	1.364 (0.640, 2.909)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	26 (46.4%)	37 (56.9%)
Number of censored participants, n (%)	30 (53.6%)	28 (43.1%)
Proportionality Test p-value[a][b]	0.8539	
Hazard ratio(interaction)	1.066 (0.542, 2.095)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	39 (69.6%)	37 (56.9%)
Number of censored participants, n (%)	17 (30.4%)	28 (43.1%)
Proportionality Test p-value[a][b]	0.4469	
Hazard ratio(interaction)	1.347 (0.625, 2.901)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	15 (26.8%)	19 (29.2%)
Number of censored participants, n (%)	41 (73.2%)	46 (70.8%)
Proportionality Test p-value[a][b]	0.6353	
Hazard ratio(interaction)	1.254 (0.492, 3.200)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Pain (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	32 (57.1%)	35 (53.8%)
Number of censored participants, n (%)	24 (42.9%)	30 (46.2%)
Proportionality Test p-value[a][b]	0.9452	
Hazard ratio(interaction)	1.026 (0.492, 2.140)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	21 (32.3%)
Number of censored participants, n (%)	27 (48.2%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.6412	
Hazard ratio(interaction)	1.170 (0.604, 2.265)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	26 (46.4%)	29 (44.6%)
Number of censored participants, n (%)	30 (53.6%)	36 (55.4%)
Proportionality Test p-value[a][b]	0.2714	
Hazard ratio(interaction)	0.624 (0.270, 1.445)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	19 (33.9%)	15 (23.1%)
Number of censored participants, n (%)	37 (66.1%)	50 (76.9%)
Proportionality Test p-value[a][b]	0.2604	
Hazard ratio(interaction)	1.787 (0.650, 4.908)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	12 (21.4%)	18 (27.7%)
Number of censored participants, n (%)	44 (78.6%)	47 (72.3%)
Proportionality Test p-value[a][b]	0.6265	
Hazard ratio(interaction)	0.795 (0.315, 2.004)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	16 (28.6%)	22 (33.8%)
Number of censored participants, n (%)	40 (71.4%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.3010	
Hazard ratio(interaction)	0.559 (0.186, 1.683)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: <65
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	14 (25.0%)	14 (21.5%)
Number of censored participants, n (%)	42 (75.0%)	51 (78.5%)
Proportionality Test p-value[a][b]	0.2671	
Hazard ratio(interaction)	0.586 (0.229, 1.505)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	76 (49.7%)	55 (39.0%)
Number of censored participants, n (%)	77 (50.3%)	86 (61.0%)
Proportionality Test p-value[a][b]	0.0418	
Hazard ratio(interaction)	0.603 (0.370, 0.981)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	66 (43.1%)	51 (36.2%)
Number of censored participants, n (%)	87 (56.9%)	90 (63.8%)
Proportionality Test p-value[a][b]	0.3014	
Hazard ratio(interaction)	0.771 (0.471, 1.262)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	88 (57.5%)	60 (42.6%)
Number of censored participants, n (%)	65 (42.5%)	81 (57.4%)
Proportionality Test p-value[a][b]	0.0641	
Hazard ratio(interaction)	0.637 (0.396, 1.027)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	58 (37.9%)	53 (37.6%)
Number of censored participants, n (%)	95 (62.1%)	88 (62.4%)
Proportionality Test p-value[a][b]	0.8287	
Hazard ratio(interaction)	0.947 (0.576, 1.556)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	74 (48.4%)	59 (41.8%)
Number of censored participants, n (%)	79 (51.6%)	82 (58.2%)
Proportionality Test p-value[a][b]	0.6695	
Hazard ratio(interaction)	0.906 (0.575, 1.427)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	79 (51.6%)	47 (33.3%)
Number of censored participants, n (%)	74 (48.4%)	94 (66.7%)
Proportionality Test p-value[a][b]	0.0308	
Hazard ratio(interaction)	0.578 (0.352, 0.950)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	97 (63.4%)	74 (52.5%)
Number of censored participants, n (%)	56 (36.6%)	67 (47.5%)
Proportionality Test p-value[a][b]	0.4480	
Hazard ratio(interaction)	0.841 (0.537, 1.316)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	46 (30.1%)	34 (24.1%)
Number of censored participants, n (%)	107 (69.9%)	107 (75.9%)
Proportionality Test p-value[a][b]	0.1641	
Hazard ratio(interaction)	0.683 (0.399, 1.169)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Pain (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	89 (58.2%)	62 (44.0%)
Number of censored participants, n (%)	64 (41.8%)	79 (56.0%)
Proportionality Test p-value[a][b]	0.0524	
Hazard ratio(interaction)	0.665 (0.441, 1.004)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	57 (37.3%)	45 (31.9%)
Number of censored participants, n (%)	96 (62.7%)	96 (68.1%)
Proportionality Test p-value[a][b]	0.0449	
Hazard ratio(interaction)	0.602 (0.366, 0.989)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	65 (42.5%)	50 (35.5%)
Number of censored participants, n (%)	88 (57.5%)	91 (64.5%)
Proportionality Test p-value[a][b]	0.4601	
Hazard ratio(interaction)	1.229 (0.711, 2.122)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	51 (33.3%)	32 (22.7%)
Number of censored participants, n (%)	102 (66.7%)	109 (77.3%)
Proportionality Test p-value[a][b]	0.0086	
Hazard ratio(interaction)	0.443 (0.242, 0.813)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	59 (38.6%)	50 (35.5%)
Number of censored participants, n (%)	94 (61.4%)	91 (64.5%)
Proportionality Test p-value[a][b]	0.9105	
Hazard ratio(interaction)	1.027 (0.649, 1.625)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	44 (28.8%)	30 (21.3%)
Number of censored participants, n (%)	109 (71.2%)	111 (78.7%)
Proportionality Test p-value[a][b]	0.9108	
Hazard ratio(interaction)	0.968 (0.553, 1.697)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 1: >=65
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	40 (26.1%)	21 (14.9%)
Number of censored participants, n (%)	113 (73.9%)	120 (85.1%)
Proportionality Test p-value[a][b]	0.8806	
Hazard ratio(interaction)	0.950 (0.489, 1.847)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	32 (49.2%)
Number of censored participants, n (%)	27 (48.2%)	33 (50.8%)
Proportionality Test p-value[a][b]	0.9638	
Hazard ratio(interaction)	0.983 (0.478, 2.022)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	23 (41.1%)	21 (32.3%)
Number of censored participants, n (%)	33 (58.9%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.6912	
Hazard ratio(interaction)	0.846 (0.371, 1.929)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	30 (53.6%)	29 (44.6%)
Number of censored participants, n (%)	26 (46.4%)	36 (55.4%)
Proportionality Test p-value[a][b]	0.4370	
Hazard ratio(interaction)	0.741 (0.348, 1.577)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	27 (41.5%)
Number of censored participants, n (%)	27 (48.2%)	38 (58.5%)
Proportionality Test p-value[a][b]	0.1817	
Hazard ratio(interaction)	1.764 (0.767, 4.055)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	33 (58.9%)	35 (53.8%)
Number of censored participants, n (%)	23 (41.1%)	30 (46.2%)
Proportionality Test p-value[a][b]	0.4212	
Hazard ratio(interaction)	1.364 (0.640, 2.909)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	26 (46.4%)	37 (56.9%)
Number of censored participants, n (%)	30 (53.6%)	28 (43.1%)
Proportionality Test p-value[a][b]	0.8539	
Hazard ratio(interaction)	1.066 (0.542, 2.095)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	39 (69.6%)	37 (56.9%)
Number of censored participants, n (%)	17 (30.4%)	28 (43.1%)
Proportionality Test p-value[a][b]	0.4469	
Hazard ratio(interaction)	1.347 (0.625, 2.901)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	15 (26.8%)	19 (29.2%)
Number of censored participants, n (%)	41 (73.2%)	46 (70.8%)
Proportionality Test p-value[a][b]	0.6353	
Hazard ratio(interaction)	1.254 (0.492, 3.200)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Pain (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	32 (57.1%)	35 (53.8%)
Number of censored participants, n (%)	24 (42.9%)	30 (46.2%)
Proportionality Test p-value[a][b]	0.9452	
Hazard ratio(interaction)	1.026 (0.492, 2.140)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	21 (32.3%)
Number of censored participants, n (%)	27 (48.2%)	44 (67.7%)
Proportionality Test p-value[a][b]	0.6412	
Hazard ratio(interaction)	1.170 (0.604, 2.265)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	26 (46.4%)	29 (44.6%)
Number of censored participants, n (%)	30 (53.6%)	36 (55.4%)
Proportionality Test p-value[a][b]	0.2714	
Hazard ratio(interaction)	0.624 (0.270, 1.445)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	19 (33.9%)	15 (23.1%)
Number of censored participants, n (%)	37 (66.1%)	50 (76.9%)
Proportionality Test p-value[a][b]	0.2604	
Hazard ratio(interaction)	1.787 (0.650, 4.908)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	12 (21.4%)	18 (27.7%)
Number of censored participants, n (%)	44 (78.6%)	47 (72.3%)
Proportionality Test p-value[a][b]	0.6265	
Hazard ratio(interaction)	0.795 (0.315, 2.004)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	16 (28.6%)	22 (33.8%)
Number of censored participants, n (%)	40 (71.4%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.3010	
Hazard ratio(interaction)	0.559 (0.186, 1.683)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: <65
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	14 (25.0%)	14 (21.5%)
Number of censored participants, n (%)	42 (75.0%)	51 (78.5%)
Proportionality Test p-value[a][b]	0.2671	
Hazard ratio(interaction)	0.586 (0.229, 1.505)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	35 (43.8%)	28 (40.6%)
Number of censored participants, n (%)	45 (56.3%)	41 (59.4%)
Proportionality Test p-value[a][b]	0.1033	
Hazard ratio(interaction)	0.570 (0.290, 1.121)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	31 (38.8%)	23 (33.3%)
Number of censored participants, n (%)	49 (61.3%)	46 (66.7%)
Proportionality Test p-value[a][b]	0.7306	
Hazard ratio(interaction)	0.875 (0.410, 1.870)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	40 (50.0%)	28 (40.6%)
Number of censored participants, n (%)	40 (50.0%)	41 (59.4%)
Proportionality Test p-value[a][b]	0.9144	
Hazard ratio(interaction)	0.960 (0.456, 2.023)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	29 (36.3%)	28 (40.6%)
Number of censored participants, n (%)	51 (63.8%)	41 (59.4%)
Proportionality Test p-value[a][b]	0.8248	
Hazard ratio(interaction)	0.922 (0.450, 1.889)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	32 (40.0%)	32 (46.4%)
Number of censored participants, n (%)	48 (60.0%)	37 (53.6%)
Proportionality Test p-value[a][b]	0.3267	
Hazard ratio(interaction)	0.725 (0.382, 1.378)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	38 (47.5%)	27 (39.1%)
Number of censored participants, n (%)	42 (52.5%)	42 (60.9%)
Proportionality Test p-value[a][b]	0.0026	
Hazard ratio(interaction)	0.350 (0.177, 0.693)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	48 (60.0%)	38 (55.1%)
Number of censored participants, n (%)	32 (40.0%)	31 (44.9%)
Proportionality Test p-value[a][b]	0.3970	
Hazard ratio(interaction)	0.753 (0.391, 1.451)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	22 (27.5%)	17 (24.6%)
Number of censored participants, n (%)	58 (72.5%)	52 (75.4%)
Proportionality Test p-value[a][b]	0.0641	
Hazard ratio(interaction)	0.488 (0.228, 1.043)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Pain (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	43 (53.8%)	34 (49.3%)
Number of censored participants, n (%)	37 (46.3%)	35 (50.7%)
Proportionality Test p-value[a][b]	0.5478	
Hazard ratio(interaction)	0.842 (0.480, 1.476)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	23 (28.8%)	22 (31.9%)
Number of censored participants, n (%)	57 (71.3%)	47 (68.1%)
Proportionality Test p-value[a][b]	0.4517	
Hazard ratio(interaction)	0.754 (0.362, 1.572)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	32 (40.0%)	28 (40.6%)
Number of censored participants, n (%)	48 (60.0%)	41 (59.4%)
Proportionality Test p-value[a][b]	0.5924	
Hazard ratio(interaction)	1.244 (0.559, 2.766)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	22 (27.5%)	16 (23.2%)
Number of censored participants, n (%)	58 (72.5%)	53 (76.8%)
Proportionality Test p-value[a][b]	0.1577	
Hazard ratio(interaction)	0.545 (0.235, 1.265)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	25 (31.3%)	23 (33.3%)
Number of censored participants, n (%)	55 (68.8%)	46 (66.7%)
Proportionality Test p-value[a][b]	0.6021	
Hazard ratio(interaction)	0.816 (0.381, 1.749)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	20 (25.0%)	15 (21.7%)
Number of censored participants, n (%)	60 (75.0%)	54 (78.3%)
Proportionality Test p-value[a][b]	0.9613	
Hazard ratio(interaction)	1.025 (0.385, 2.724)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	22 (27.5%)	13 (18.8%)
Number of censored participants, n (%)	58 (72.5%)	56 (81.2%)
Proportionality Test p-value[a][b]	0.3601	
Hazard ratio(interaction)	0.675 (0.291, 1.567)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	41 (56.2%)	27 (37.5%)
Number of censored participants, n (%)	32 (43.8%)	45 (62.5%)
Proportionality Test p-value[a][b]	0.2318	
Hazard ratio(interaction)	0.639 (0.306, 1.332)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	35 (47.9%)	28 (38.9%)
Number of censored participants, n (%)	38 (52.1%)	44 (61.1%)
Proportionality Test p-value[a][b]	0.1566	
Hazard ratio(interaction)	0.613 (0.311, 1.207)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	48 (65.8%)	32 (44.4%)
Number of censored participants, n (%)	25 (34.2%)	40 (55.6%)
Proportionality Test p-value[a][b]	0.0171	
Hazard ratio(interaction)	0.429 (0.214, 0.860)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	29 (39.7%)	25 (34.7%)
Number of censored participants, n (%)	44 (60.3%)	47 (65.3%)
Proportionality Test p-value[a][b]	0.9929	
Hazard ratio(interaction)	1.003 (0.485, 2.076)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	42 (57.5%)	27 (37.5%)
Number of censored participants, n (%)	31 (42.5%)	45 (62.5%)
Proportionality Test p-value[a][b]	0.8925	
Hazard ratio(interaction)	1.048 (0.532, 2.066)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	41 (56.2%)	20 (27.8%)
Number of censored participants, n (%)	32 (43.8%)	52 (72.2%)
Proportionality Test p-value[a][b]	0.6161	
Hazard ratio(interaction)	0.818 (0.373, 1.793)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	49 (67.1%)	36 (50.0%)
Number of censored participants, n (%)	24 (32.9%)	36 (50.0%)
Proportionality Test p-value[a][b]	0.8621	
Hazard ratio(interaction)	0.940 (0.467, 1.891)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	24 (32.9%)	17 (23.6%)
Number of censored participants, n (%)	49 (67.1%)	55 (76.4%)
Proportionality Test p-value[a][b]	0.6848	
Hazard ratio(interaction)	0.847 (0.380, 1.887)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Pain (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	46 (63.0%)	28 (38.9%)
Number of censored participants, n (%)	27 (37.0%)	44 (61.1%)
Proportionality Test p-value[a][b]	0.0047	
Hazard ratio(interaction)	0.331 (0.154, 0.712)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	34 (46.6%)	23 (31.9%)
Number of censored participants, n (%)	39 (53.4%)	49 (68.1%)
Proportionality Test p-value[a][b]	0.0762	
Hazard ratio(interaction)	0.519 (0.251, 1.072)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	33 (45.2%)	22 (30.6%)
Number of censored participants, n (%)	40 (54.8%)	50 (69.4%)
Proportionality Test p-value[a][b]	0.4949	
Hazard ratio(interaction)	1.313 (0.601, 2.871)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	29 (39.7%)	16 (22.2%)
Number of censored participants, n (%)	44 (60.3%)	56 (77.8%)
Proportionality Test p-value[a][b]	0.0319	
Hazard ratio(interaction)	0.350 (0.134, 0.913)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	34 (46.6%)	27 (37.5%)
Number of censored participants, n (%)	39 (53.4%)	45 (62.5%)
Proportionality Test p-value[a][b]	0.6237	
Hazard ratio(interaction)	1.178 (0.613, 2.262)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	24 (32.9%)	15 (20.8%)
Number of censored participants, n (%)	49 (67.1%)	57 (79.2%)
Proportionality Test p-value[a][b]	0.9114	
Hazard ratio(interaction)	1.043 (0.501, 2.171)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Age group 2: >=75
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	18 (24.7%)	8 (11.1%)
Number of censored participants, n (%)	55 (75.3%)	64 (88.9%)
Proportionality Test p-value[a][b]	0.6347	
Hazard ratio(interaction)	1.298 (0.443, 3.803)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	88 (50.6%)	71 (40.8%)
Number of censored participants, n (%)	86 (49.4%)	103 (59.2%)
Proportionality Test p-value[a][b]	0.0352	
Hazard ratio(interaction)	0.629 (0.408, 0.968)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	76 (43.7%)	61 (35.1%)
Number of censored participants, n (%)	98 (56.3%)	113 (64.9%)
Proportionality Test p-value[a][b]	0.1598	
Hazard ratio(interaction)	0.720 (0.455, 1.139)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	99 (56.9%)	76 (43.7%)
Number of censored participants, n (%)	75 (43.1%)	98 (56.3%)
Proportionality Test p-value[a][b]	0.0106	
Hazard ratio(interaction)	0.572 (0.373, 0.878)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	73 (42.0%)	66 (37.9%)
Number of censored participants, n (%)	101 (58.0%)	108 (62.1%)
Proportionality Test p-value[a][b]	0.7129	
Hazard ratio(interaction)	1.087 (0.696, 1.698)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	92 (52.9%)	80 (46.0%)
Number of censored participants, n (%)	82 (47.1%)	94 (54.0%)
Proportionality Test p-value[a][b]	0.5041	
Hazard ratio(interaction)	0.871 (0.582, 1.305)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	88 (50.6%)	72 (41.4%)
Number of censored participants, n (%)	86 (49.4%)	102 (58.6%)
Proportionality Test p-value[a][b]	0.0046	
Hazard ratio(interaction)	0.538 (0.351, 0.826)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	116 (66.7%)	90 (51.7%)
Number of censored participants, n (%)	58 (33.3%)	84 (48.3%)
Proportionality Test p-value[a][b]	0.4302	
Hazard ratio(interaction)	0.842 (0.550, 1.290)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	54 (31.0%)	40 (23.0%)
Number of censored participants, n (%)	120 (69.0%)	134 (77.0%)
Proportionality Test p-value[a][b]	0.1105	
Hazard ratio(interaction)	0.670 (0.410, 1.096)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Pain (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	103 (59.2%)	78 (44.8%)
Number of censored participants, n (%)	71 (40.8%)	96 (55.2%)
Proportionality Test p-value[a][b]	0.0634	
Hazard ratio(interaction)	0.691 (0.467, 1.021)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	74 (42.5%)	55 (31.6%)
Number of censored participants, n (%)	100 (57.5%)	119 (68.4%)
Proportionality Test p-value[a][b]	0.1444	
Hazard ratio(interaction)	0.725 (0.470, 1.117)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	74 (42.5%)	66 (37.9%)
Number of censored participants, n (%)	100 (57.5%)	108 (62.1%)
Proportionality Test p-value[a][b]	0.9829	
Hazard ratio(interaction)	1.005 (0.637, 1.587)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	60 (34.5%)	36 (20.7%)
Number of censored participants, n (%)	114 (65.5%)	138 (79.3%)
Proportionality Test p-value[a][b]	0.0542	
Hazard ratio(interaction)	0.581 (0.334, 1.010)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	62 (35.6%)	55 (31.6%)
Number of censored participants, n (%)	112 (64.4%)	119 (68.4%)
Proportionality Test p-value[a][b]	0.9905	
Hazard ratio(interaction)	1.003 (0.652, 1.541)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	49 (28.2%)	42 (24.1%)
Number of censored participants, n (%)	125 (71.8%)	132 (75.9%)
Proportionality Test p-value[a][b]	0.4646	
Hazard ratio(interaction)	0.816 (0.473, 1.408)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Male
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	45 (25.9%)	29 (16.7%)
Number of censored participants, n (%)	129 (74.1%)	145 (83.3%)
Proportionality Test p-value[a][b]	0.1547	
Hazard ratio(interaction)	0.645 (0.353, 1.180)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	17 (48.6%)	16 (50.0%)
Number of censored participants, n (%)	18 (51.4%)	16 (50.0%)
Proportionality Test p-value[a][b]	0.9807	
Hazard ratio(interaction)	0.986 (0.322, 3.023)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	13 (37.1%)	11 (34.4%)
Number of censored participants, n (%)	22 (62.9%)	21 (65.6%)
Proportionality Test p-value[a][b]	0.8854	
Hazard ratio(interaction)	1.081 (0.375, 3.115)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	19 (54.3%)	13 (40.6%)
Number of censored participants, n (%)	16 (45.7%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.1327	
Hazard ratio(interaction)	2.487 (0.758, 8.158)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	14 (40.0%)	14 (43.8%)
Number of censored participants, n (%)	21 (60.0%)	18 (56.3%)
Proportionality Test p-value[a][b]	0.4917	
Hazard ratio(interaction)	0.706 (0.262, 1.904)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	15 (42.9%)	14 (43.8%)
Number of censored participants, n (%)	20 (57.1%)	18 (56.3%)
Proportionality Test p-value[a][b]	0.1494	
Hazard ratio(interaction)	2.073 (0.769, 5.587)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	17 (48.6%)	12 (37.5%)
Number of censored participants, n (%)	18 (51.4%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.2496	
Hazard ratio(interaction)	2.028 (0.609, 6.757)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	20 (57.1%)	21 (65.6%)
Number of censored participants, n (%)	15 (42.9%)	11 (34.4%)
Proportionality Test p-value[a][b]	0.3081	
Hazard ratio(interaction)	1.855 (0.565, 6.088)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	7 (20.0%)	13 (40.6%)
Number of censored participants, n (%)	28 (80.0%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.1921	
Hazard ratio(interaction)	2.993 (0.576, 15.548)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Pain (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	18 (51.4%)	19 (59.4%)
Number of censored participants, n (%)	17 (48.6%)	13 (40.6%)
Proportionality Test p-value[a][b]	0.1807	
Hazard ratio(interaction)	0.469 (0.155, 1.421)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	12 (34.3%)	11 (34.4%)
Number of censored participants, n (%)	23 (65.7%)	21 (65.6%)
Proportionality Test p-value[a][b]	0.7290	
Hazard ratio(interaction)	0.831 (0.291, 2.372)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	17 (48.6%)	13 (40.6%)
Number of censored participants, n (%)	18 (51.4%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.3253	
Hazard ratio(interaction)	1.950 (0.516, 7.374)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	10 (28.6%)	11 (34.4%)
Number of censored participants, n (%)	25 (71.4%)	21 (65.6%)
Proportionality Test p-value[a][b]	0.8797	
Hazard ratio(interaction)	1.106 (0.299, 4.096)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	9 (25.7%)	13 (40.6%)
Number of censored participants, n (%)	26 (74.3%)	19 (59.4%)
Proportionality Test p-value[a][b]	0.9647	
Hazard ratio(interaction)	1.028 (0.308, 3.428)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	11 (31.4%)	10 (31.3%)
Number of censored participants, n (%)	24 (68.6%)	22 (68.8%)
Proportionality Test p-value[a][b]	0.3535	
Hazard ratio(interaction)	0.501 (0.116, 2.158)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Gender group: Female
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	9 (25.7%)	6 (18.8%)
Number of censored participants, n (%)	26 (74.3%)	26 (81.3%)
Proportionality Test p-value[a][b]	0.6418	
Hazard ratio(interaction)	1.301 (0.429, 3.949)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	11 (29.7%)	11 (35.5%)
Number of censored participants, n (%)	26 (70.3%)	20 (64.5%)
Proportionality Test p-value[a][b]	0.9638	
Hazard ratio(interaction)	0.976 (0.339, 2.807)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	10 (27.0%)	6 (19.4%)
Number of censored participants, n (%)	27 (73.0%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.2683	
Hazard ratio(interaction)	0.370 (0.064, 2.152)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	15 (40.5%)	11 (35.5%)
Number of censored participants, n (%)	22 (59.5%)	20 (64.5%)
Proportionality Test p-value[a][b]	0.3218	
Hazard ratio(interaction)	0.571 (0.189, 1.729)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	13 (35.1%)	10 (32.3%)
Number of censored participants, n (%)	24 (64.9%)	21 (67.7%)
Proportionality Test p-value[a][b]	0.6689	
Hazard ratio(interaction)	0.700 (0.136, 3.591)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	19 (51.4%)	10 (32.3%)
Number of censored participants, n (%)	18 (48.6%)	21 (67.7%)
Proportionality Test p-value[a][b]	0.0932	
Hazard ratio(interaction)	0.323 (0.087, 1.208)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	16 (43.2%)	12 (38.7%)
Number of censored participants, n (%)	21 (56.8%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.0386	
Hazard ratio(interaction)	0.104 (0.012, 0.888)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	20 (54.1%)	12 (38.7%)
Number of censored participants, n (%)	17 (45.9%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.5322	
Hazard ratio(interaction)	0.702 (0.231, 2.130)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	7 (18.9%)	4 (12.9%)
Number of censored participants, n (%)	30 (81.1%)	27 (87.1%)
Proportionality Test p-value[a][b]	0.2570	
Hazard ratio(interaction)	0.102 (0.002, 5.273)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Pain (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	15 (40.5%)	9 (29.0%)
Number of censored participants, n (%)	22 (59.5%)	22 (71.0%)
Proportionality Test p-value[a][b]	0.0500	
Hazard ratio(interaction)	0.244 (0.060, 1.000)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	11 (29.7%)	8 (25.8%)
Number of censored participants, n (%)	26 (70.3%)	23 (74.2%)
Proportionality Test p-value[a][b]	0.0952	
Hazard ratio(interaction)	0.297 (0.071, 1.236)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	14 (37.8%)	9 (29.0%)
Number of censored participants, n (%)	23 (62.2%)	22 (71.0%)
Proportionality Test p-value[a][b]	0.9167	
Hazard ratio(interaction)	1.066 (0.322, 3.528)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	9 (24.3%)	4 (12.9%)
Number of censored participants, n (%)	28 (75.7%)	27 (87.1%)
Proportionality Test p-value[a][b]	0.1327	
Hazard ratio(interaction)	0.078 (0.003, 2.169)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	13 (35.1%)	6 (19.4%)
Number of censored participants, n (%)	24 (64.9%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.7176	
Hazard ratio(interaction)	0.809 (0.256, 2.556)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	11 (29.7%)	4 (12.9%)
Number of censored participants, n (%)	26 (70.3%)	27 (87.1%)
Proportionality Test p-value[a][b]	0.3815	
Hazard ratio(interaction)	0.314 (0.023, 4.209)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	4 (10.8%)	6 (19.4%)
Number of censored participants, n (%)	33 (89.2%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.8036	
Hazard ratio(interaction)	1.275 (0.188, 8.662)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	48 (53.3%)	37 (41.1%)
Number of censored participants, n (%)	42 (46.7%)	53 (58.9%)
Proportionality Test p-value[a][b]	0.0291	
Hazard ratio(interaction)	0.532 (0.302, 0.938)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	41 (45.6%)	34 (37.8%)
Number of censored participants, n (%)	49 (54.4%)	56 (62.2%)
Proportionality Test p-value[a][b]	0.5685	
Hazard ratio(interaction)	0.842 (0.466, 1.522)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	58 (64.4%)	39 (43.3%)
Number of censored participants, n (%)	32 (35.6%)	51 (56.7%)
Proportionality Test p-value[a][b]	0.2538	
Hazard ratio(interaction)	0.698 (0.377, 1.294)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	39 (43.3%)	40 (44.4%)
Number of censored participants, n (%)	51 (56.7%)	50 (55.6%)
Proportionality Test p-value[a][b]	0.5743	
Hazard ratio(interaction)	1.178 (0.665, 2.085)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	51 (56.7%)	47 (52.2%)
Number of censored participants, n (%)	39 (43.3%)	43 (47.8%)
Proportionality Test p-value[a][b]	0.2168	
Hazard ratio(interaction)	1.418 (0.815, 2.466)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	53 (58.9%)	40 (44.4%)
Number of censored participants, n (%)	37 (41.1%)	50 (55.6%)
Proportionality Test p-value[a][b]	0.0306	
Hazard ratio(interaction)	0.517 (0.284, 0.940)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	64 (71.1%)	54 (60.0%)
Number of censored participants, n (%)	26 (28.9%)	36 (40.0%)
Proportionality Test p-value[a][b]	0.7478	
Hazard ratio(interaction)	1.093 (0.637, 1.875)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	29 (32.2%)	29 (32.2%)
Number of censored participants, n (%)	61 (67.8%)	61 (67.8%)
Proportionality Test p-value[a][b]	0.3690	
Hazard ratio(interaction)	0.745 (0.393, 1.415)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Pain (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	60 (66.7%)	50 (55.6%)
Number of censored participants, n (%)	30 (33.3%)	40 (44.4%)
Proportionality Test p-value[a][b]	0.4254	
Hazard ratio(interaction)	0.824 (0.512, 1.326)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	40 (44.4%)	28 (31.1%)
Number of censored participants, n (%)	50 (55.6%)	62 (68.9%)
Proportionality Test p-value[a][b]	0.7108	
Hazard ratio(interaction)	0.893 (0.491, 1.624)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	35 (38.9%)	39 (43.3%)
Number of censored participants, n (%)	55 (61.1%)	51 (56.7%)
Proportionality Test p-value[a][b]	0.4353	
Hazard ratio(interaction)	1.291 (0.679, 2.453)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	31 (34.4%)	24 (26.7%)
Number of censored participants, n (%)	59 (65.6%)	66 (73.3%)
Proportionality Test p-value[a][b]	0.5254	
Hazard ratio(interaction)	0.792 (0.385, 1.628)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	35 (38.9%)	34 (37.8%)
Number of censored participants, n (%)	55 (61.1%)	56 (62.2%)
Proportionality Test p-value[a][b]	0.6696	
Hazard ratio(interaction)	0.879 (0.487, 1.589)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	26 (28.9%)	30 (33.3%)
Number of censored participants, n (%)	64 (71.1%)	60 (66.7%)
Proportionality Test p-value[a][b]	0.0732	
Hazard ratio(interaction)	0.500 (0.234, 1.067)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	26 (28.9%)	15 (16.7%)
Number of censored participants, n (%)	64 (71.1%)	75 (83.3%)
Proportionality Test p-value[a][b]	0.2545	
Hazard ratio(interaction)	0.651 (0.311, 1.362)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	46 (56.1%)	39 (45.9%)
Number of censored participants, n (%)	36 (43.9%)	46 (54.1%)
Proportionality Test p-value[a][b]	0.8359	
Hazard ratio(interaction)	0.938 (0.512, 1.718)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	38 (46.3%)	32 (37.6%)
Number of censored participants, n (%)	44 (53.7%)	53 (62.4%)
Proportionality Test p-value[a][b]	0.2879	
Hazard ratio(interaction)	0.711 (0.380, 1.333)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	45 (54.9%)	39 (45.9%)
Number of censored participants, n (%)	37 (45.1%)	46 (54.1%)
Proportionality Test p-value[a][b]	0.2217	
Hazard ratio(interaction)	0.711 (0.412, 1.229)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	35 (42.7%)	30 (35.3%)
Number of censored participants, n (%)	47 (57.3%)	55 (64.7%)
Proportionality Test p-value[a][b]	0.7489	
Hazard ratio(interaction)	1.107 (0.595, 2.059)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	37 (45.1%)	37 (43.5%)
Number of censored participants, n (%)	45 (54.9%)	48 (56.5%)
Proportionality Test p-value[a][b]	0.5148	
Hazard ratio(interaction)	0.825 (0.462, 1.472)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	36 (43.9%)	32 (37.6%)
Number of censored participants, n (%)	46 (56.1%)	53 (62.4%)
Proportionality Test p-value[a][b]	0.6186	
Hazard ratio(interaction)	1.165 (0.639, 2.123)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	52 (63.4%)	45 (52.9%)
Number of censored participants, n (%)	30 (36.6%)	40 (47.1%)
Proportionality Test p-value[a][b]	0.7478	
Hazard ratio(interaction)	0.903 (0.484, 1.685)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	25 (30.5%)	20 (23.5%)
Number of censored participants, n (%)	57 (69.5%)	65 (76.5%)
Proportionality Test p-value[a][b]	0.6684	
Hazard ratio(interaction)	0.872 (0.465, 1.633)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Pain (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	46 (56.1%)	38 (44.7%)
Number of censored participants, n (%)	36 (43.9%)	47 (55.3%)
Proportionality Test p-value[a][b]	0.1828	
Hazard ratio(interaction)	0.676 (0.381, 1.202)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	35 (42.7%)	30 (35.3%)
Number of censored participants, n (%)	47 (57.3%)	55 (64.7%)
Proportionality Test p-value[a][b]	0.3219	
Hazard ratio(interaction)	0.751 (0.426, 1.324)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	42 (51.2%)	31 (36.5%)
Number of censored participants, n (%)	40 (48.8%)	54 (63.5%)
Proportionality Test p-value[a][b]	0.9178	
Hazard ratio(interaction)	0.966 (0.497, 1.875)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	30 (36.6%)	19 (22.4%)
Number of censored participants, n (%)	52 (63.4%)	66 (77.6%)
Proportionality Test p-value[a][b]	0.1571	
Hazard ratio(interaction)	0.607 (0.304, 1.212)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	23 (28.0%)	28 (32.9%)
Number of censored participants, n (%)	59 (72.0%)	57 (67.1%)
Proportionality Test p-value[a][b]	0.5444	
Hazard ratio(interaction)	1.215 (0.647, 2.282)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	23 (28.0%)	18 (21.2%)
Number of censored participants, n (%)	59 (72.0%)	67 (78.8%)
Proportionality Test p-value[a][b]	0.3732	
Hazard ratio(interaction)	1.379 (0.680, 2.800)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	24 (29.3%)	14 (16.5%)
Number of censored participants, n (%)	58 (70.7%)	71 (83.5%)
Proportionality Test p-value[a][b]	0.4267	
Hazard ratio(interaction)	0.722 (0.323, 1.612)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	99 (52.4%)	78 (41.3%)
Number of censored participants, n (%)	90 (47.6%)	111 (58.7%)
Proportionality Test p-value[a][b]	0.0724	
Hazard ratio(interaction)	0.698 (0.471, 1.033)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	82 (43.4%)	63 (33.3%)
Number of censored participants, n (%)	107 (56.6%)	126 (66.7%)
Proportionality Test p-value[a][b]	0.3405	
Hazard ratio(interaction)	0.810 (0.524, 1.250)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	108 (57.1%)	80 (42.3%)
Number of censored participants, n (%)	81 (42.9%)	109 (57.7%)
Proportionality Test p-value[a][b]	0.1473	
Hazard ratio(interaction)	0.742 (0.495, 1.111)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	84 (44.4%)	73 (38.6%)
Number of censored participants, n (%)	105 (55.6%)	116 (61.4%)
Proportionality Test p-value[a][b]	0.8058	
Hazard ratio(interaction)	1.054 (0.695, 1.597)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	99 (52.4%)	85 (45.0%)
Number of censored participants, n (%)	90 (47.6%)	104 (55.0%)
Proportionality Test p-value[a][b]	0.7422	
Hazard ratio(interaction)	0.937 (0.636, 1.380)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	98 (51.9%)	76 (40.2%)
Number of censored participants, n (%)	91 (48.1%)	113 (59.8%)
Proportionality Test p-value[a][b]	0.0055	
Hazard ratio(interaction)	0.564 (0.377, 0.845)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	126 (66.7%)	99 (52.4%)
Number of censored participants, n (%)	63 (33.3%)	90 (47.6%)
Proportionality Test p-value[a][b]	0.6055	
Hazard ratio(interaction)	0.899 (0.599, 1.348)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	58 (30.7%)	50 (26.5%)
Number of censored participants, n (%)	131 (69.3%)	139 (73.5%)
Proportionality Test p-value[a][b]	0.2156	
Hazard ratio(interaction)	0.748 (0.473, 1.184)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Pain (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	111 (58.7%)	88 (46.6%)
Number of censored participants, n (%)	78 (41.3%)	101 (53.4%)
Proportionality Test p-value[a][b]	0.0622	
Hazard ratio(interaction)	0.710 (0.495, 1.018)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	79 (41.8%)	61 (32.3%)
Number of censored participants, n (%)	110 (58.2%)	128 (67.7%)
Proportionality Test p-value[a][b]	0.1333	
Hazard ratio(interaction)	0.740 (0.500, 1.096)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	83 (43.9%)	71 (37.6%)
Number of censored participants, n (%)	106 (56.1%)	118 (62.4%)
Proportionality Test p-value[a][b]	0.9848	
Hazard ratio(interaction)	1.004 (0.644, 1.565)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	66 (34.9%)	41 (21.7%)
Number of censored participants, n (%)	123 (65.1%)	148 (78.3%)
Proportionality Test p-value[a][b]	0.0282	
Hazard ratio(interaction)	0.556 (0.329, 0.939)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	67 (35.4%)	62 (32.8%)
Number of censored participants, n (%)	122 (64.6%)	127 (67.2%)
Proportionality Test p-value[a][b]	0.6583	
Hazard ratio(interaction)	0.910 (0.599, 1.382)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	57 (30.2%)	47 (24.9%)
Number of censored participants, n (%)	132 (69.8%)	142 (75.1%)
Proportionality Test p-value[a][b]	0.3147	
Hazard ratio(interaction)	0.778 (0.477, 1.269)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: White
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	52 (27.5%)	33 (17.5%)
Number of censored participants, n (%)	137 (72.5%)	156 (82.5%)
Proportionality Test p-value[a][b]	0.1377	
Hazard ratio(interaction)	0.675 (0.401, 1.134)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	6 (30.0%)	9 (52.9%)
Number of censored participants, n (%)	14 (70.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.8182	
Hazard ratio(interaction)	0.741 (0.057, 9.574)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	7 (35.0%)	9 (52.9%)
Number of censored participants, n (%)	13 (65.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.1078	
Hazard ratio(interaction)	0.256 (0.048, 1.348)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	10 (50.0%)	9 (52.9%)
Number of censored participants, n (%)	10 (50.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.1340	
Hazard ratio(interaction)	0.326 (0.075, 1.412)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	7 (41.2%)
Number of censored participants, n (%)	17 (85.0%)	10 (58.8%)
Proportionality Test p-value[a][b]	0.4756	
Hazard ratio(interaction)	188.44 (0.000, 3.36E8)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	8 (40.0%)	9 (52.9%)
Number of censored participants, n (%)	12 (60.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.8014	
Hazard ratio(interaction)	1.254 (0.215, 7.326)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	7 (35.0%)	8 (47.1%)
Number of censored participants, n (%)	13 (65.0%)	9 (52.9%)
Proportionality Test p-value[a][b]	0.6188	
Hazard ratio(interaction)	0.605 (0.083, 4.383)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	10 (50.0%)	12 (70.6%)
Number of censored participants, n (%)	10 (50.0%)	5 (29.4%)
Proportionality Test p-value[a][b]	0.2553	
Hazard ratio(interaction)	4.010 (0.366, 43.883)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	3 (17.6%)
Number of censored participants, n (%)	17 (85.0%)	14 (82.4%)
Proportionality Test p-value[a][b]	0.2420	
Hazard ratio(interaction)	0.181 (0.010, 3.173)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Pain (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	10 (50.0%)	9 (52.9%)
Number of censored participants, n (%)	10 (50.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.1033	
Hazard ratio(interaction)	0.138 (0.013, 1.495)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	7 (35.0%)	5 (29.4%)
Number of censored participants, n (%)	13 (65.0%)	12 (70.6%)
Proportionality Test p-value[a][b]	0.9947	
Hazard ratio(interaction)	0.000 (0.000, NE)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	8 (40.0%)	8 (47.1%)
Number of censored participants, n (%)	12 (60.0%)	9 (52.9%)
Proportionality Test p-value[a][b]	0.2141	
Hazard ratio(interaction)	4.988 (0.395, 62.941)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	4 (20.0%)	6 (35.3%)
Number of censored participants, n (%)	16 (80.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	0.3876	
Hazard ratio(interaction)	0.396 (0.048, 3.241)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	4 (20.0%)	6 (35.3%)
Number of censored participants, n (%)	16 (80.0%)	11 (64.7%)
Proportionality Test p-value[a][b]	0.2407	
Hazard ratio(interaction)	8.151 (0.245, 271.35)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	3 (15.0%)	5 (29.4%)
Number of censored participants, n (%)	17 (85.0%)	12 (70.6%)
Proportionality Test p-value[a][b]	0.9378	
Hazard ratio(interaction)	1.105 (0.089, 13.735)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Race: Non-white
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	2 (10.0%)	2 (11.8%)
Number of censored participants, n (%)	18 (90.0%)	15 (88.2%)
Proportionality Test p-value[a][b]	0.5286	
Hazard ratio(interaction)	0.368 (0.016, 8.263)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	84 (50.6%)	72 (40.7%)
Number of censored participants, n (%)	82 (49.4%)	105 (59.3%)
Proportionality Test p-value[a][b]	0.1586	
Hazard ratio(interaction)	0.744 (0.493, 1.123)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	69 (41.6%)	56 (31.6%)
Number of censored participants, n (%)	97 (58.4%)	121 (68.4%)
Proportionality Test p-value[a][b]	0.1908	
Hazard ratio(interaction)	0.734 (0.463, 1.166)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	89 (53.6%)	73 (41.2%)
Number of censored participants, n (%)	77 (46.4%)	104 (58.8%)
Proportionality Test p-value[a][b]	0.1621	
Hazard ratio(interaction)	0.745 (0.493, 1.126)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	66 (39.8%)	69 (39.0%)
Number of censored participants, n (%)	100 (60.2%)	108 (61.0%)
Proportionality Test p-value[a][b]	0.8221	
Hazard ratio(interaction)	1.052 (0.674, 1.642)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	88 (53.0%)	78 (44.1%)
Number of censored participants, n (%)	78 (47.0%)	99 (55.9%)
Proportionality Test p-value[a][b]	0.9627	
Hazard ratio(interaction)	0.991 (0.668, 1.470)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	85 (51.2%)	71 (40.1%)
Number of censored participants, n (%)	81 (48.8%)	106 (59.9%)
Proportionality Test p-value[a][b]	0.0085	
Hazard ratio(interaction)	0.555 (0.358, 0.861)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	109 (65.7%)	90 (50.8%)
Number of censored participants, n (%)	57 (34.3%)	87 (49.2%)
Proportionality Test p-value[a][b]	0.7879	
Hazard ratio(interaction)	0.945 (0.628, 1.423)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	51 (30.7%)	47 (26.6%)
Number of censored participants, n (%)	115 (69.3%)	130 (73.4%)
Proportionality Test p-value[a][b]	0.1277	
Hazard ratio(interaction)	0.687 (0.424, 1.114)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Pain (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	98 (59.0%)	79 (44.6%)
Number of censored participants, n (%)	68 (41.0%)	98 (55.4%)
Proportionality Test p-value[a][b]	0.0863	
Hazard ratio(interaction)	0.721 (0.496, 1.048)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	70 (42.2%)	52 (29.4%)
Number of censored participants, n (%)	96 (57.8%)	125 (70.6%)
Proportionality Test p-value[a][b]	0.0624	
Hazard ratio(interaction)	0.656 (0.421, 1.022)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	67 (40.4%)	64 (36.2%)
Number of censored participants, n (%)	99 (59.6%)	113 (63.8%)
Proportionality Test p-value[a][b]	0.3465	
Hazard ratio(interaction)	1.258 (0.780, 2.031)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	54 (32.5%)	37 (20.9%)
Number of censored participants, n (%)	112 (67.5%)	140 (79.1%)
Proportionality Test p-value[a][b]	0.0040	
Hazard ratio(interaction)	0.430 (0.242, 0.764)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	60 (36.1%)	59 (33.3%)
Number of censored participants, n (%)	106 (63.9%)	118 (66.7%)
Proportionality Test p-value[a][b]	0.7833	
Hazard ratio(interaction)	1.060 (0.700, 1.605)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	48 (28.9%)	40 (22.6%)
Number of censored participants, n (%)	118 (71.1%)	137 (77.4%)
Proportionality Test p-value[a][b]	0.1640	
Hazard ratio(interaction)	0.680 (0.395, 1.170)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	45 (27.1%)	26 (14.7%)
Number of censored participants, n (%)	121 (72.9%)	151 (85.3%)
Proportionality Test p-value[a][b]	0.1858	
Hazard ratio(interaction)	0.666 (0.365, 1.216)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	21 (48.8%)	15 (51.7%)
Number of censored participants, n (%)	22 (51.2%)	14 (48.3%)
Proportionality Test p-value[a][b]	0.3364	
Hazard ratio(interaction)	0.603 (0.215, 1.691)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	20 (46.5%)	16 (55.2%)
Number of censored participants, n (%)	23 (53.5%)	13 (44.8%)
Proportionality Test p-value[a][b]	0.7412	
Hazard ratio(interaction)	0.852 (0.331, 2.198)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	29 (67.4%)	16 (55.2%)
Number of censored participants, n (%)	14 (32.6%)	13 (44.8%)
Proportionality Test p-value[a][b]	0.1304	
Hazard ratio(interaction)	0.423 (0.139, 1.290)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	21 (48.8%)	11 (37.9%)
Number of censored participants, n (%)	22 (51.2%)	18 (62.1%)
Proportionality Test p-value[a][b]	0.4959	
Hazard ratio(interaction)	1.446 (0.500, 4.182)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	19 (44.2%)	16 (55.2%)
Number of censored participants, n (%)	24 (55.8%)	13 (44.8%)
Proportionality Test p-value[a][b]	0.7543	
Hazard ratio(interaction)	1.179 (0.421, 3.299)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	20 (46.5%)	13 (44.8%)
Number of censored participants, n (%)	23 (53.5%)	16 (55.2%)
Proportionality Test p-value[a][b]	0.8426	
Hazard ratio(interaction)	1.092 (0.459, 2.600)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	27 (62.8%)	21 (72.4%)
Number of censored participants, n (%)	16 (37.2%)	8 (27.6%)
Proportionality Test p-value[a][b]	0.7331	
Hazard ratio(interaction)	1.218 (0.392, 3.790)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	10 (23.3%)	6 (20.7%)
Number of censored participants, n (%)	33 (76.7%)	23 (79.3%)
Proportionality Test p-value[a][b]	0.7584	
Hazard ratio(interaction)	1.189 (0.395, 3.581)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Pain (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	23 (53.5%)	18 (62.1%)
Number of censored participants, n (%)	20 (46.5%)	11 (37.9%)
Proportionality Test p-value[a][b]	0.3453	
Hazard ratio(interaction)	0.616 (0.225, 1.685)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	16 (37.2%)	14 (48.3%)
Number of censored participants, n (%)	27 (62.8%)	15 (51.7%)
Proportionality Test p-value[a][b]	0.8881	
Hazard ratio(interaction)	1.060 (0.468, 2.401)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	24 (55.8%)	15 (51.7%)
Number of censored participants, n (%)	19 (44.2%)	14 (48.3%)
Proportionality Test p-value[a][b]	0.3168	
Hazard ratio(interaction)	0.596 (0.216, 1.643)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	16 (37.2%)	10 (34.5%)
Number of censored participants, n (%)	27 (62.8%)	19 (65.5%)
Proportionality Test p-value[a][b]	0.2074	
Hazard ratio(interaction)	1.940 (0.693, 5.433)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	11 (25.6%)	9 (31.0%)
Number of censored participants, n (%)	32 (74.4%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.3455	
Hazard ratio(interaction)	0.515 (0.130, 2.043)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	12 (27.9%)	12 (41.4%)
Number of censored participants, n (%)	31 (72.1%)	17 (58.6%)
Proportionality Test p-value[a][b]	0.2279	
Hazard ratio(interaction)	2.033 (0.642, 6.442)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	9 (20.9%)	9 (31.0%)
Number of censored participants, n (%)	34 (79.1%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.5015	
Hazard ratio(interaction)	0.724 (0.282, 1.857)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	61 (45.9%)	60 (45.8%)
Number of censored participants, n (%)	72 (54.1%)	71 (54.2%)
Proportionality Test p-value[a][b]	0.0472	
Hazard ratio(interaction)	0.611 (0.376, 0.994)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	45 (33.8%)	42 (32.1%)
Number of censored participants, n (%)	88 (66.2%)	89 (67.9%)
Proportionality Test p-value[a][b]	0.2445	
Hazard ratio(interaction)	0.690 (0.370, 1.289)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	72 (54.1%)	61 (46.6%)
Number of censored participants, n (%)	61 (45.9%)	70 (53.4%)
Proportionality Test p-value[a][b]	0.0505	
Hazard ratio(interaction)	0.626 (0.391, 1.001)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	51 (38.3%)	49 (37.4%)
Number of censored participants, n (%)	82 (61.7%)	82 (62.6%)
Proportionality Test p-value[a][b]	0.3978	
Hazard ratio(interaction)	0.779 (0.437, 1.389)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	63 (47.4%)	60 (45.8%)
Number of censored participants, n (%)	70 (52.6%)	71 (54.2%)
Proportionality Test p-value[a][b]	0.3245	
Hazard ratio(interaction)	0.799 (0.511, 1.249)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	60 (45.1%)	51 (38.9%)
Number of censored participants, n (%)	73 (54.9%)	80 (61.1%)
Proportionality Test p-value[a][b]	0.0115	
Hazard ratio(interaction)	0.522 (0.315, 0.864)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	83 (62.4%)	77 (58.8%)
Number of censored participants, n (%)	50 (37.6%)	54 (41.2%)
Proportionality Test p-value[a][b]	0.4929	
Hazard ratio(interaction)	1.201 (0.711, 2.031)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	40 (30.1%)	32 (24.4%)
Number of censored participants, n (%)	93 (69.9%)	99 (75.6%)
Proportionality Test p-value[a][b]	0.1405	
Hazard ratio(interaction)	0.647 (0.363, 1.154)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Pain (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	75 (56.4%)	65 (49.6%)
Number of censored participants, n (%)	58 (43.6%)	66 (50.4%)
Proportionality Test p-value[a][b]	0.0382	
Hazard ratio(interaction)	0.599 (0.369, 0.973)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	50 (37.6%)	44 (33.6%)
Number of censored participants, n (%)	83 (62.4%)	87 (66.4%)
Proportionality Test p-value[a][b]	0.9601	
Hazard ratio(interaction)	0.986 (0.572, 1.700)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	60 (45.1%)	51 (38.9%)
Number of censored participants, n (%)	73 (54.9%)	80 (61.1%)
Proportionality Test p-value[a][b]	0.3146	
Hazard ratio(interaction)	0.758 (0.442, 1.300)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	46 (34.6%)	27 (20.6%)
Number of censored participants, n (%)	87 (65.4%)	104 (79.4%)
Proportionality Test p-value[a][b]	0.0886	
Hazard ratio(interaction)	0.587 (0.318, 1.084)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	43 (32.3%)	44 (33.6%)
Number of censored participants, n (%)	90 (67.7%)	87 (66.4%)
Proportionality Test p-value[a][b]	0.2411	
Hazard ratio(interaction)	0.718 (0.413, 1.249)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	37 (27.8%)	35 (26.7%)
Number of censored participants, n (%)	96 (72.2%)	96 (73.3%)
Proportionality Test p-value[a][b]	0.4245	
Hazard ratio(interaction)	0.786 (0.435, 1.419)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 0
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	25 (18.8%)	22 (16.8%)
Number of censored participants, n (%)	108 (81.2%)	109 (83.2%)
Proportionality Test p-value[a][b]	0.6127	
Hazard ratio(interaction)	0.838 (0.422, 1.664)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	44 (57.9%)	27 (36.0%)
Number of censored participants, n (%)	32 (42.1%)	48 (64.0%)
Proportionality Test p-value[a][b]	0.5869	
Hazard ratio(interaction)	0.831 (0.426, 1.621)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	44 (57.9%)	30 (40.0%)
Number of censored participants, n (%)	32 (42.1%)	45 (60.0%)
Proportionality Test p-value[a][b]	0.9629	
Hazard ratio(interaction)	1.014 (0.561, 1.832)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	46 (60.5%)	28 (37.3%)
Number of censored participants, n (%)	30 (39.5%)	47 (62.7%)
Proportionality Test p-value[a][b]	0.6946	
Hazard ratio(interaction)	0.865 (0.418, 1.788)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	36 (47.4%)	31 (41.3%)
Number of censored participants, n (%)	40 (52.6%)	44 (58.7%)
Proportionality Test p-value[a][b]	0.1741	
Hazard ratio(interaction)	1.546 (0.825, 2.896)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	44 (57.9%)	34 (45.3%)
Number of censored participants, n (%)	32 (42.1%)	41 (54.7%)
Proportionality Test p-value[a][b]	0.1418	
Hazard ratio(interaction)	1.674 (0.842, 3.329)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	45 (59.2%)	33 (44.0%)
Number of censored participants, n (%)	31 (40.8%)	42 (56.0%)
Proportionality Test p-value[a][b]	0.8507	
Hazard ratio(interaction)	0.939 (0.489, 1.806)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	53 (69.7%)	34 (45.3%)
Number of censored participants, n (%)	23 (30.3%)	41 (54.7%)
Proportionality Test p-value[a][b]	0.5703	
Hazard ratio(interaction)	0.835 (0.448, 1.556)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	21 (27.6%)	21 (28.0%)
Number of censored participants, n (%)	55 (72.4%)	54 (72.0%)
Proportionality Test p-value[a][b]	0.6675	
Hazard ratio(interaction)	0.848 (0.401, 1.796)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Pain (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	46 (60.5%)	32 (42.7%)
Number of censored participants, n (%)	30 (39.5%)	43 (57.3%)
Proportionality Test p-value[a][b]	0.6629	
Hazard ratio(interaction)	0.880 (0.496, 1.562)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	36 (47.4%)	22 (29.3%)
Number of censored participants, n (%)	40 (52.6%)	53 (70.7%)
Proportionality Test p-value[a][b]	0.0390	
Hazard ratio(interaction)	0.473 (0.232, 0.963)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	31 (40.8%)	28 (37.3%)
Number of censored participants, n (%)	45 (59.2%)	47 (62.7%)
Proportionality Test p-value[a][b]	0.0259	
Hazard ratio(interaction)	2.532 (1.118, 5.735)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	24 (31.6%)	20 (26.7%)
Number of censored participants, n (%)	52 (68.4%)	55 (73.3%)
Proportionality Test p-value[a][b]	0.6499	
Hazard ratio(interaction)	0.828 (0.366, 1.871)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	28 (36.8%)	24 (32.0%)
Number of censored participants, n (%)	48 (63.2%)	51 (68.0%)
Proportionality Test p-value[a][b]	0.2481	
Hazard ratio(interaction)	1.432 (0.779, 2.632)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	23 (30.3%)	17 (22.7%)
Number of censored participants, n (%)	53 (69.7%)	58 (77.3%)
Proportionality Test p-value[a][b]	0.5855	
Hazard ratio(interaction)	0.770 (0.302, 1.967)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

ECOG status: 1
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	29 (38.2%)	13 (17.3%)
Number of censored participants, n (%)	47 (61.8%)	62 (82.7%)
Proportionality Test p-value[a][b]	0.0692	
Hazard ratio(interaction)	0.413 (0.159, 1.072)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	61 (48.8%)	49 (41.9%)
Number of censored participants, n (%)	64 (51.2%)	68 (58.1%)
Proportionality Test p-value[a][b]	0.3249	
Hazard ratio(interaction)	0.760 (0.441, 1.312)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	49 (39.2%)	40 (34.2%)
Number of censored participants, n (%)	76 (60.8%)	77 (65.8%)
Proportionality Test p-value[a][b]	0.1987	
Hazard ratio(interaction)	0.703 (0.411, 1.203)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	74 (59.2%)	45 (38.5%)
Number of censored participants, n (%)	51 (40.8%)	72 (61.5%)
Proportionality Test p-value[a][b]	0.0355	
Hazard ratio(interaction)	0.566 (0.333, 0.962)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	50 (40.0%)	42 (35.9%)
Number of censored participants, n (%)	75 (60.0%)	75 (64.1%)
Proportionality Test p-value[a][b]	0.8566	
Hazard ratio(interaction)	0.948 (0.533, 1.686)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	66 (52.8%)	53 (45.3%)
Number of censored participants, n (%)	59 (47.2%)	64 (54.7%)
Proportionality Test p-value[a][b]	0.5953	
Hazard ratio(interaction)	0.867 (0.512, 1.467)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	57 (45.6%)	46 (39.3%)
Number of censored participants, n (%)	68 (54.4%)	71 (60.7%)
Proportionality Test p-value[a][b]	0.7149	
Hazard ratio(interaction)	0.889 (0.473, 1.670)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	79 (63.2%)	62 (53.0%)
Number of censored participants, n (%)	46 (36.8%)	55 (47.0%)
Proportionality Test p-value[a][b]	0.7295	
Hazard ratio(interaction)	1.094 (0.657, 1.823)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	34 (27.2%)	27 (23.1%)
Number of censored participants, n (%)	91 (72.8%)	90 (76.9%)
Proportionality Test p-value[a][b]	0.5614	
Hazard ratio(interaction)	0.841 (0.470, 1.507)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Pain (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	71 (56.8%)	55 (47.0%)
Number of censored participants, n (%)	54 (43.2%)	62 (53.0%)
Proportionality Test p-value[a][b]	0.0644	
Hazard ratio(interaction)	0.641 (0.400, 1.027)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	49 (39.2%)	35 (29.9%)
Number of censored participants, n (%)	76 (60.8%)	82 (70.1%)
Proportionality Test p-value[a][b]	0.1000	
Hazard ratio(interaction)	0.638 (0.374, 1.090)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	55 (44.0%)	51 (43.6%)
Number of censored participants, n (%)	70 (56.0%)	66 (56.4%)
Proportionality Test p-value[a][b]	0.5947	
Hazard ratio(interaction)	1.172 (0.654, 2.099)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	40 (32.0%)	27 (23.1%)
Number of censored participants, n (%)	85 (68.0%)	90 (76.9%)
Proportionality Test p-value[a][b]	0.1831	
Hazard ratio(interaction)	0.660 (0.357, 1.217)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	43 (34.4%)	41 (35.0%)
Number of censored participants, n (%)	82 (65.6%)	76 (65.0%)
Proportionality Test p-value[a][b]	0.4354	
Hazard ratio(interaction)	1.224 (0.737, 2.033)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	36 (28.8%)	34 (29.1%)
Number of censored participants, n (%)	89 (71.2%)	83 (70.9%)
Proportionality Test p-value[a][b]	0.8685	
Hazard ratio(interaction)	0.947 (0.500, 1.795)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	30 (24.0%)	19 (16.2%)
Number of censored participants, n (%)	95 (76.0%)	98 (83.8%)
Proportionality Test p-value[a][b]	0.3965	
Hazard ratio(interaction)	0.722 (0.340, 1.533)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Global health status / QoL (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	44 (52.4%)	38 (42.7%)
Number of censored participants, n (%)	40 (47.6%)	51 (57.3%)
Proportionality Test p-value[a][b]	0.0722	
Hazard ratio(interaction)	0.551 (0.288, 1.055)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Physical Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	40 (47.6%)	32 (36.0%)
Number of censored participants, n (%)	44 (52.4%)	57 (64.0%)
Proportionality Test p-value[a][b]	0.2702	
Hazard ratio(interaction)	0.691 (0.359, 1.332)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Role Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	44 (52.4%)	44 (49.4%)
Number of censored participants, n (%)	40 (47.6%)	45 (50.6%)
Proportionality Test p-value[a][b]	0.4173	
Hazard ratio(interaction)	0.775 (0.418, 1.436)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Emotional Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	37 (44.0%)	38 (42.7%)
Number of censored participants, n (%)	47 (56.0%)	51 (57.3%)
Proportionality Test p-value[a][b]	0.7606	
Hazard ratio(interaction)	1.102 (0.590, 2.060)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Cognitive Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	41 (48.8%)	41 (46.1%)
Number of censored participants, n (%)	43 (51.2%)	48 (53.9%)
Proportionality Test p-value[a][b]	0.7031	
Hazard ratio(interaction)	1.117 (0.633, 1.969)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Social Functioning (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	48 (57.1%)	38 (42.7%)
Number of censored participants, n (%)	36 (42.9%)	51 (57.3%)
Proportionality Test p-value[a][b]	0.0330	
Hazard ratio(interaction)	0.525 (0.290, 0.949)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Fatigue (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	57 (67.9%)	49 (55.1%)
Number of censored participants, n (%)	27 (32.1%)	40 (44.9%)
Proportionality Test p-value[a][b]	0.3773	
Hazard ratio(interaction)	0.731 (0.365, 1.466)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Nausea / Vomiting (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	27 (32.1%)	26 (29.2%)
Number of censored participants, n (%)	57 (67.9%)	63 (70.8%)
Proportionality Test p-value[a][b]	0.1447	
Hazard ratio(interaction)	0.565 (0.262, 1.217)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Pain (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	50 (59.5%)	42 (47.2%)
Number of censored participants, n (%)	34 (40.5%)	47 (52.8%)
Proportionality Test p-value[a][b]	0.2081	
Hazard ratio(interaction)	0.690 (0.387, 1.230)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Dyspnoea (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	37 (44.0%)	31 (34.8%)
Number of censored participants, n (%)	47 (56.0%)	58 (65.2%)
Proportionality Test p-value[a][b]	0.2295	
Hazard ratio(interaction)	0.669 (0.347, 1.289)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Insomnia (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	36 (42.9%)	28 (31.5%)
Number of censored participants, n (%)	48 (57.1%)	61 (68.5%)
Proportionality Test p-value[a][b]	0.4646	
Hazard ratio(interaction)	0.771 (0.385, 1.547)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Appetite loss (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	30 (35.7%)	20 (22.5%)
Number of censored participants, n (%)	54 (64.3%)	69 (77.5%)
Proportionality Test p-value[a][b]	0.0526	
Hazard ratio(interaction)	0.455 (0.205, 1.009)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Constipation (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	28 (33.3%)	27 (30.3%)
Number of censored participants, n (%)	56 (66.7%)	62 (69.7%)
Proportionality Test p-value[a][b]	0.4026	
Hazard ratio(interaction)	0.739 (0.364, 1.500)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
Diarhoea (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	24 (28.6%)	18 (20.2%)
Number of censored participants, n (%)	60 (71.4%)	71 (79.8%)
Proportionality Test p-value[a][b]	0.7787	
Hazard ratio(interaction)	0.894 (0.410, 1.949)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.8.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EORTC QLQ-C30 scales (excluding death) by Subgroup
(Full Analysis Set)

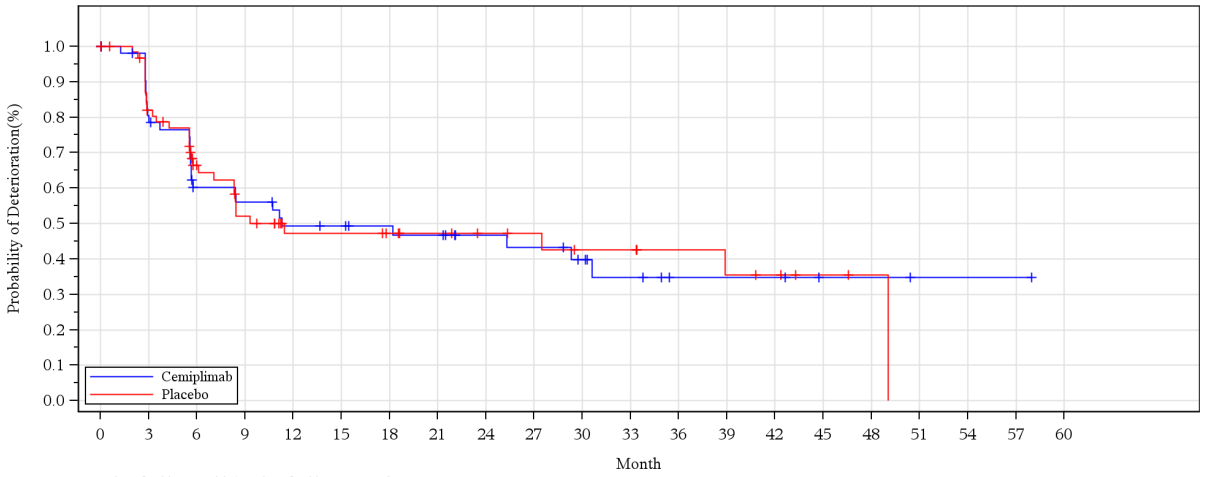
High risk feature: Non-Nodal
Financial Problems (Deterioration threshold = 10)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	24 (28.6%)	16 (18.0%)
Number of censored participants, n (%)	60 (71.4%)	73 (82.0%)
Proportionality Test p-value[a][b]	0.3647	
Hazard ratio(interaction)	0.719 (0.353, 1.466)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (5)	28 (8)	26 (8)	22 (9)	21 (10)	19 (12)	18 (12)	14 (16)	13 (16)	10 (18)	7 (20)	4 (23)	4 (23)	4 (23)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)
Placebo	65 (0)	49 (5)	34 (11)	25 (13)	17 (19)	17 (19)	15 (21)	13 (23)	11 (25)	10 (26)	8 (27)	8 (27)	6 (29)	5 (29)	4 (30)	2 (32)	1 (33)	0 (33)	0 (33)	0 (33)	0 (33)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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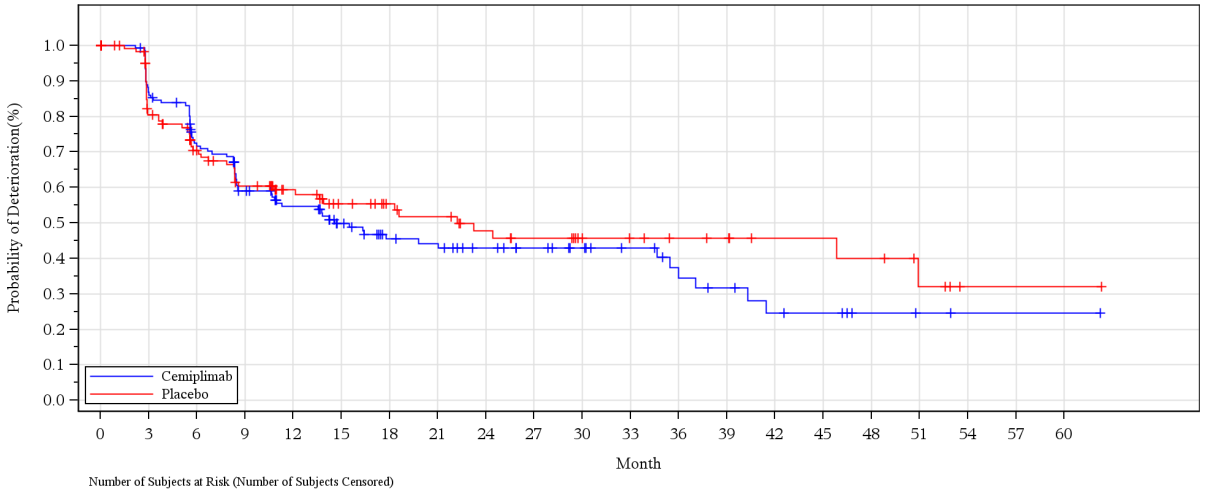
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	118 (17)	93 (22)	72 (27)	61 (33)	48 (41)	37 (48)	35 (49)	29 (54)	25 (58)	21 (62)	17 (66)	12 (68)	10 (69)	7 (70)	6 (71)	3 (74)	2 (75)	1 (76)	1 (76)	1 (76)
Placebo	141 (0)	93 (25)	72 (35)	59 (38)	47 (49)	37 (56)	31 (62)	28 (63)	23 (66)	20 (68)	15 (73)	14 (74)	12 (76)	11 (77)	8 (80)	8 (80)	7 (80)	4 (82)	1 (85)	1 (85)	1 (85)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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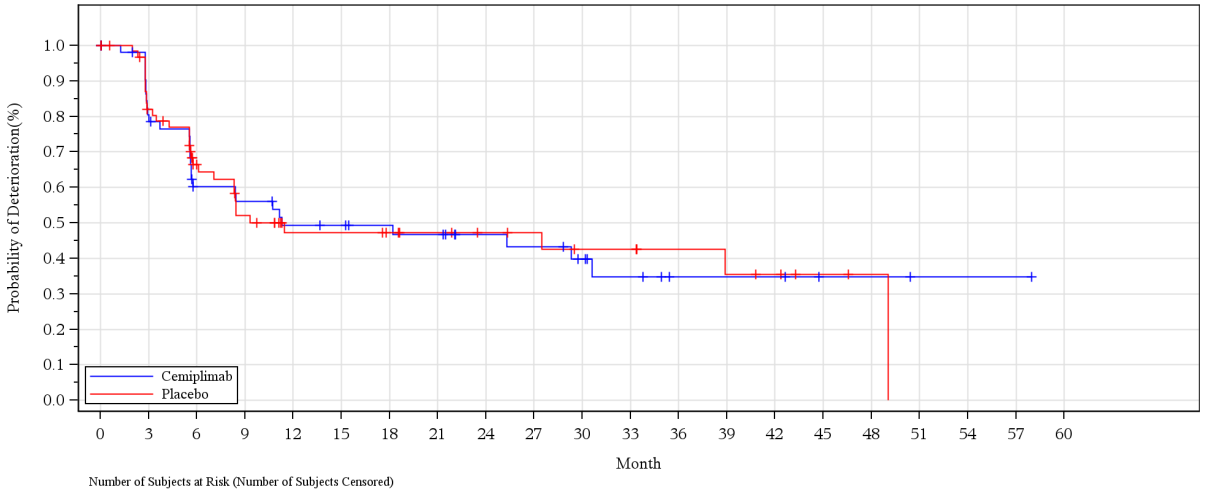
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (5)	28 (8)	26 (8)	22 (9)	21 (10)	19 (12)	18 (12)	14 (16)	13 (16)	10 (18)	7 (20)	4 (23)	4 (23)	4 (23)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)
Placebo	65 (0)	49 (5)	34 (11)	25 (13)	17 (19)	17 (19)	15 (21)	13 (23)	11 (25)	10 (26)	8 (27)	8 (27)	6 (29)	5 (29)	4 (30)	2 (32)	1 (33)	0 (33)	0 (33)	0 (33)	0 (33)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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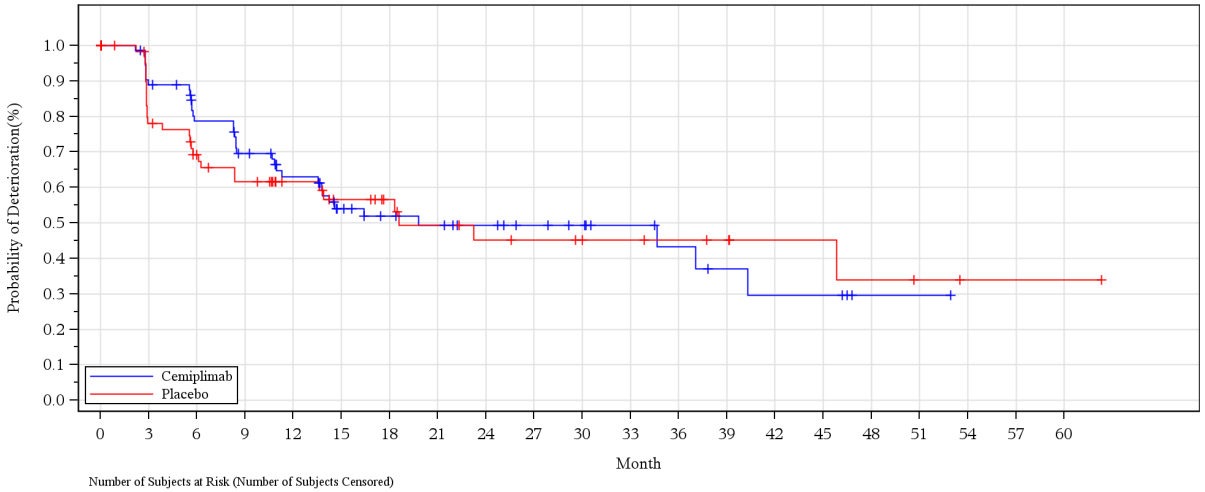
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	64 (8)	53 (12)	45 (14)	37 (18)	27 (23)	22 (27)	20 (28)	17 (31)	14 (34)	12 (36)	9 (39)	7 (40)	5 (41)	4 (41)	4 (41)	1 (44)	1 (44)	0 (45)	0 (45)	0 (45)
Placebo	69 (0)	46 (10)	37 (14)	32 (15)	25 (22)	20 (25)	16 (29)	13 (30)	11 (31)	10 (32)	8 (34)	8 (34)	7 (35)	6 (36)	4 (38)	4 (38)	3 (38)	2 (39)	1 (40)	1 (40)	1 (40)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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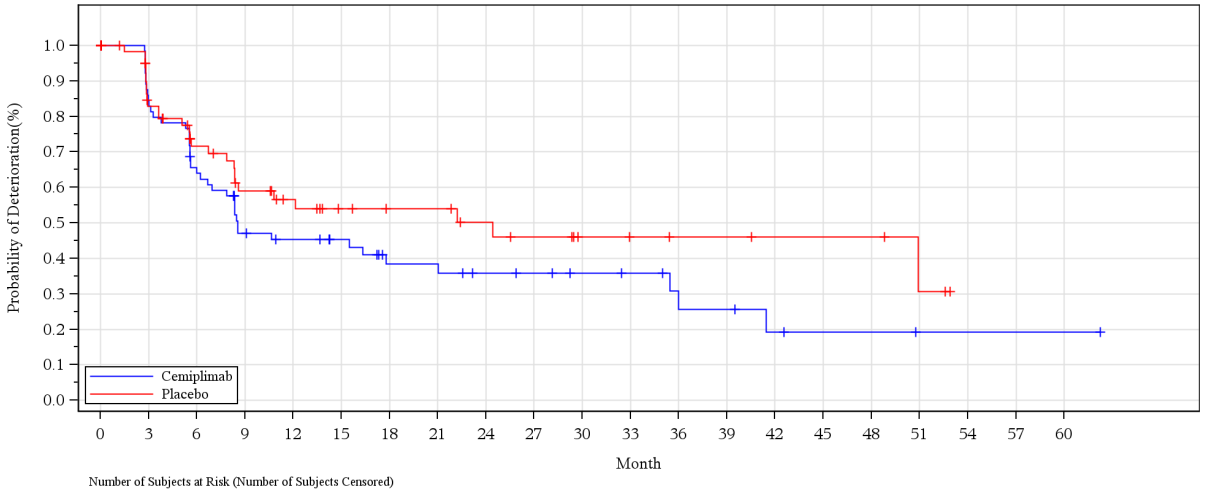
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	54 (9)	40 (10)	27 (13)	24 (15)	21 (18)	15 (21)	15 (21)	12 (23)	11 (24)	9 (26)	8 (27)	5 (28)	5 (28)	3 (29)	2 (30)	2 (30)	1 (31)	1 (31)	1 (31)	1 (31)
Placebo	72 (0)	47 (15)	35 (21)	27 (23)	22 (27)	17 (31)	15 (33)	15 (33)	12 (35)	10 (36)	7 (39)	6 (40)	5 (41)	5 (41)	4 (42)	4 (42)	4 (42)	2 (43)	0 (45)	0 (45)	0 (45)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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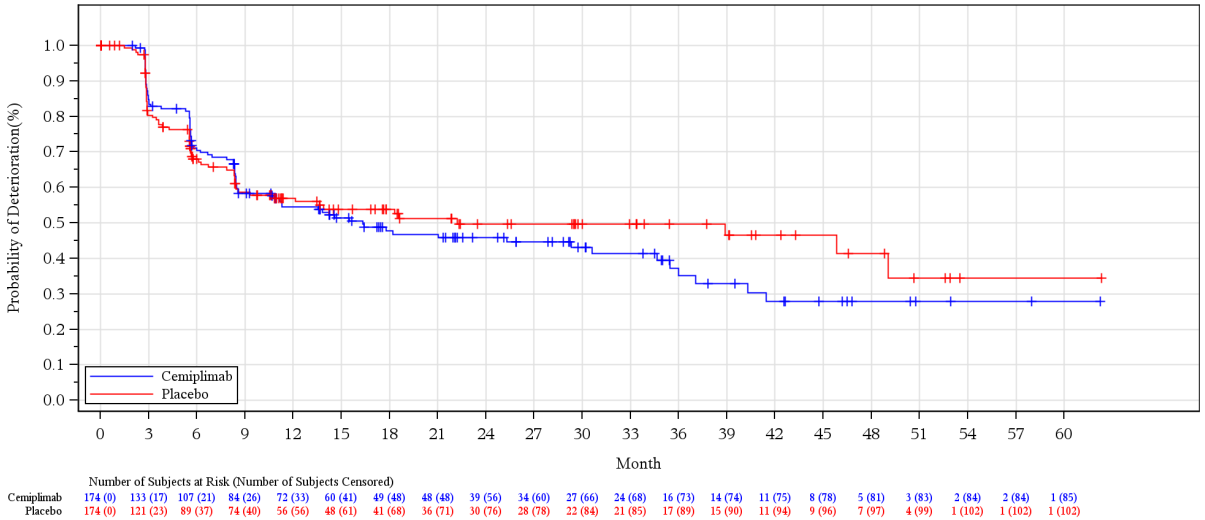
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	133 (17)	107 (21)	84 (26)	72 (33)	60 (41)	49 (48)	48 (48)	39 (56)	34 (60)	27 (66)	24 (68)	16 (73)	14 (74)	11 (75)	8 (78)	5 (81)	3 (83)	2 (84)	2 (84)	1 (85)
Placebo	174 (0)	121 (23)	89 (37)	74 (40)	56 (56)	48 (61)	41 (68)	36 (71)	30 (76)	28 (78)	22 (84)	21 (85)	17 (89)	15 (90)	11 (94)	9 (96)	7 (97)	4 (99)	1 (102)	1 (102)	1 (102)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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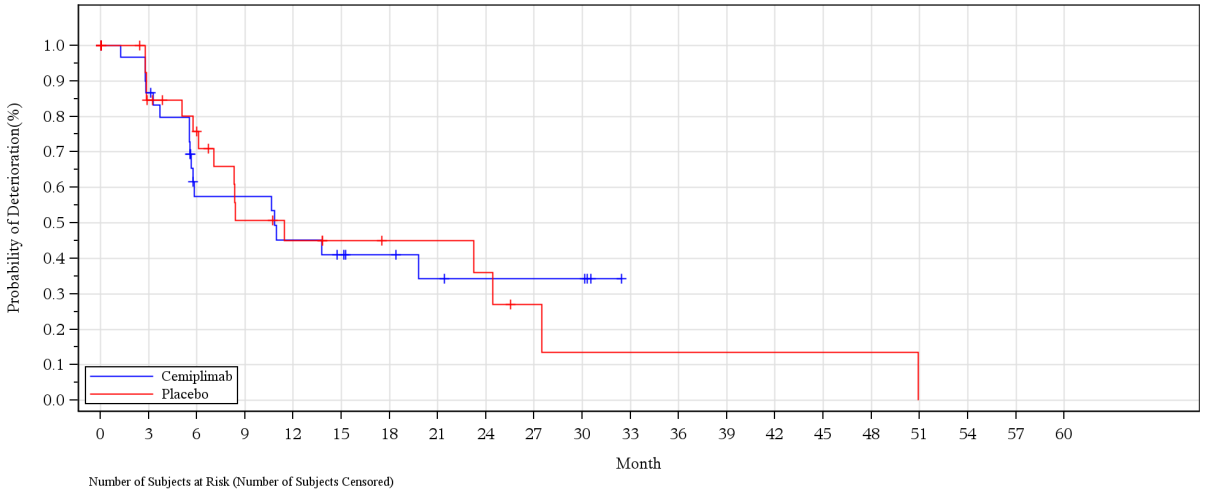
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Gender group: Female



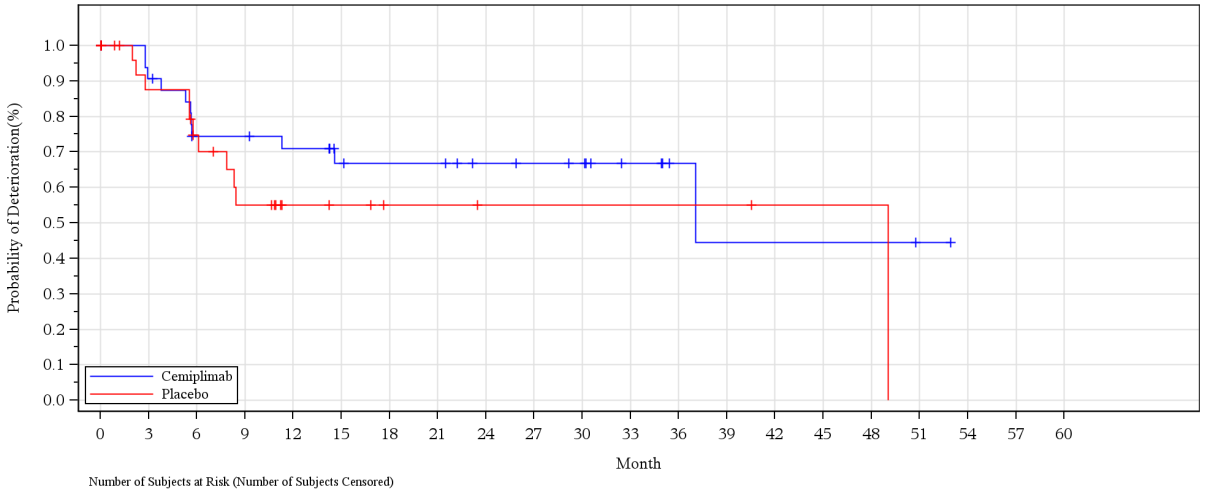
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	26 (5)	14 (9)	14 (9)	11 (9)	9 (10)	7 (12)	5 (13)	4 (14)	4 (14)	4 (14)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	32 (0)	21 (7)	17 (9)	10 (11)	8 (12)	6 (14)	5 (15)	5 (15)	4 (15)	2 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	0 (16)	0 (16)	0 (16)	0 (16)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



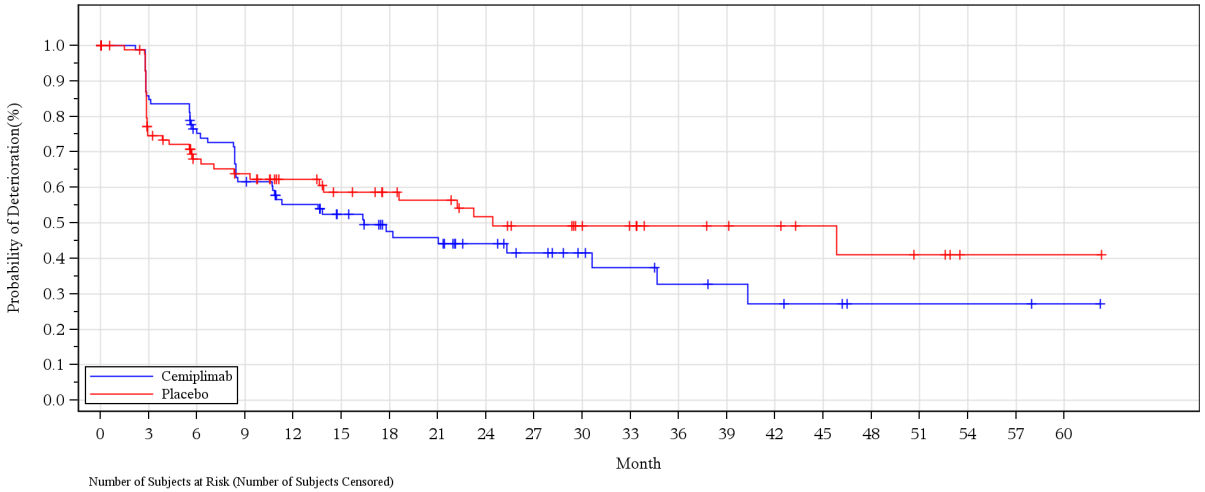
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (5)	22 (7)	22 (7)	20 (8)	16 (11)	15 (12)	15 (12)	12 (15)	11 (16)	10 (17)	6 (21)	3 (24)	2 (24)	2 (24)	2 (24)	2 (24)	1 (25)	0 (26)	0 (26)	0 (26)
Placebo	31 (0)	21 (7)	16 (9)	11 (10)	6 (15)	5 (16)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	1 (20)	1 (20)	0 (20)	0 (20)	0 (20)	0 (20)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



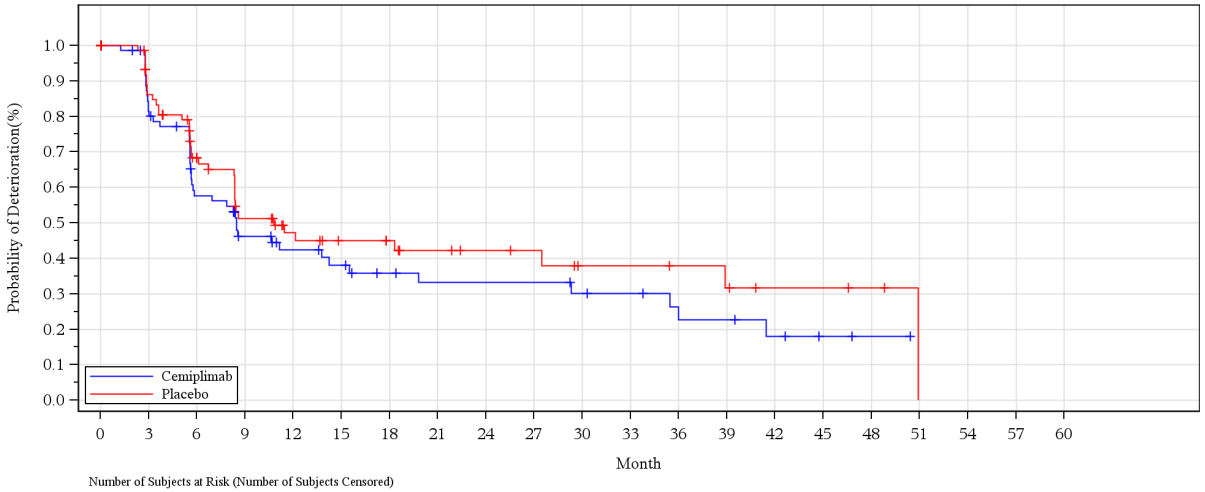
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	73 (5)	61 (8)	50 (8)	42 (11)	35 (16)	27 (21)	26 (21)	19 (27)	15 (30)	11 (34)	9 (35)	7 (36)	6 (37)	5 (37)	4 (38)	2 (40)	2 (40)	2 (40)	2 (40)	1 (41)
Placebo	90 (0)	60 (9)	48 (16)	44 (17)	36 (24)	31 (27)	27 (31)	25 (32)	21 (34)	18 (36)	14 (40)	13 (41)	10 (44)	9 (45)	8 (46)	6 (48)	5 (48)	4 (49)	1 (52)	1 (52)	1 (52)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



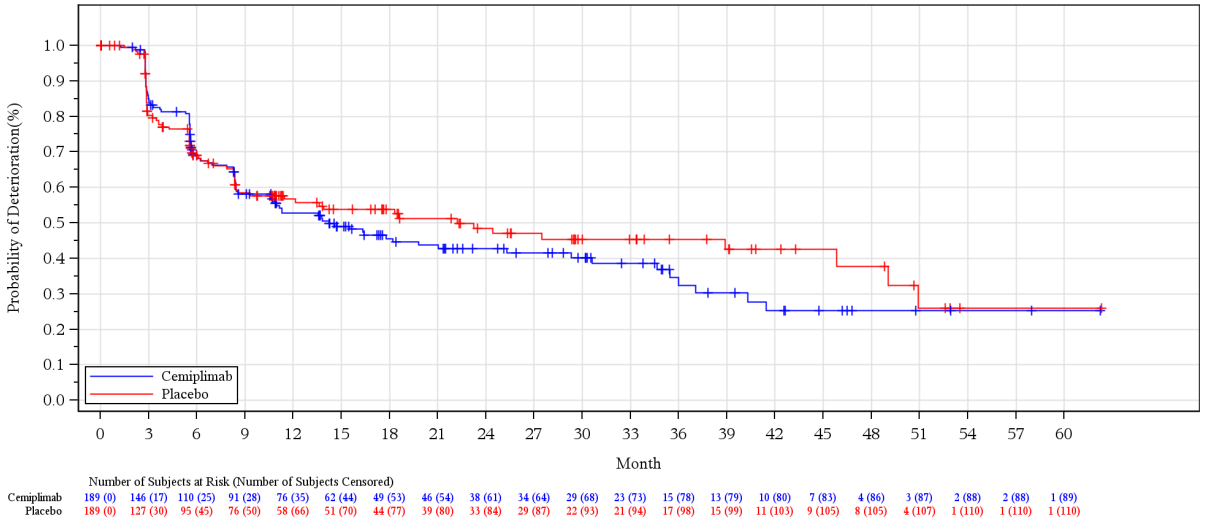
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	57 (12)	38 (15)	26 (20)	21 (23)	18 (24)	14 (27)	12 (28)	12 (28)	12 (28)	10 (29)	9 (30)	6 (31)	6 (31)	4 (32)	2 (34)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)
Placebo	85 (0)	61 (14)	42 (21)	29 (24)	22 (29)	18 (32)	16 (34)	13 (36)	11 (38)	10 (39)	7 (41)	7 (41)	6 (42)	5 (42)	3 (44)	3 (44)	2 (45)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Race: White



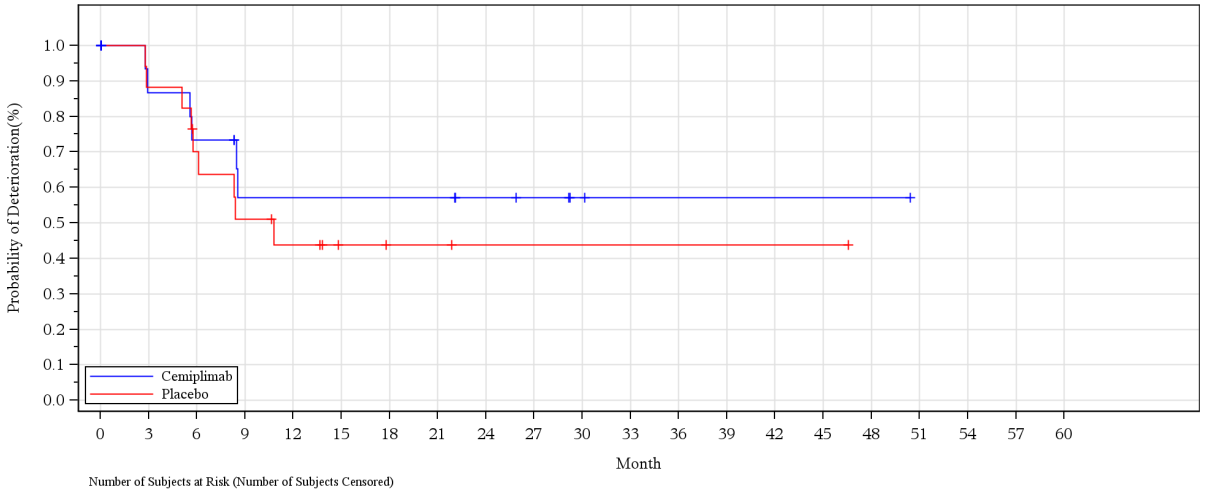
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	146 (17)	110 (25)	91 (28)	76 (35)	62 (44)	49 (53)	46 (54)	38 (61)	34 (64)	29 (68)	23 (73)	15 (78)	13 (79)	10 (80)	7 (83)	4 (86)	3 (87)	2 (88)	2 (88)	1 (89)
Placebo	189 (0)	127 (30)	95 (45)	76 (50)	58 (66)	51 (70)	44 (77)	39 (80)	33 (84)	29 (87)	22 (93)	21 (94)	17 (98)	15 (99)	11 (103)	9 (105)	8 (105)	4 (107)	1 (110)	1 (110)	1 (110)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Race: Non-white



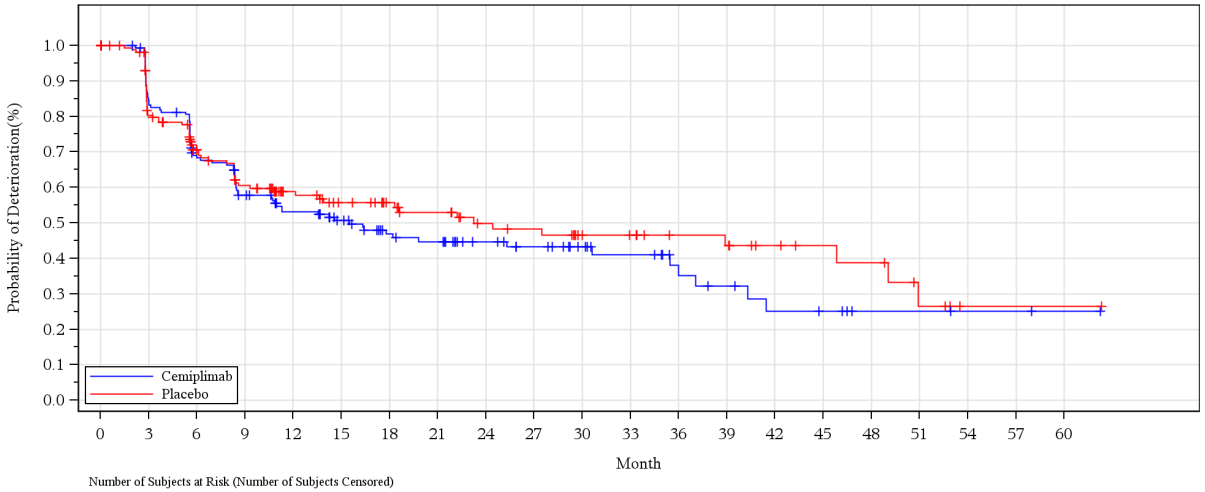
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	13 (5)	11 (5)	7 (7)	7 (7)	7 (7)	7 (7)	7 (7)	5 (9)	4 (10)	2 (12)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)	0 (14)
Placebo	17 (0)	15 (0)	11 (1)	8 (1)	6 (2)	3 (5)	2 (6)	2 (6)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



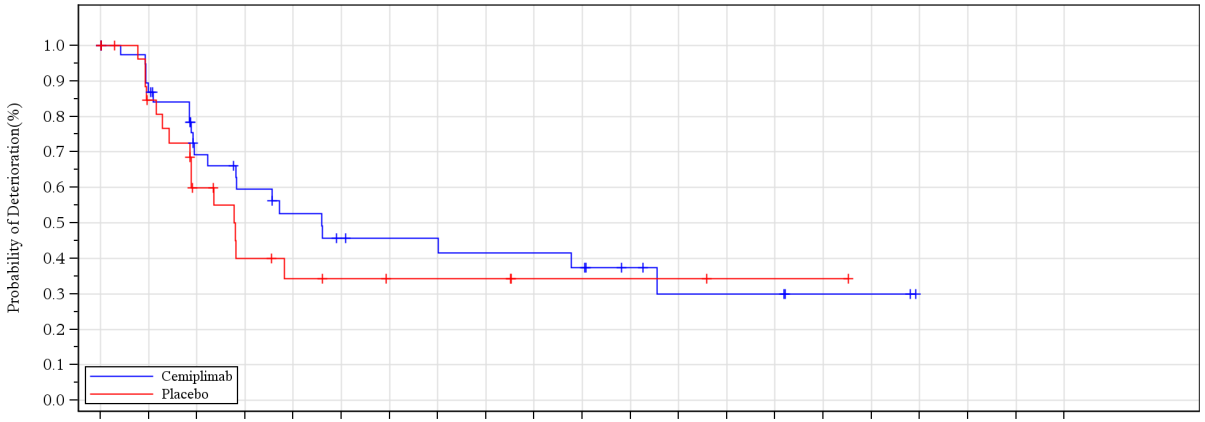
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	126 (17)	99 (20)	80 (24)	68 (30)	57 (38)	45 (46)	42 (47)	33 (56)	28 (60)	22 (66)	18 (69)	12 (73)	10 (74)	7 (75)	6 (76)	3 (79)	3 (79)	2 (80)	2 (80)	1 (81)
Placebo	177 (0)	121 (26)	93 (40)	76 (44)	58 (60)	49 (66)	42 (73)	37 (76)	30 (81)	28 (82)	21 (88)	20 (89)	16 (93)	15 (93)	11 (97)	9 (99)	8 (99)	4 (101)	1 (104)	1 (104)	1 (104)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



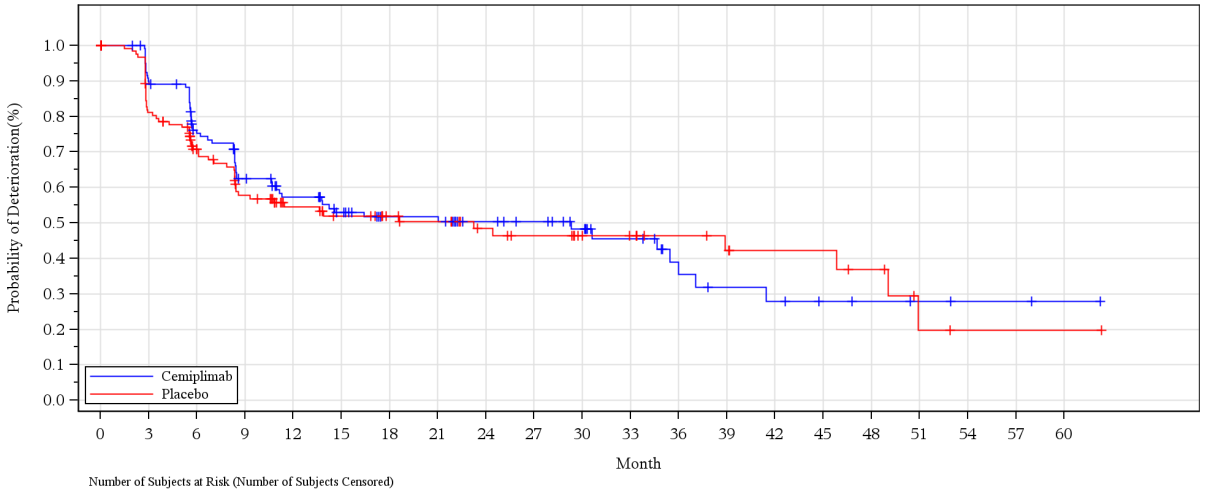
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	33 (5)	22 (10)	18 (11)	15 (12)	12 (13)	11 (14)	11 (14)	10 (14)	10 (14)	9 (14)	6 (17)	4 (18)	4 (18)	4 (18)	2 (20)	2 (20)	0 (22)	0 (22)	0 (22)	0 (22)
Placebo	29 (0)	21 (4)	13 (6)	8 (7)	6 (8)	5 (9)	4 (10)	4 (10)	4 (10)	2 (12)	2 (12)	2 (12)	2 (12)	1 (13)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



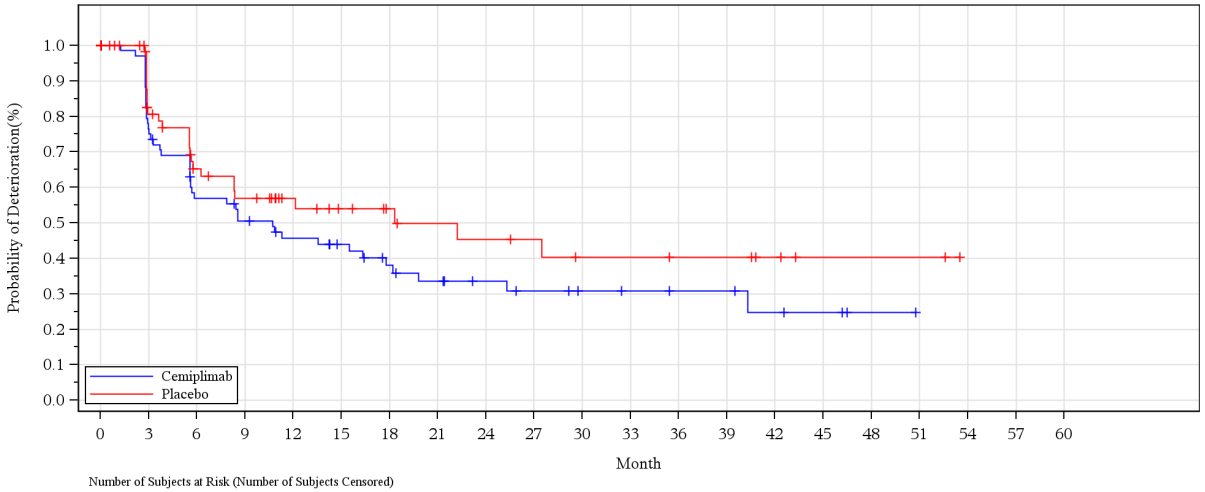
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	107 (14)	84 (20)	66 (24)	56 (29)	46 (35)	38 (42)	38 (42)	31 (48)	28 (51)	23 (55)	17 (60)	10 (64)	8 (65)	7 (65)	5 (67)	4 (68)	3 (69)	2 (70)	2 (70)	1 (71)
Placebo	131 (0)	98 (10)	74 (22)	57 (26)	44 (36)	38 (40)	33 (45)	30 (47)	24 (52)	21 (54)	16 (59)	15 (60)	12 (63)	10 (64)	8 (66)	8 (66)	6 (67)	2 (69)	1 (70)	1 (70)	1 (70)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



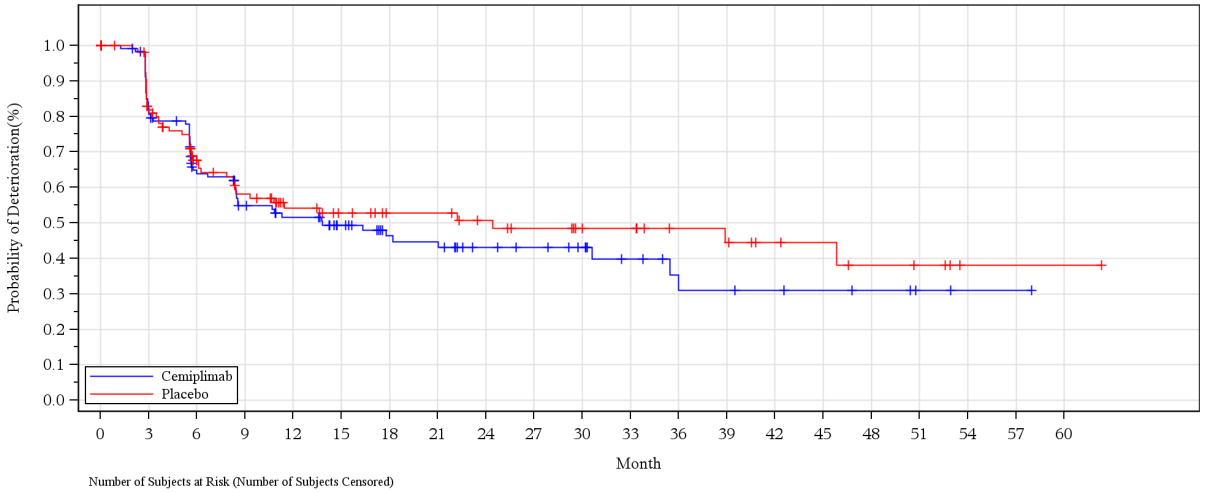
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	52 (8)	37 (10)	32 (11)	27 (13)	23 (16)	18 (18)	15 (19)	12 (22)	10 (23)	8 (25)	7 (26)	6 (27)	6 (27)	4 (28)	3 (29)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	75 (0)	44 (20)	32 (24)	27 (25)	20 (32)	16 (35)	13 (38)	11 (39)	10 (39)	9 (40)	7 (41)	7 (41)	6 (42)	6 (42)	4 (44)	2 (46)	2 (46)	2 (46)	0 (48)	0 (48)	0 (48)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	93 (12)	66 (19)	53 (23)	47 (26)	38 (33)	29 (40)	28 (40)	21 (46)	19 (48)	16 (51)	11 (55)	7 (57)	7 (57)	6 (58)	5 (59)	4 (60)	2 (62)	1 (63)	1 (63)	0 (64)
Placebo	117 (0)	84 (14)	59 (25)	48 (28)	37 (36)	32 (40)	27 (45)	27 (45)	23 (48)	20 (50)	16 (54)	16 (54)	12 (58)	11 (58)	8 (61)	7 (62)	5 (63)	4 (64)	1 (67)	1 (67)	1 (67)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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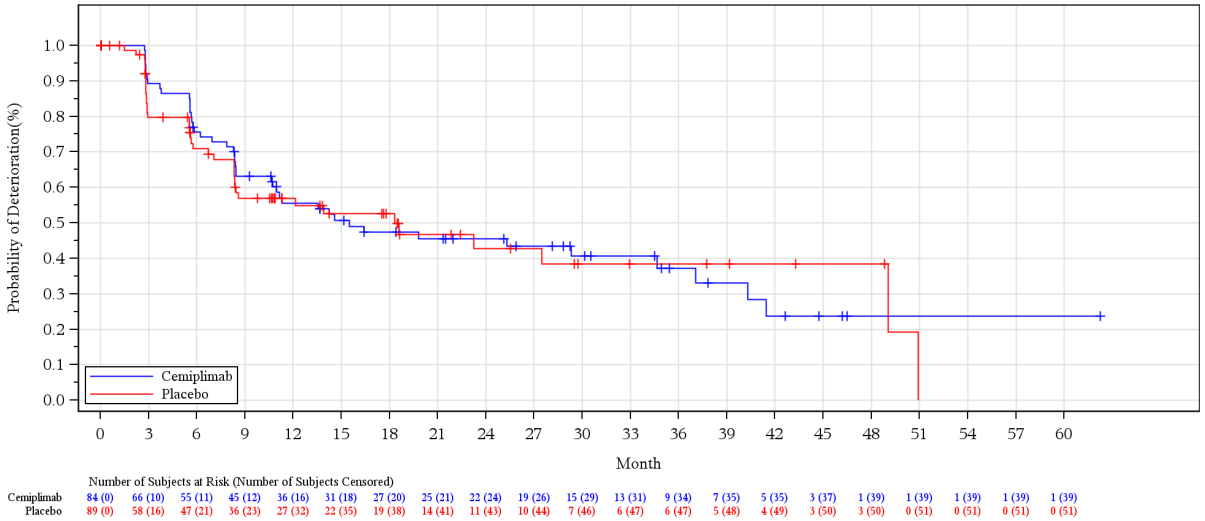
Figure 14.2.8.1.1 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 GHS/QoL Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	66 (10)	55 (11)	45 (12)	36 (16)	31 (18)	27 (20)	25 (21)	22 (24)	19 (26)	15 (29)	13 (31)	9 (34)	7 (35)	5 (35)	3 (37)	1 (39)	1 (39)	1 (39)	1 (39)	1 (39)
Placebo	89 (0)	58 (16)	47 (21)	36 (23)	27 (32)	22 (35)	19 (38)	14 (41)	11 (43)	10 (44)	7 (46)	6 (47)	6 (47)	5 (48)	4 (49)	3 (50)	3 (50)	0 (51)	0 (51)	0 (51)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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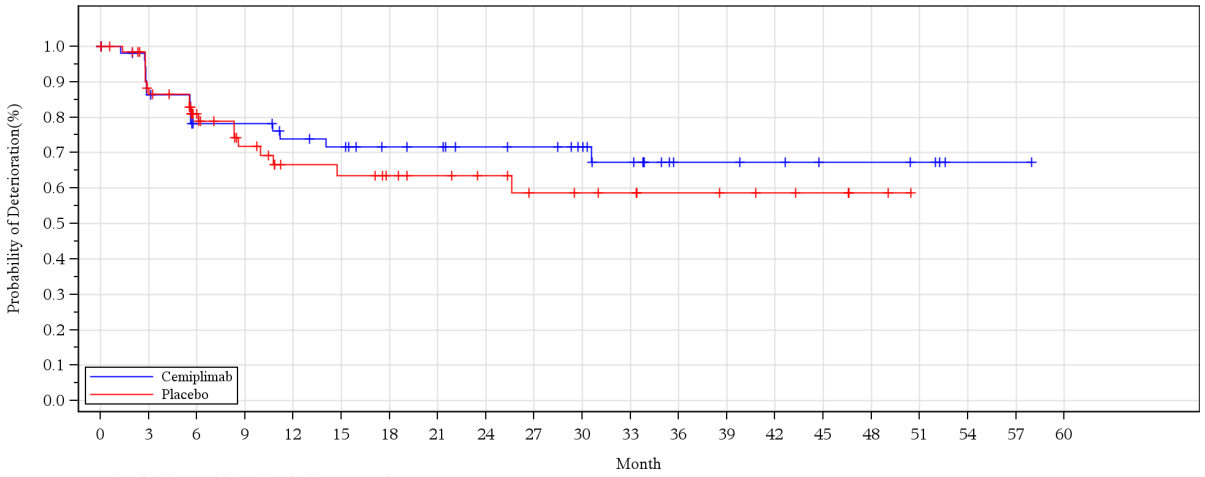
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	44 (5)	37 (8)	37 (8)	33 (10)	31 (11)	27 (15)	26 (16)	23 (19)	22 (20)	19 (23)	15 (26)	8 (33)	8 (33)	7 (34)	5 (36)	5 (36)	4 (37)	1 (40)	1 (40)	0 (41)
Placebo	65 (0)	51 (7)	39 (15)	29 (21)	22 (26)	21 (26)	18 (29)	16 (31)	14 (33)	11 (35)	10 (36)	9 (37)	7 (39)	6 (40)	5 (41)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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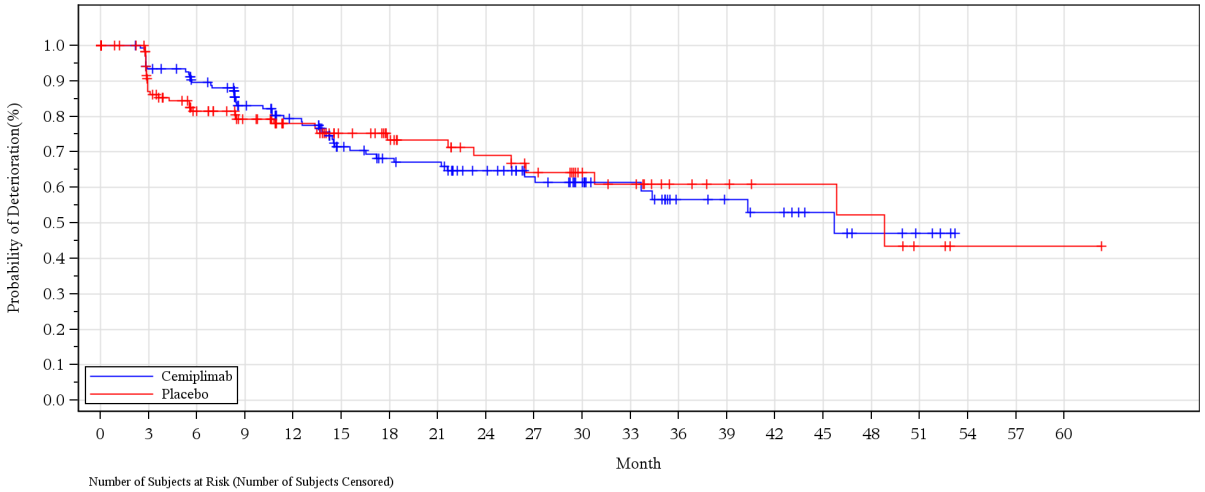
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	126 (18)	115 (24)	96 (35)	85 (42)	67 (52)	59 (57)	57 (58)	47 (66)	38 (74)	30 (81)	26 (85)	17 (92)	15 (94)	13 (95)	9 (99)	6 (101)	4 (103)	0 (107)	0 (107)	0 (107)
Placebo	141 (0)	99 (27)	81 (39)	69 (49)	57 (60)	47 (68)	39 (75)	35 (79)	30 (82)	26 (84)	19 (91)	17 (92)	11 (98)	9 (100)	7 (102)	7 (102)	6 (102)	3 (104)	1 (106)	1 (106)	1 (106)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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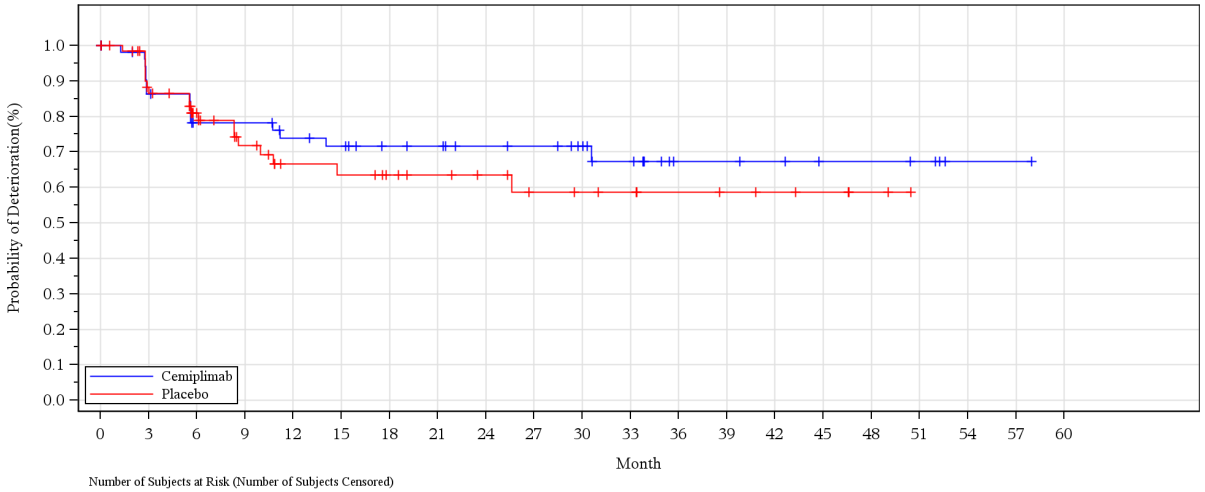
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



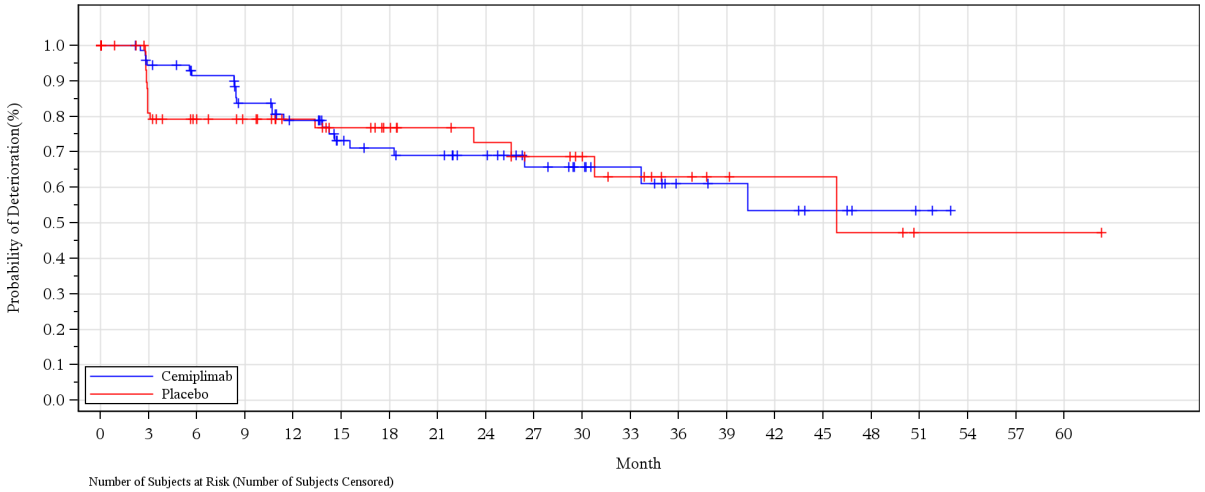
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	44 (5)	37 (8)	37 (8)	33 (10)	31 (11)	27 (15)	26 (16)	23 (19)	22 (20)	19 (23)	15 (26)	8 (33)	8 (33)	7 (34)	5 (36)	5 (36)	4 (37)	1 (40)	1 (40)	0 (41)
Placebo	65 (0)	51 (7)	39 (15)	29 (21)	22 (26)	21 (26)	18 (29)	16 (31)	14 (33)	11 (35)	10 (36)	9 (37)	7 (39)	6 (40)	5 (41)	4 (42)	2 (44)	0 (46)	0 (46)	0 (46)	0 (46)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



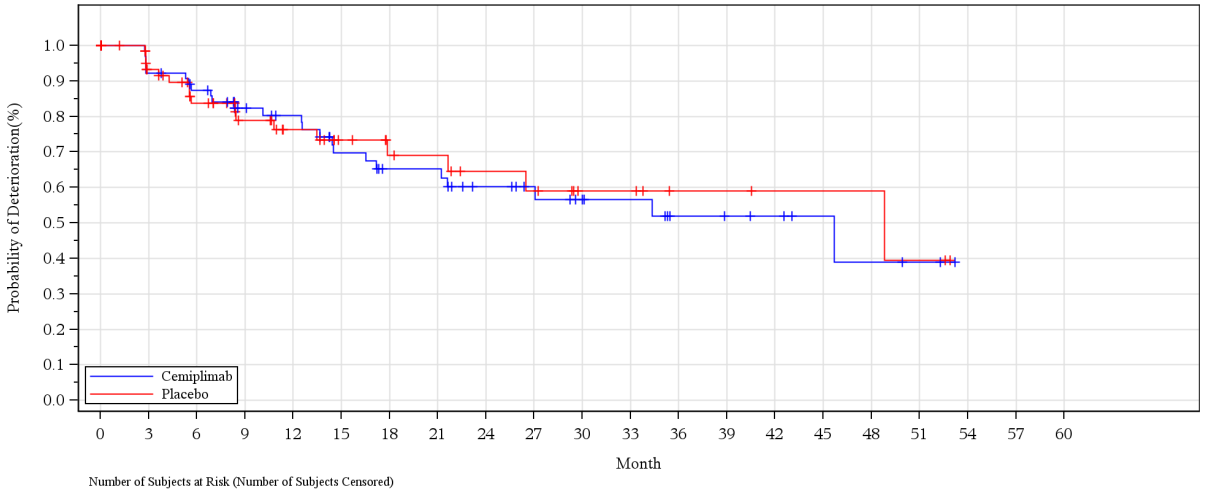
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	67 (9)	61 (13)	53 (16)	46 (20)	36 (27)	33 (29)	31 (30)	27 (34)	21 (39)	17 (43)	14 (46)	9 (50)	8 (51)	7 (51)	5 (53)	3 (55)	2 (56)	0 (58)	0 (58)	0 (58)
Placebo	69 (0)	47 (11)	40 (17)	37 (20)	31 (26)	27 (29)	23 (33)	20 (36)	18 (37)	15 (39)	12 (42)	10 (43)	7 (46)	5 (48)	4 (49)	4 (49)	3 (49)	1 (51)	1 (51)	1 (51)	1 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



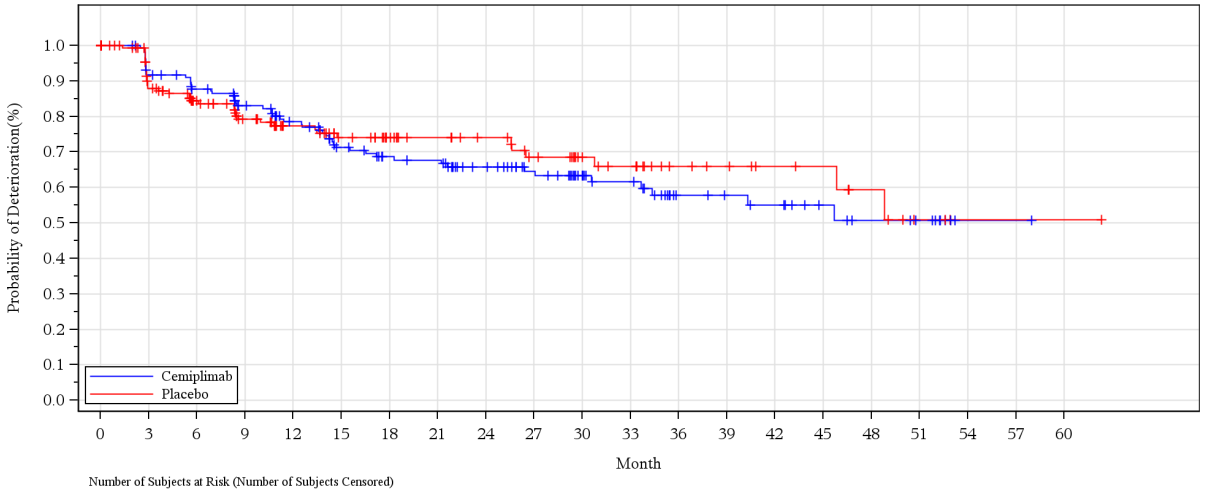
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	59 (9)	54 (11)	43 (19)	39 (22)	31 (25)	26 (28)	26 (28)	20 (32)	17 (35)	13 (38)	12 (39)	8 (42)	7 (43)	6 (44)	4 (46)	3 (46)	2 (47)	0 (49)	0 (49)	0 (49)
Placebo	72 (0)	52 (16)	41 (22)	32 (29)	26 (34)	20 (39)	16 (42)	15 (43)	12 (45)	11 (45)	7 (49)	7 (49)	4 (52)	4 (52)	3 (53)	3 (53)	3 (53)	2 (53)	0 (55)	0 (55)	0 (55)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Gender group: Male



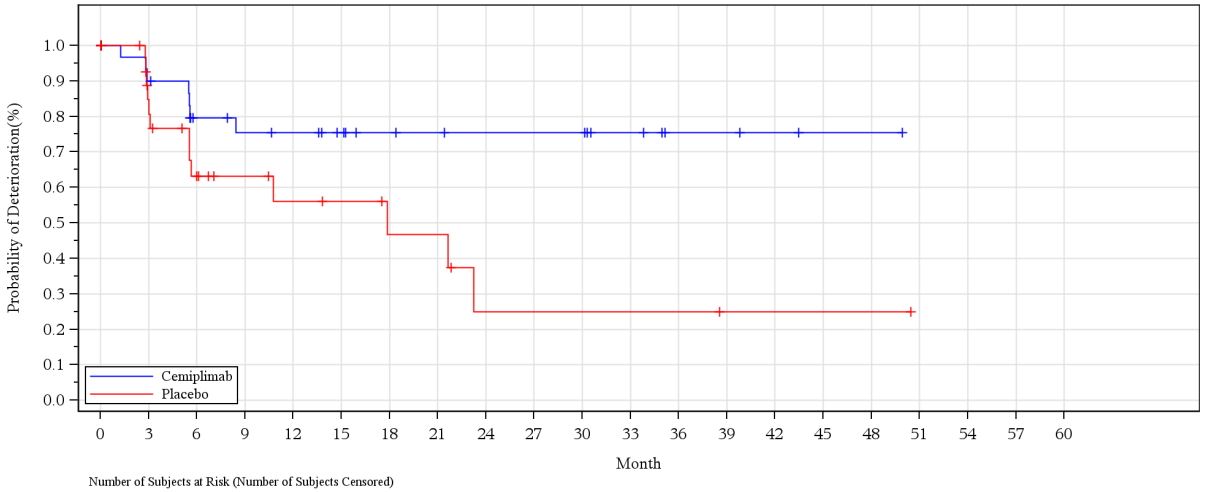
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	143 (18)	132 (23)	115 (33)	101 (41)	84 (49)	75 (55)	73 (56)	61 (66)	51 (75)	40 (85)	35 (89)	22 (100)	20 (102)	18 (103)	13 (108)	10 (110)	8 (112)	1 (119)	1 (119)	0 (120)
Placebo	174 (0)	129 (27)	106 (45)	88 (57)	71 (72)	61 (79)	52 (88)	46 (94)	42 (98)	35 (102)	27 (110)	24 (112)	16 (120)	14 (122)	11 (125)	10 (126)	7 (128)	3 (131)	1 (133)	1 (133)	1 (133)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Gender group: Female



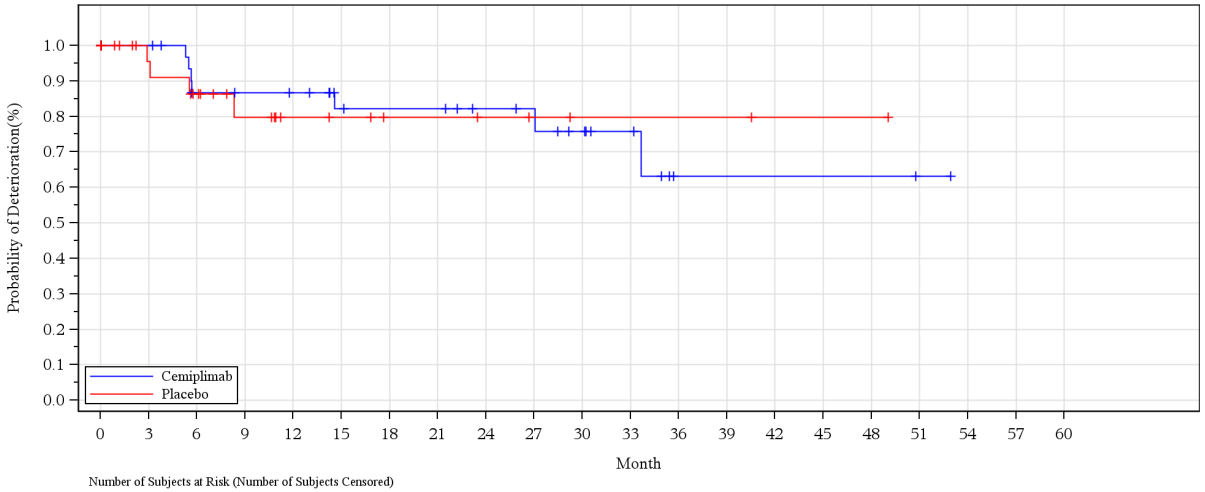
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	27 (5)	20 (9)	18 (10)	17 (11)	14 (14)	11 (17)	10 (18)	9 (19)	9 (19)	9 (19)	6 (22)	3 (25)	3 (25)	2 (26)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)	0 (28)
Placebo	32 (0)	21 (7)	14 (9)	10 (13)	8 (14)	7 (15)	5 (16)	5 (16)	2 (17)	2 (17)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



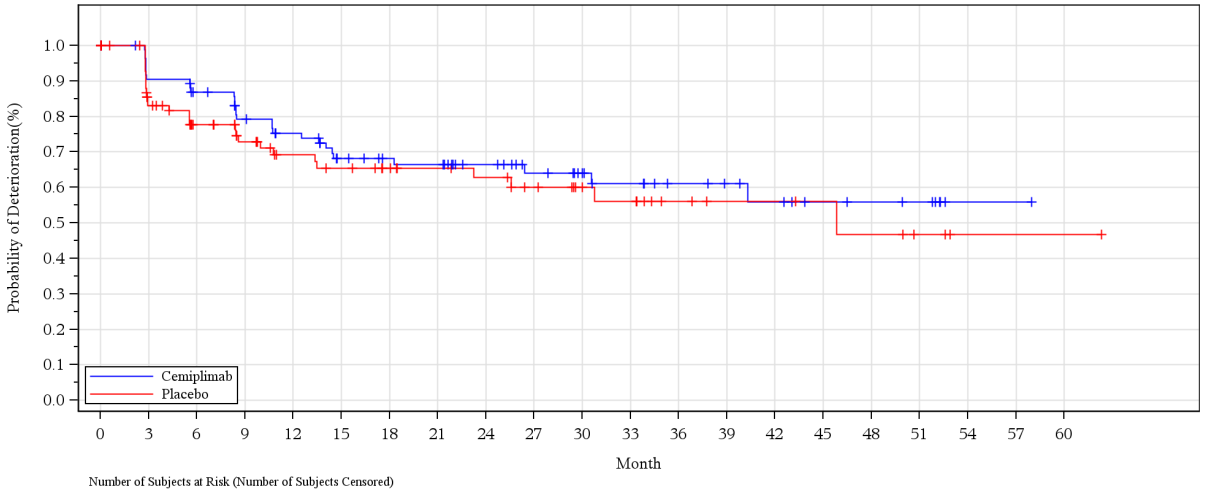
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	32 (5)	25 (8)	24 (9)	23 (10)	18 (14)	17 (15)	17 (15)	14 (18)	13 (19)	10 (21)	7 (24)	2 (28)	2 (28)	2 (28)	2 (28)	2 (28)	1 (29)	0 (30)	0 (30)	0 (30)
Placebo	31 (0)	21 (9)	17 (11)	12 (15)	8 (19)	7 (20)	5 (22)	5 (22)	4 (23)	3 (24)	2 (25)	2 (25)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



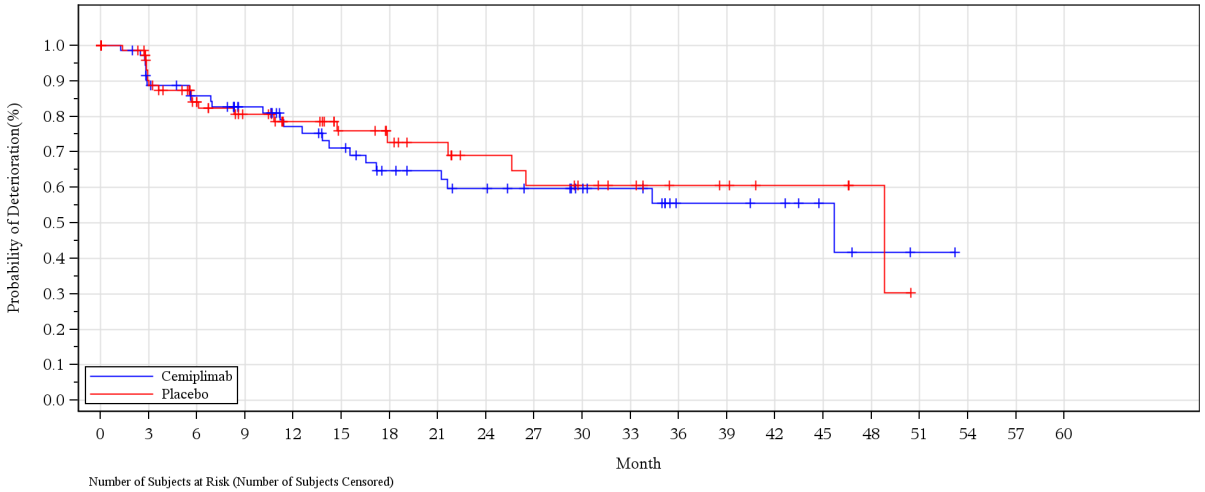
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	76 (6)	70 (9)	61 (12)	55 (15)	45 (20)	41 (24)	40 (24)	33 (31)	27 (36)	22 (41)	19 (43)	15 (47)	13 (49)	11 (50)	8 (53)	7 (54)	6 (55)	1 (60)	1 (60)	0 (61)
Placebo	90 (0)	66 (10)	53 (19)	44 (25)	36 (31)	33 (32)	29 (36)	26 (39)	24 (40)	20 (43)	15 (48)	14 (48)	9 (53)	7 (55)	7 (55)	6 (56)	5 (56)	3 (58)	1 (60)	1 (60)	1 (60)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	62 (12)	57 (15)	48 (22)	40 (27)	35 (29)	28 (33)	26 (35)	23 (36)	20 (39)	17 (42)	15 (44)	8 (50)	8 (50)	7 (51)	4 (54)	2 (55)	1 (56)	0 (57)	0 (57)	0 (57)
Placebo	85 (0)	63 (15)	50 (24)	42 (30)	35 (36)	28 (42)	23 (46)	20 (49)	16 (52)	14 (52)	12 (54)	10 (56)	7 (59)	6 (60)	4 (62)	4 (62)	2 (64)	0 (65)	0 (65)	0 (65)	0 (65)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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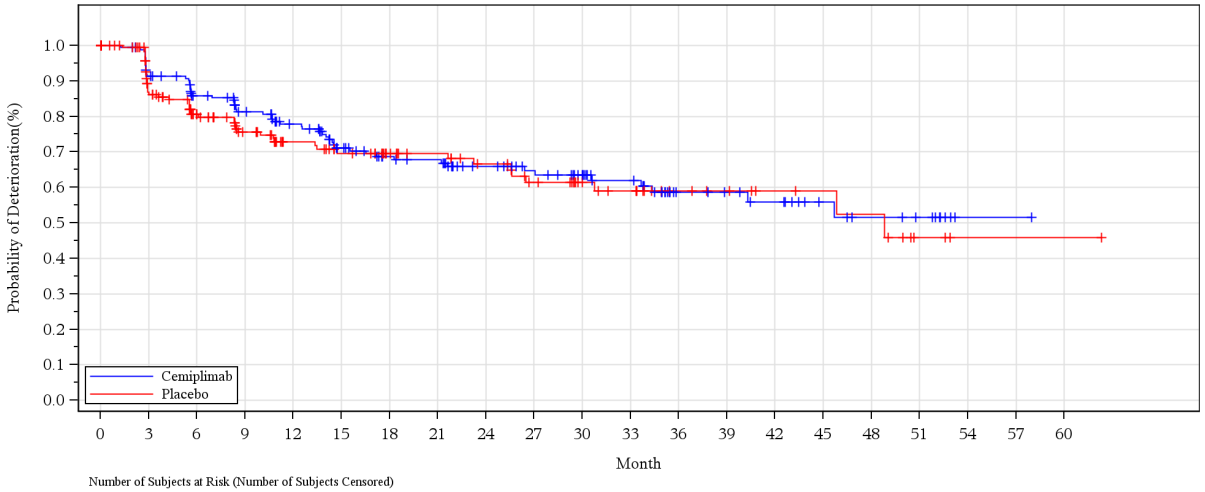
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	156 (18)	138 (27)	123 (35)	109 (44)	89 (55)	77 (64)	74 (66)	62 (76)	55 (82)	47 (89)	40 (95)	24 (109)	22 (111)	19 (113)	13 (119)	10 (121)	8 (123)	1 (130)	1 (130)	0 (131)
Placebo	189 (0)	134 (34)	107 (52)	86 (67)	69 (81)	61 (86)	52 (95)	47 (100)	41 (104)	34 (108)	26 (116)	23 (118)	15 (126)	13 (128)	10 (131)	9 (132)	8 (132)	3 (136)	1 (138)	1 (138)	1 (138)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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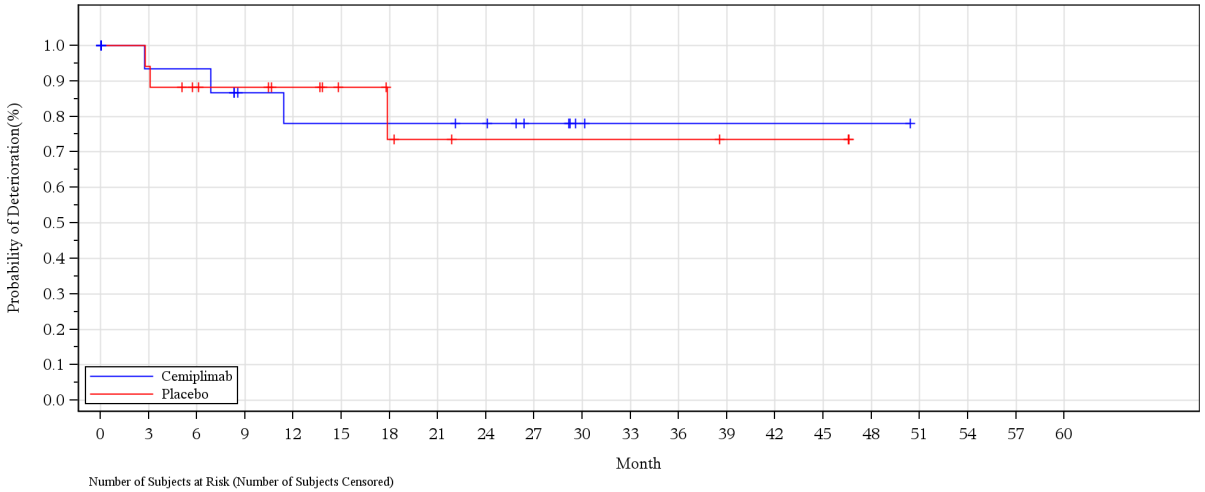
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	14 (5)	14 (5)	10 (8)	9 (8)	9 (8)	9 (8)	9 (8)	8 (9)	5 (12)	2 (15)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	17 (0)	16 (0)	13 (2)	12 (3)	10 (5)	7 (8)	5 (9)	4 (10)	3 (11)	3 (11)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	2 (12)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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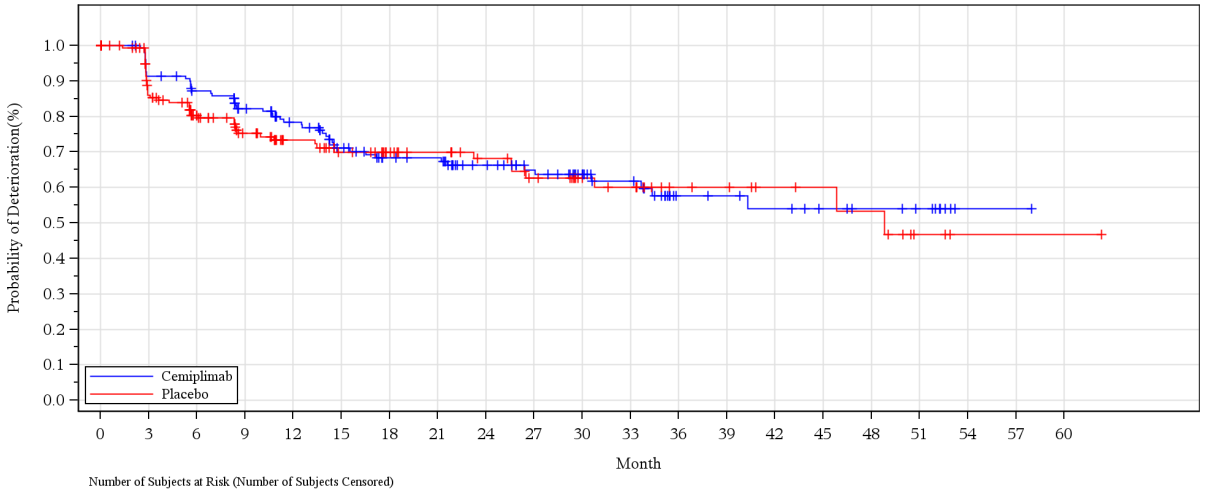
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	136 (17)	126 (21)	112 (28)	100 (35)	82 (44)	71 (52)	69 (54)	56 (65)	48 (72)	38 (81)	32 (86)	18 (98)	17 (99)	15 (100)	12 (103)	10 (105)	8 (107)	1 (114)	1 (114)	0 (115)
Placebo	177 (0)	127 (29)	103 (45)	83 (59)	67 (73)	57 (80)	49 (88)	44 (93)	38 (98)	32 (101)	24 (109)	22 (110)	14 (118)	13 (119)	10 (122)	9 (123)	8 (123)	3 (127)	1 (129)	1 (129)	1 (129)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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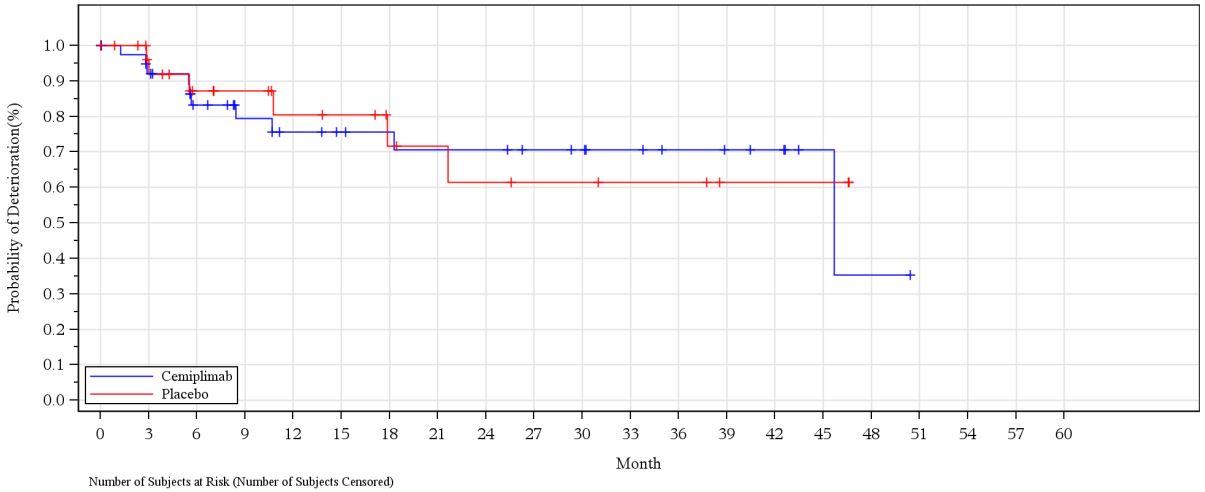
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	34 (6)	26 (11)	21 (15)	18 (17)	16 (19)	15 (20)	14 (20)	14 (20)	12 (22)	11 (23)	9 (25)	7 (27)	6 (28)	5 (29)	2 (32)	1 (32)	0 (33)	0 (33)	0 (33)	0 (33)
Placebo	29 (0)	23 (5)	17 (9)	15 (11)	12 (13)	11 (14)	8 (16)	7 (17)	6 (17)	5 (18)	5 (18)	4 (19)	4 (19)	2 (21)	2 (21)	2 (21)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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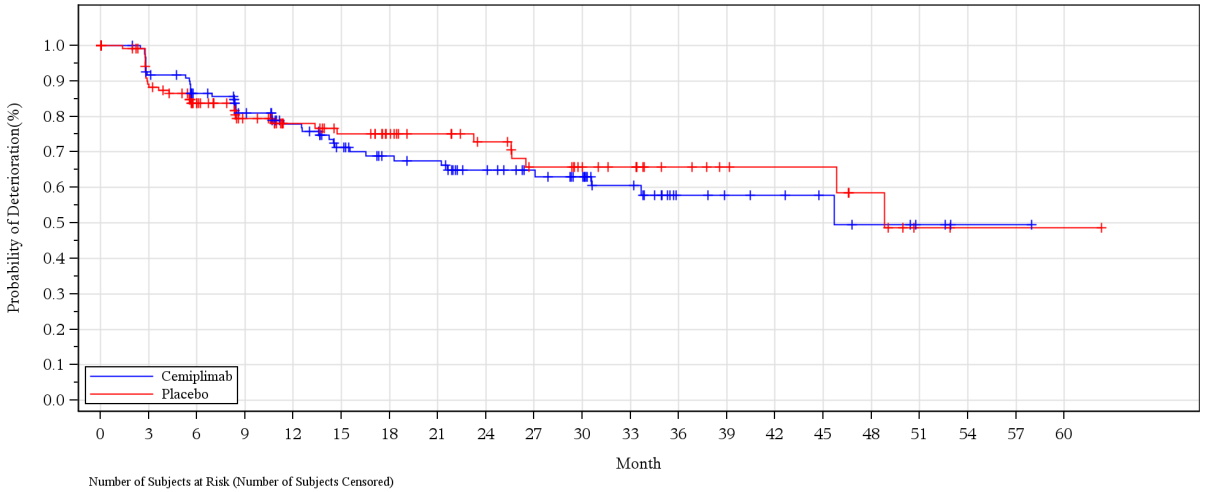
Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



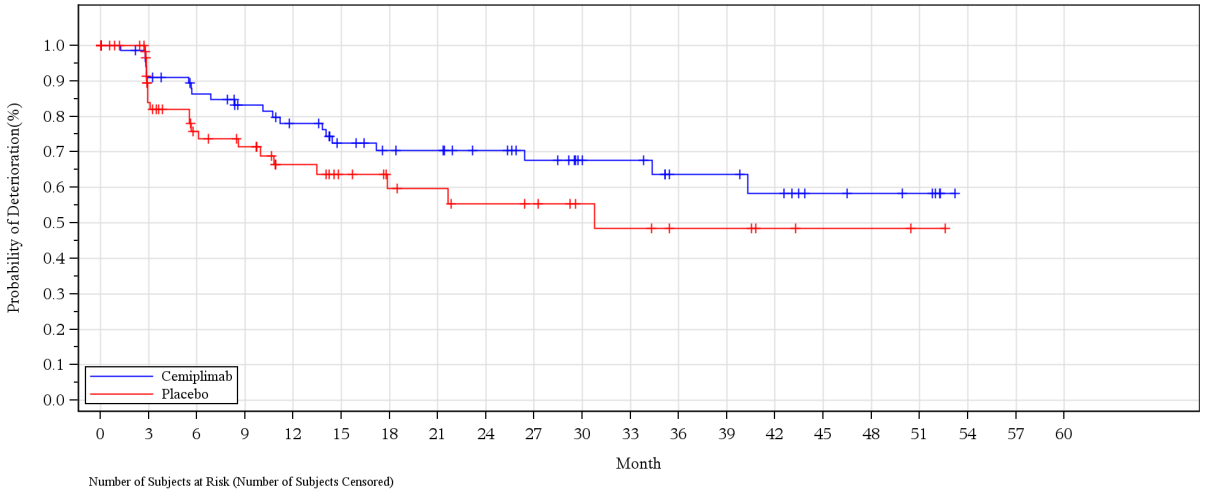
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	109 (14)	97 (20)	84 (27)	74 (34)	61 (41)	53 (47)	51 (48)	42 (55)	36 (61)	31 (65)	23 (72)	12 (82)	10 (84)	9 (85)	7 (87)	5 (88)	3 (90)	1 (92)	1 (92)	0 (93)
Placebo	131 (0)	105 (13)	85 (27)	67 (41)	55 (52)	49 (56)	42 (63)	37 (68)	32 (72)	26 (75)	21 (80)	19 (82)	13 (88)	10 (91)	9 (92)	9 (92)	6 (94)	2 (97)	1 (98)	1 (98)	1 (98)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



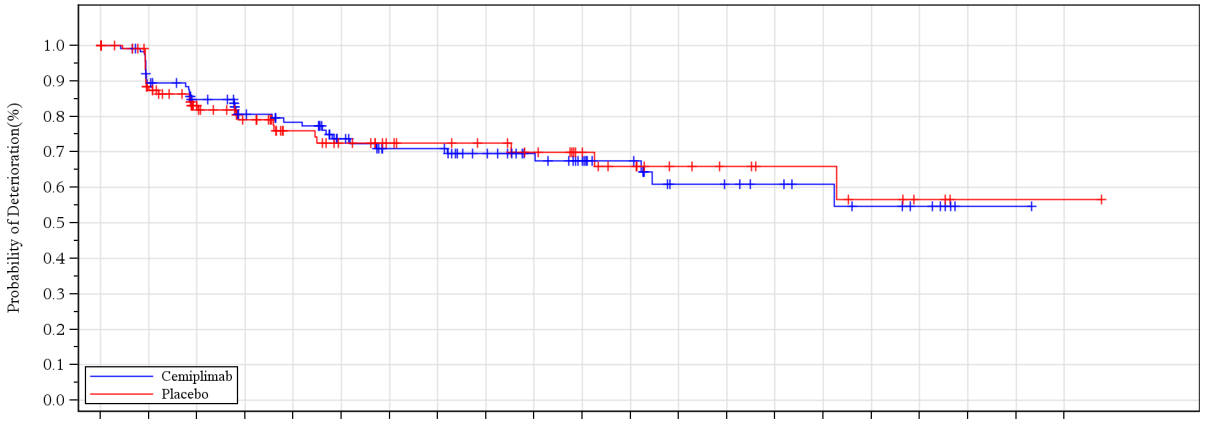
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	61 (9)	55 (12)	49 (16)	44 (18)	37 (22)	33 (25)	32 (26)	28 (30)	24 (33)	18 (39)	18 (39)	13 (43)	13 (43)	11 (44)	7 (48)	6 (49)	5 (50)	0 (55)	0 (55)	0 (55)
Placebo	75 (0)	45 (21)	35 (27)	31 (29)	24 (34)	19 (38)	15 (41)	14 (42)	12 (43)	11 (44)	8 (47)	7 (47)	5 (49)	5 (49)	3 (51)	2 (52)	2 (52)	1 (53)	0 (54)	0 (54)	0 (54)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



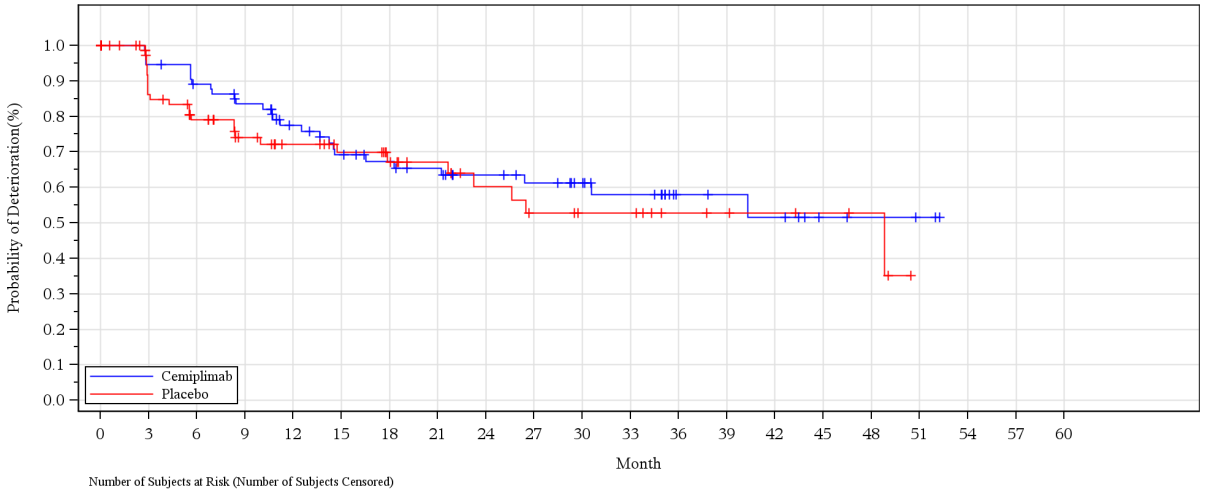
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	100 (13)	88 (20)	75 (29)	70 (32)	57 (41)	49 (47)	49 (47)	41 (54)	34 (61)	27 (67)	23 (71)	15 (77)	14 (78)	12 (80)	10 (82)	8 (83)	6 (85)	1 (90)	1 (90)	0 (91)
Placebo	117 (0)	88 (17)	68 (32)	56 (41)	44 (51)	38 (55)	32 (61)	30 (63)	28 (65)	24 (68)	18 (74)	15 (76)	11 (80)	9 (82)	7 (84)	7 (84)	5 (85)	3 (87)	1 (89)	1 (89)	1 (89)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.10 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Nausea/Vomiting Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



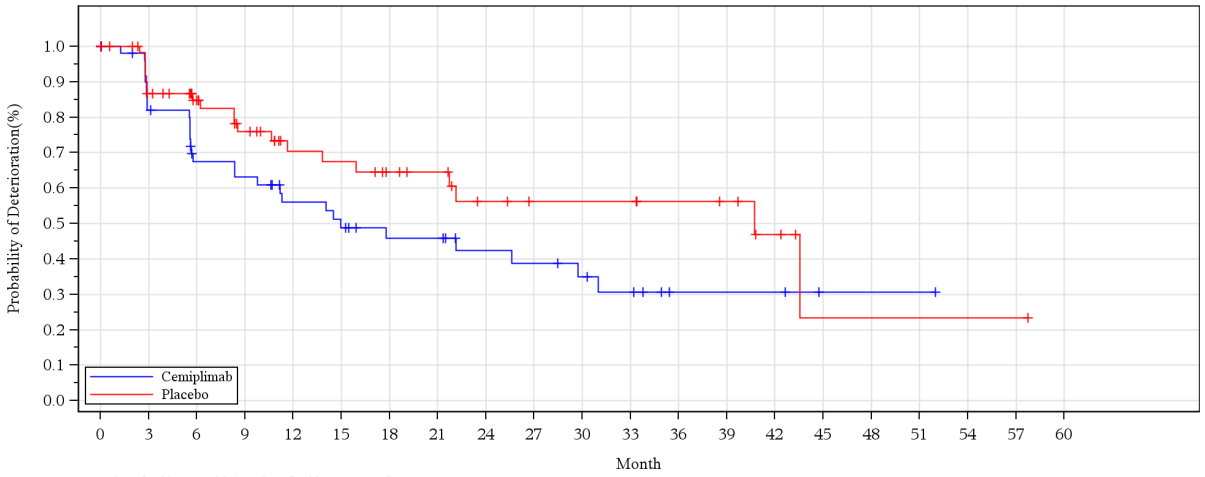
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	70 (10)	64 (12)	58 (14)	48 (20)	41 (22)	37 (25)	34 (27)	29 (31)	26 (33)	22 (37)	18 (40)	10 (48)	9 (49)	8 (49)	4 (53)	3 (54)	2 (55)	0 (57)	0 (57)	0 (57)
Placebo	89 (0)	62 (17)	52 (22)	42 (29)	35 (35)	30 (39)	25 (43)	21 (47)	16 (50)	13 (51)	11 (53)	11 (53)	7 (57)	6 (58)	5 (59)	4 (60)	3 (61)	0 (63)	0 (63)	0 (63)	0 (63)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



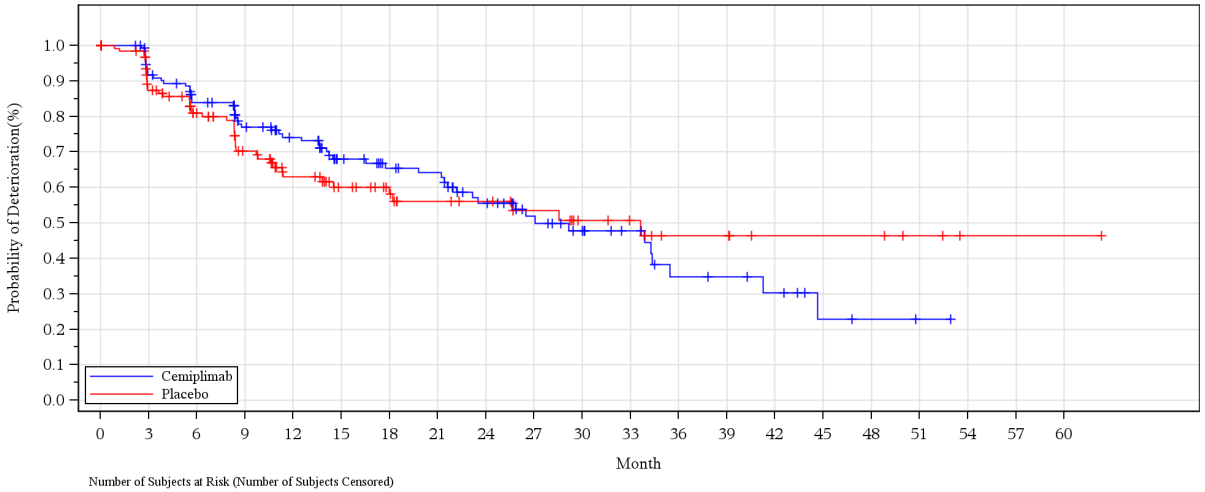
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (6)	31 (9)	29 (9)	23 (12)	20 (12)	16 (15)	16 (15)	12 (18)	11 (18)	9 (19)	7 (20)	3 (24)	3 (24)	3 (24)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	51 (6)	42 (14)	33 (19)	24 (26)	23 (26)	19 (29)	17 (31)	12 (34)	10 (36)	10 (36)	10 (36)	8 (38)	7 (39)	4 (41)	1 (43)	1 (43)	1 (43)	1 (43)	1 (43)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



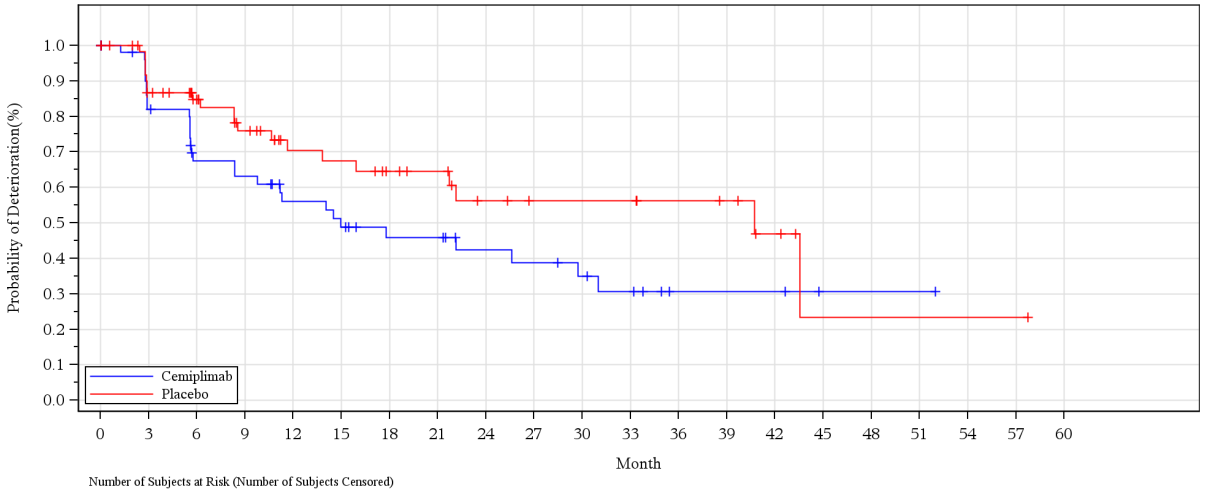
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	120 (22)	105 (27)	87 (37)	76 (45)	59 (56)	51 (62)	48 (64)	36 (70)	27 (77)	20 (82)	16 (86)	10 (88)	9 (89)	7 (90)	3 (93)	2 (94)	1 (95)	0 (96)	0 (96)	0 (96)
Placebo	141 (0)	101 (25)	81 (38)	63 (46)	47 (56)	37 (64)	30 (70)	25 (74)	23 (76)	19 (79)	14 (83)	12 (85)	8 (88)	8 (88)	5 (91)	5 (91)	5 (91)	3 (93)	1 (95)	1 (95)	1 (95)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



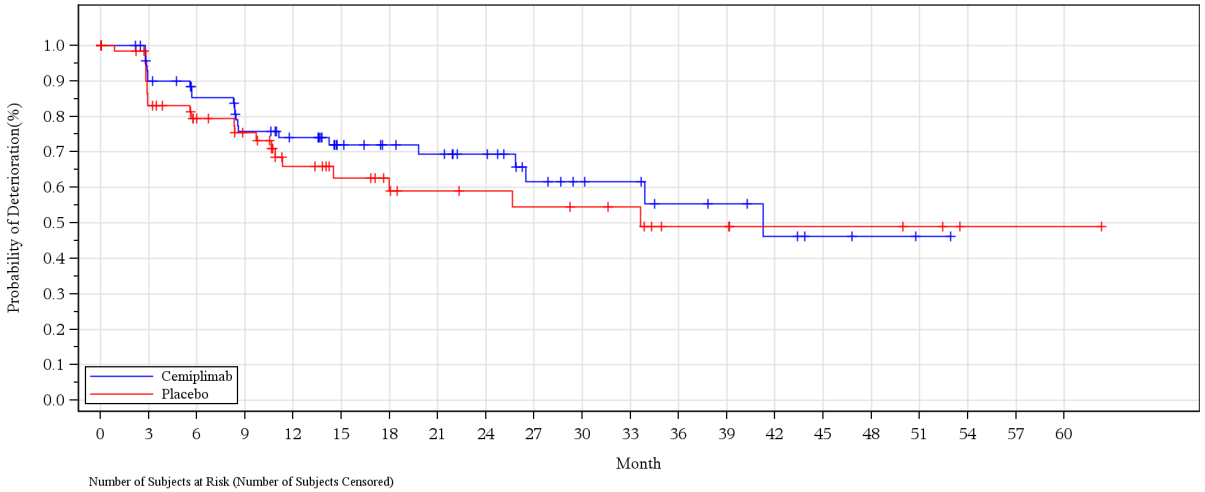
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (6)	31 (9)	29 (9)	23 (12)	20 (12)	16 (15)	16 (15)	12 (18)	11 (18)	9 (19)	7 (20)	3 (24)	3 (24)	3 (24)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	51 (6)	42 (14)	33 (19)	24 (26)	23 (26)	19 (29)	17 (31)	12 (34)	10 (36)	10 (36)	10 (36)	8 (38)	7 (39)	4 (41)	1 (43)	1 (43)	1 (43)	1 (43)	1 (43)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



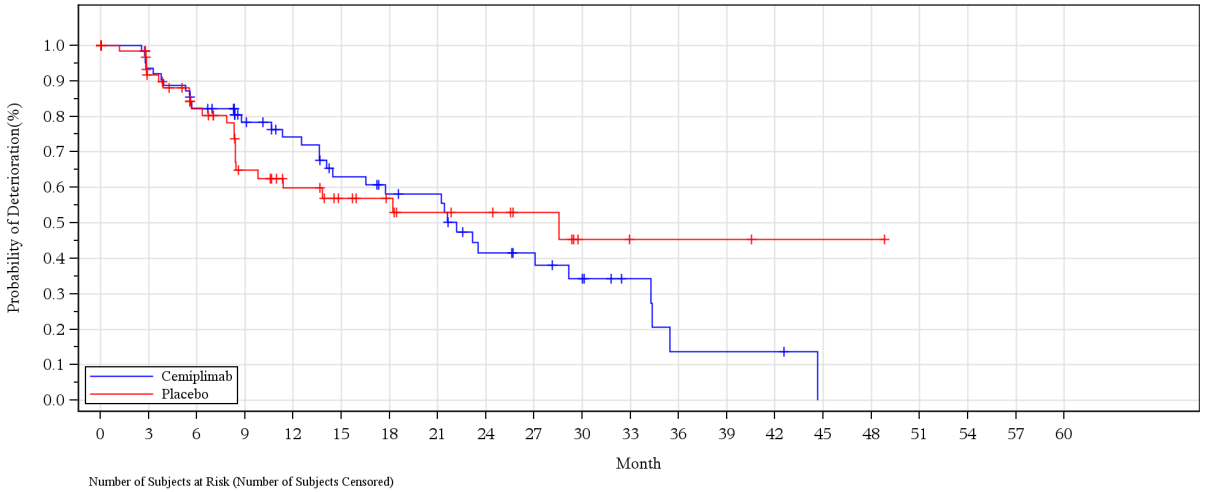
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	62 (11)	55 (15)	47 (17)	42 (21)	32 (30)	28 (34)	26 (35)	22 (39)	15 (44)	12 (47)	11 (48)	8 (50)	7 (51)	5 (52)	3 (54)	2 (55)	1 (56)	0 (57)	0 (57)	0 (57)
Placebo	69 (0)	49 (10)	40 (17)	35 (20)	25 (26)	20 (30)	16 (33)	14 (35)	13 (36)	12 (36)	11 (37)	10 (38)	6 (41)	6 (41)	4 (43)	4 (43)	4 (43)	3 (44)	1 (46)	1 (46)	1 (46)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



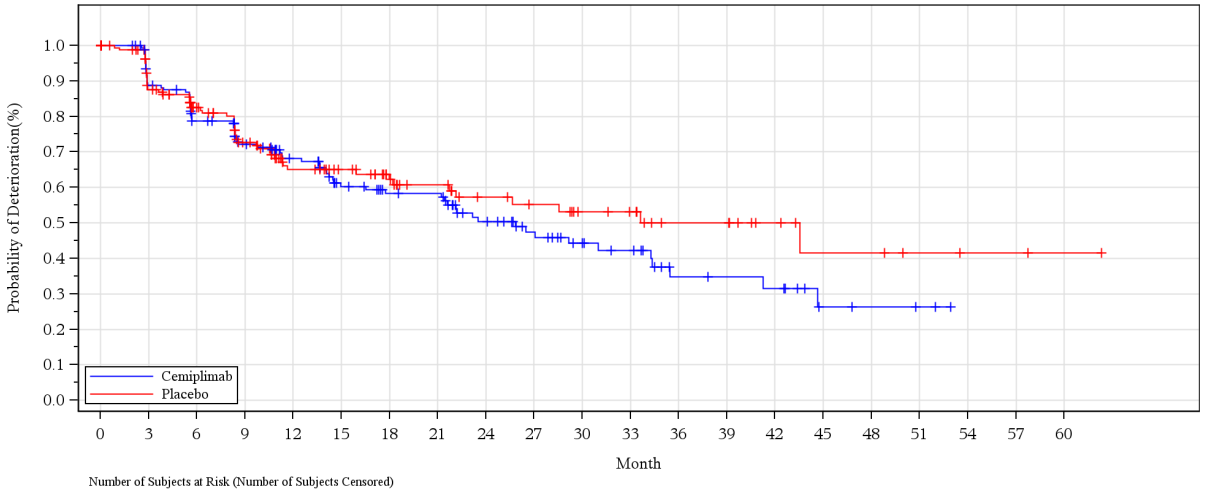
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	58 (11)	50 (12)	40 (20)	34 (24)	27 (26)	23 (28)	22 (29)	14 (31)	12 (33)	8 (35)	5 (38)	2 (38)	2 (38)	2 (38)	0 (39)	0 (39)	0 (39)	0 (39)	0 (39)	0 (39)
Placebo	72 (0)	52 (15)	41 (21)	28 (26)	22 (30)	17 (34)	14 (37)	11 (39)	10 (40)	7 (43)	3 (46)	2 (47)	2 (47)	2 (47)	1 (48)	1 (48)	1 (48)	0 (49)	0 (49)	0 (49)	0 (49)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Gender group: Male



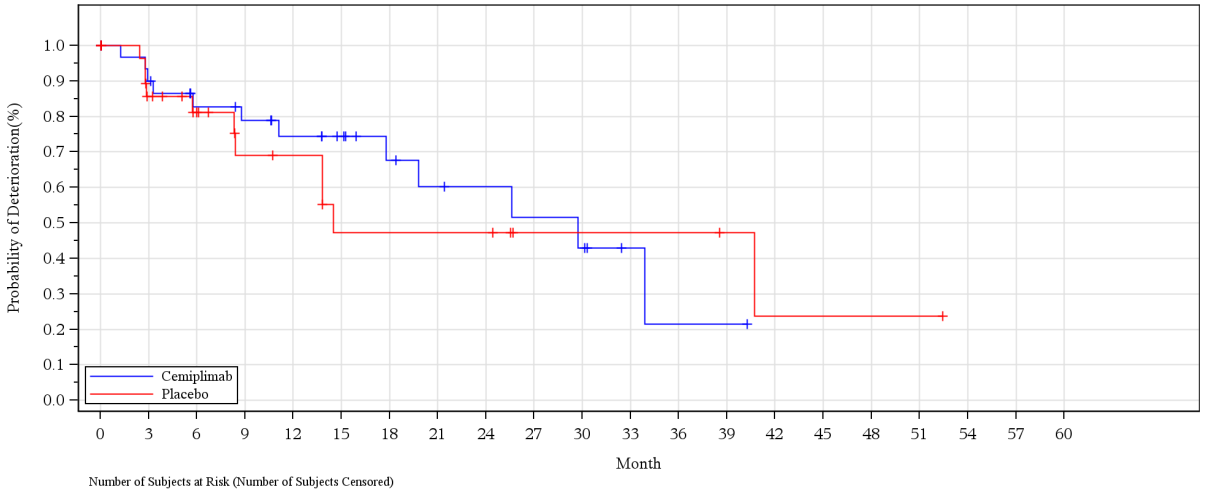
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	134 (23)	114 (28)	96 (37)	82 (46)	65 (54)	57 (60)	56 (61)	41 (69)	32 (76)	24 (82)	21 (84)	12 (90)	11 (91)	10 (91)	4 (96)	3 (97)	2 (98)	0 (100)	0 (100)	0 (100)
Placebo	174 (0)	130 (25)	106 (42)	85 (51)	61 (67)	54 (74)	43 (83)	36 (89)	29 (94)	26 (96)	21 (100)	19 (102)	13 (107)	13 (107)	8 (112)	5 (114)	5 (114)	3 (116)	2 (117)	2 (117)	1 (118)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Gender group: Female



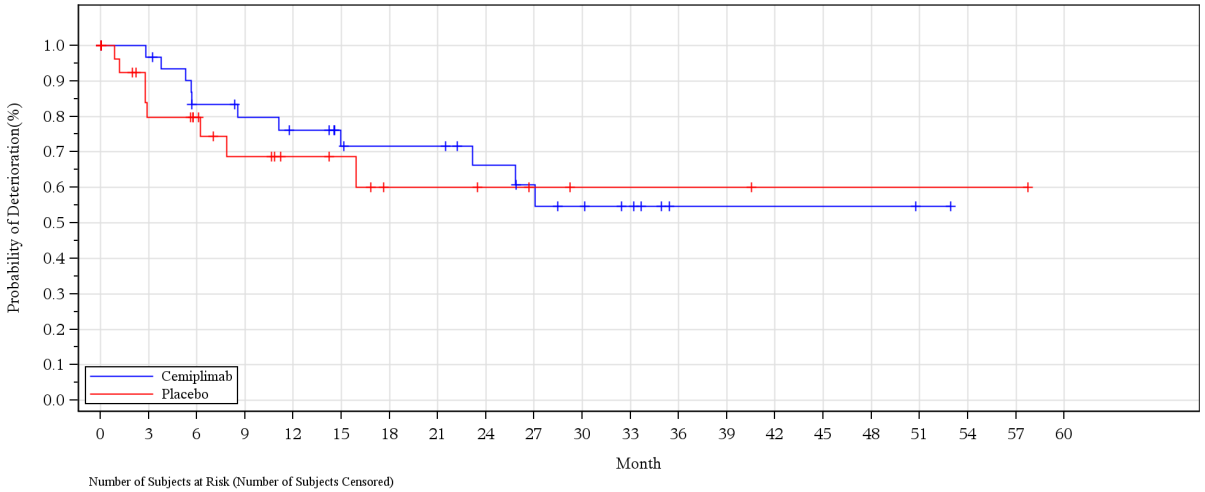
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	27 (5)	22 (8)	20 (9)	17 (11)	14 (14)	10 (17)	8 (18)	7 (19)	6 (19)	5 (19)	2 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	32 (0)	22 (6)	17 (10)	11 (14)	10 (15)	6 (16)	6 (16)	6 (16)	6 (16)	3 (19)	3 (19)	3 (19)	3 (19)	2 (20)	1 (20)	1 (20)	1 (20)	1 (20)	0 (21)	0 (21)	0 (21)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



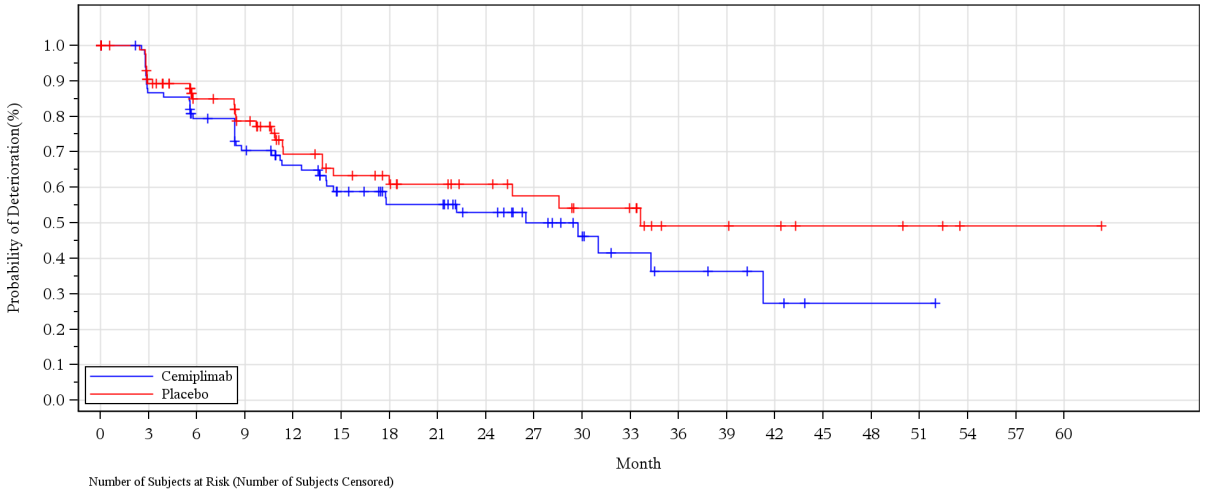
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (6)	24 (8)	22 (9)	20 (10)	16 (13)	15 (14)	15 (14)	12 (16)	10 (17)	8 (18)	6 (20)	2 (24)	2 (24)	2 (24)	2 (24)	2 (24)	1 (25)	0 (26)	0 (26)	0 (26)
Placebo	31 (0)	19 (7)	16 (10)	12 (12)	9 (15)	8 (16)	5 (18)	5 (18)	4 (19)	3 (20)	2 (21)	2 (21)	2 (21)	2 (21)	1 (22)	1 (22)	1 (22)	1 (22)	1 (22)	1 (22)	0 (23)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



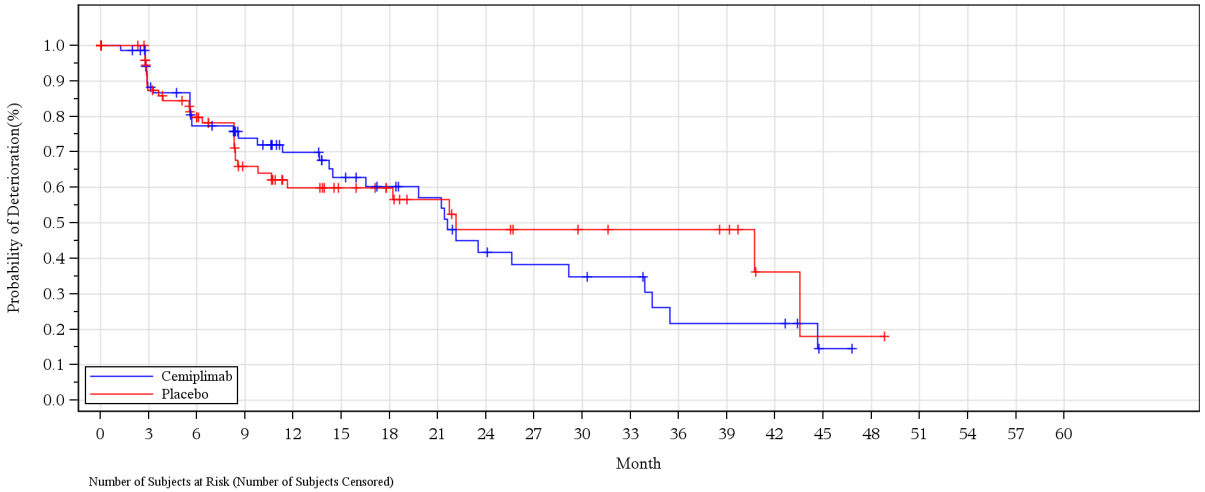
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	72 (7)	63 (10)	54 (12)	47 (16)	37 (21)	30 (26)	30 (26)	23 (32)	17 (37)	11 (42)	8 (44)	6 (45)	5 (46)	3 (47)	1 (49)	1 (49)	1 (49)	0 (50)	0 (50)	0 (50)
Placebo	90 (0)	72 (9)	57 (21)	49 (25)	35 (34)	30 (36)	26 (39)	23 (42)	20 (45)	17 (47)	14 (49)	13 (50)	7 (55)	7 (55)	6 (56)	4 (58)	4 (58)	3 (59)	1 (61)	1 (61)	1 (61)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



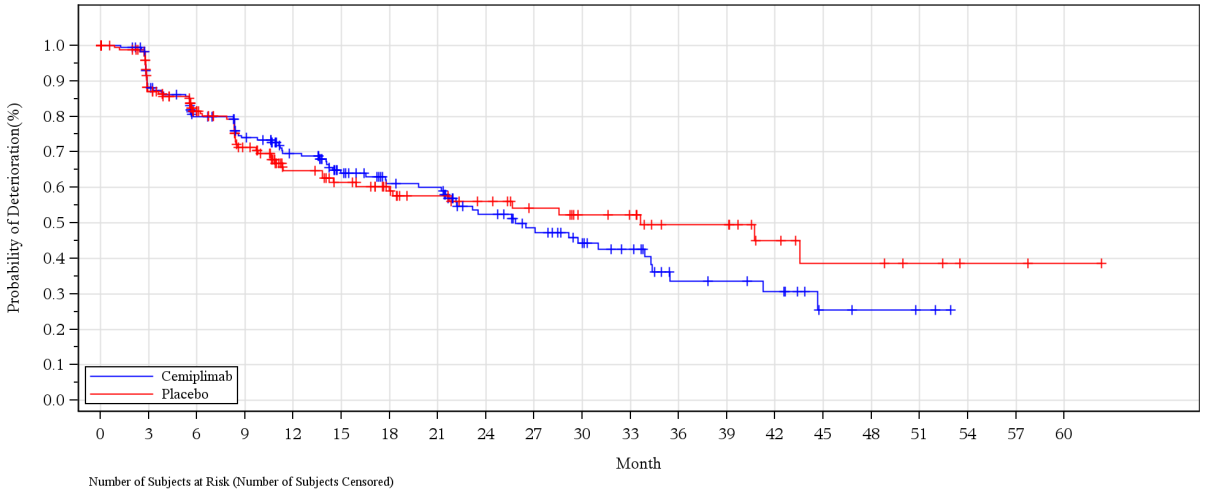
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	59 (15)	49 (18)	40 (25)	32 (31)	26 (34)	22 (37)	19 (39)	13 (40)	11 (41)	10 (41)	9 (42)	5 (43)	5 (43)	5 (43)	1 (46)	0 (47)	0 (47)	0 (47)	0 (47)	0 (47)
Placebo	85 (0)	61 (15)	50 (21)	35 (28)	27 (33)	22 (38)	18 (42)	14 (45)	11 (46)	9 (48)	8 (49)	7 (50)	7 (50)	6 (51)	2 (54)	1 (54)	1 (54)	0 (55)	0 (55)	0 (55)	0 (55)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Race: White



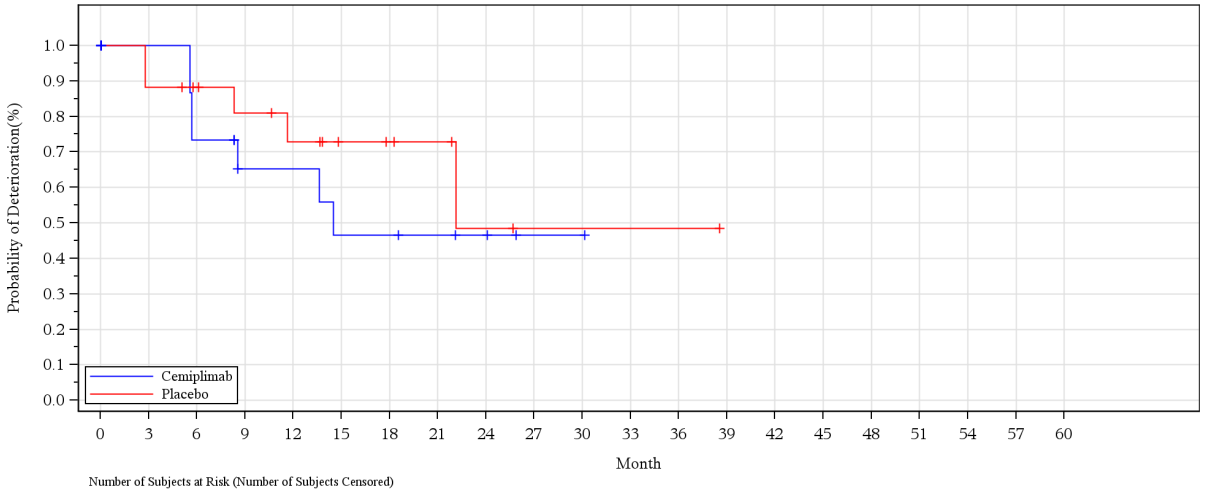
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	146 (23)	125 (31)	109 (38)	92 (49)	74 (60)	62 (69)	60 (70)	45 (78)	37 (83)	28 (89)	23 (93)	13 (99)	12 (100)	10 (101)	4 (106)	3 (107)	2 (108)	0 (110)	0 (110)	0 (110)
Placebo	189 (0)	137 (31)	110 (50)	85 (62)	62 (78)	54 (83)	44 (91)	38 (96)	33 (100)	28 (104)	23 (108)	21 (110)	15 (115)	15 (115)	9 (120)	6 (122)	6 (122)	4 (124)	2 (126)	2 (126)	1 (127)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Race: Non-white



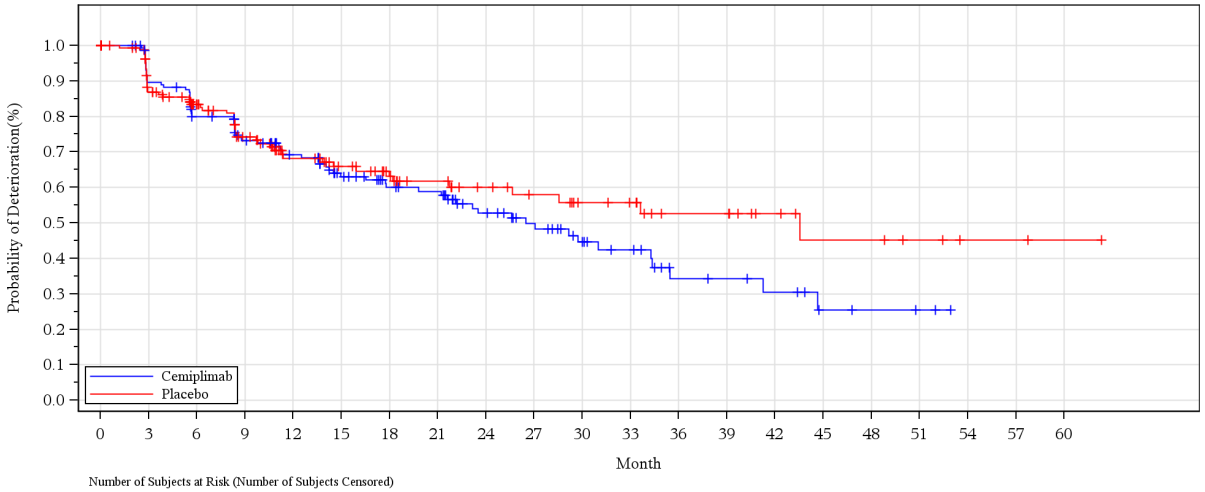
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	15 (5)	11 (5)	7 (8)	7 (8)	5 (8)	5 (8)	4 (9)	3 (10)	1 (12)	1 (12)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)
Placebo	17 (0)	15 (0)	13 (2)	11 (3)	9 (4)	6 (7)	5 (8)	4 (9)	2 (10)	1 (11)	1 (11)	1 (11)	1 (11)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



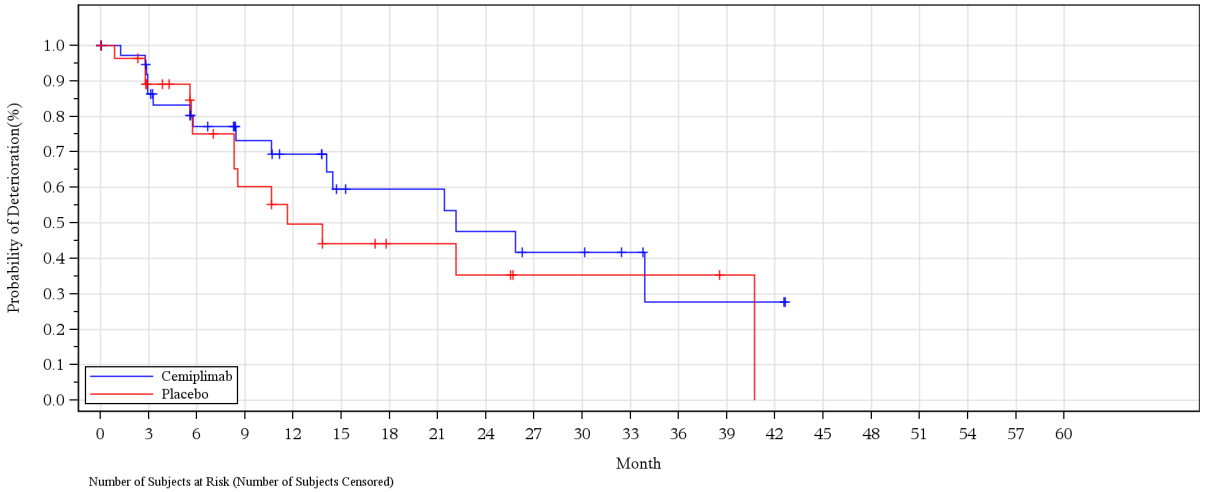
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	130 (21)	112 (25)	97 (31)	83 (40)	68 (48)	57 (56)	54 (58)	40 (67)	32 (73)	23 (79)	19 (82)	11 (87)	10 (88)	8 (89)	4 (92)	3 (93)	2 (94)	0 (96)	0 (96)	0 (96)
Placebo	177 (0)	130 (27)	107 (45)	84 (57)	62 (73)	53 (80)	44 (87)	37 (93)	31 (98)	27 (101)	22 (105)	20 (107)	14 (112)	14 (112)	9 (117)	6 (119)	6 (119)	4 (121)	2 (123)	2 (123)	1 (124)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



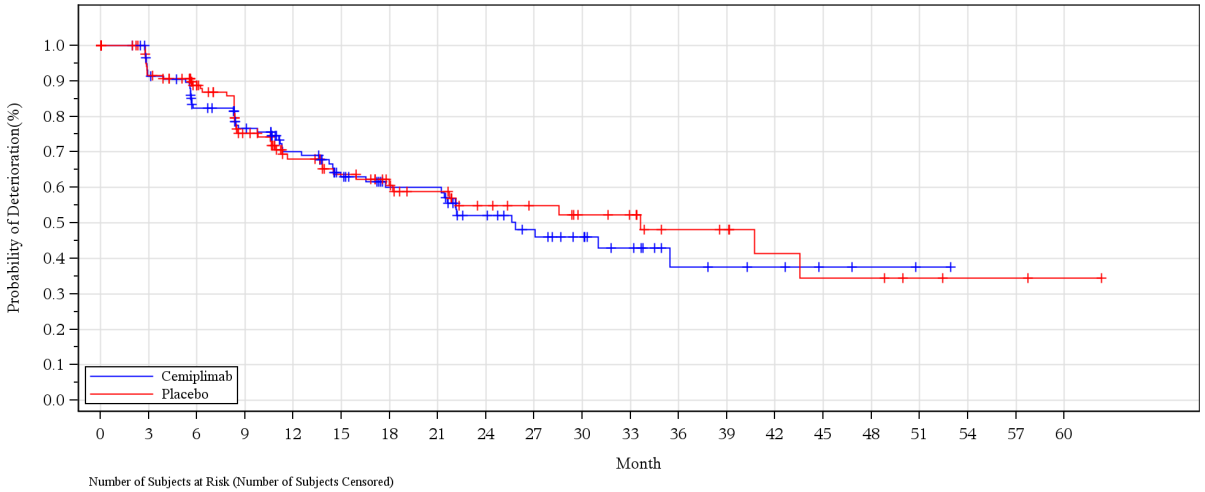
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	31 (7)	24 (11)	19 (15)	16 (17)	11 (20)	10 (21)	10 (21)	8 (21)	6 (22)	6 (22)	4 (24)	2 (25)	2 (25)	2 (25)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	29 (0)	22 (4)	16 (7)	12 (8)	9 (9)	7 (10)	5 (12)	5 (12)	4 (12)	2 (14)	2 (14)	2 (14)	2 (14)	1 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



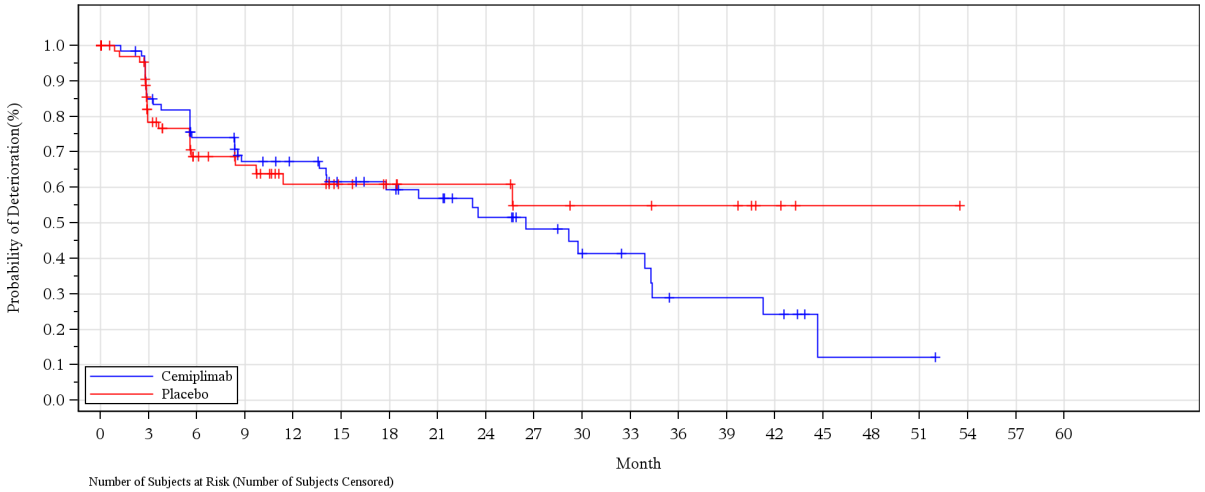
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	105 (18)	90 (23)	77 (30)	63 (38)	49 (46)	40 (53)	40 (53)	29 (59)	23 (63)	18 (67)	13 (71)	7 (76)	6 (77)	5 (78)	3 (80)	2 (81)	1 (82)	0 (83)	0 (83)	0 (83)
Placebo	131 (0)	108 (13)	91 (27)	68 (37)	51 (48)	44 (52)	36 (58)	31 (62)	24 (67)	21 (70)	17 (73)	15 (75)	10 (79)	9 (80)	6 (82)	5 (82)	5 (82)	3 (84)	2 (85)	2 (85)	1 (86)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



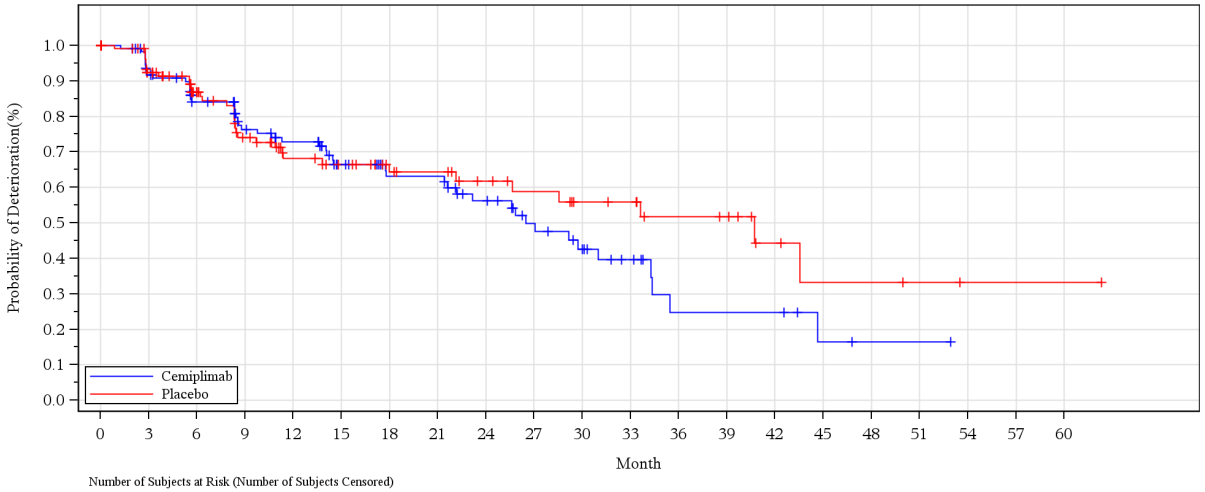
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	56 (10)	46 (13)	39 (16)	36 (19)	30 (22)	27 (24)	24 (26)	19 (29)	15 (32)	11 (34)	10 (35)	6 (36)	6 (36)	5 (36)	1 (39)	1 (39)	1 (39)	0 (40)	0 (40)	0 (40)
Placebo	75 (0)	44 (18)	32 (25)	28 (28)	20 (34)	16 (38)	13 (41)	11 (43)	11 (43)	8 (45)	7 (46)	7 (46)	6 (47)	6 (47)	3 (50)	1 (52)	1 (52)	1 (52)	0 (53)	0 (53)	0 (53)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	99 (17)	83 (25)	68 (33)	61 (37)	47 (46)	39 (52)	39 (52)	30 (57)	22 (62)	16 (65)	11 (69)	5 (72)	5 (72)	5 (72)	2 (74)	1 (75)	1 (75)	0 (76)	0 (76)	0 (76)
Placebo	117 (0)	93 (16)	72 (32)	55 (39)	43 (47)	38 (51)	30 (58)	28 (60)	23 (64)	20 (66)	16 (69)	15 (70)	11 (73)	10 (74)	5 (78)	3 (79)	3 (79)	2 (80)	1 (81)	1 (81)	1 (81)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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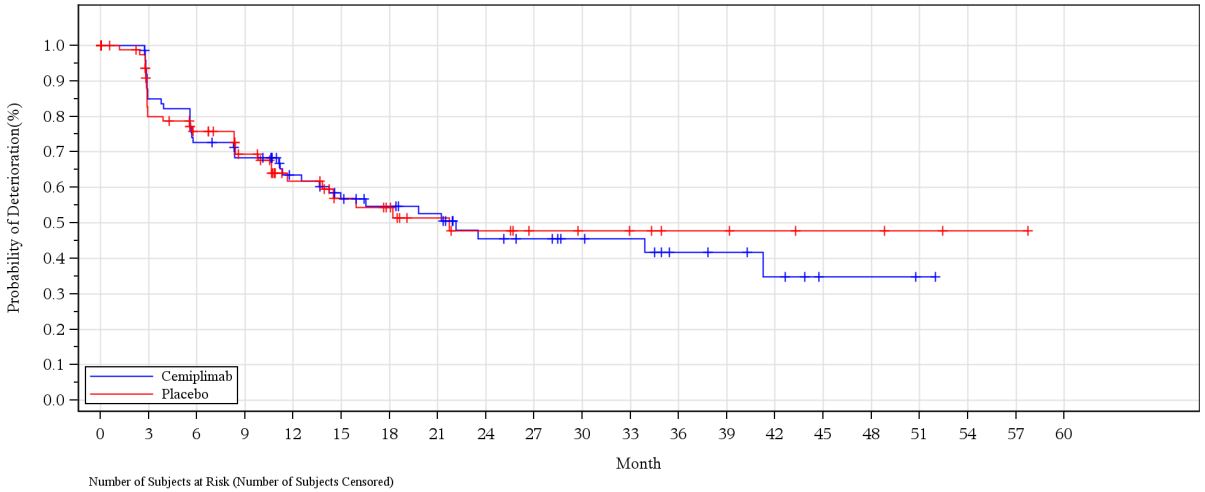
Figure 14.2.8.1.11 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Dyspnoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



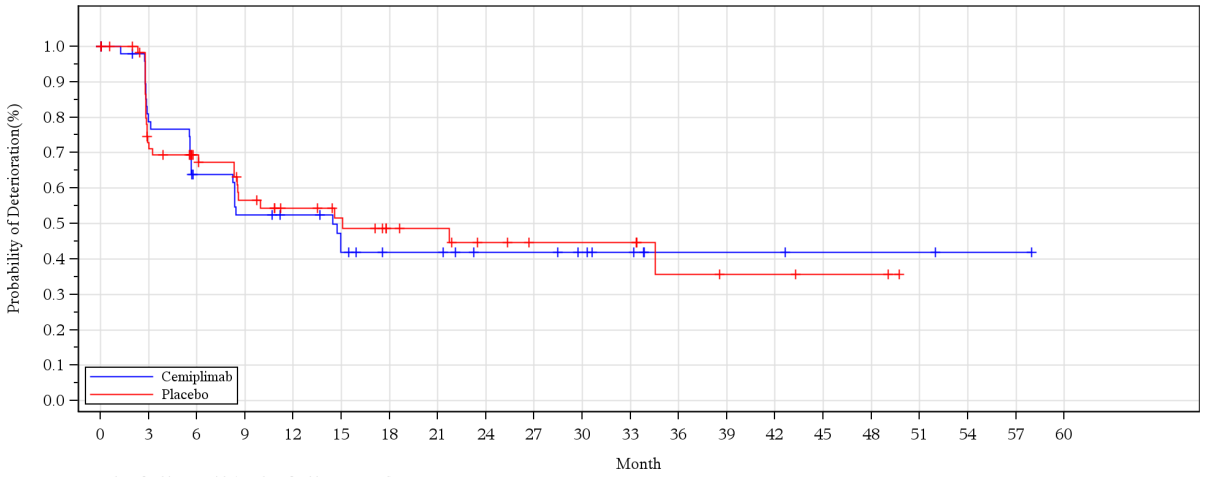
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	62 (11)	53 (11)	48 (13)	38 (20)	32 (22)	28 (25)	25 (27)	18 (31)	16 (33)	13 (36)	12 (37)	8 (40)	7 (41)	5 (42)	2 (45)	2 (45)	1 (46)	0 (47)	0 (47)	0 (47)
Placebo	89 (0)	59 (15)	51 (20)	41 (26)	28 (35)	22 (39)	19 (41)	14 (45)	12 (46)	9 (49)	8 (50)	7 (51)	5 (53)	5 (53)	4 (54)	3 (55)	3 (55)	2 (56)	1 (57)	1 (57)	0 (58)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



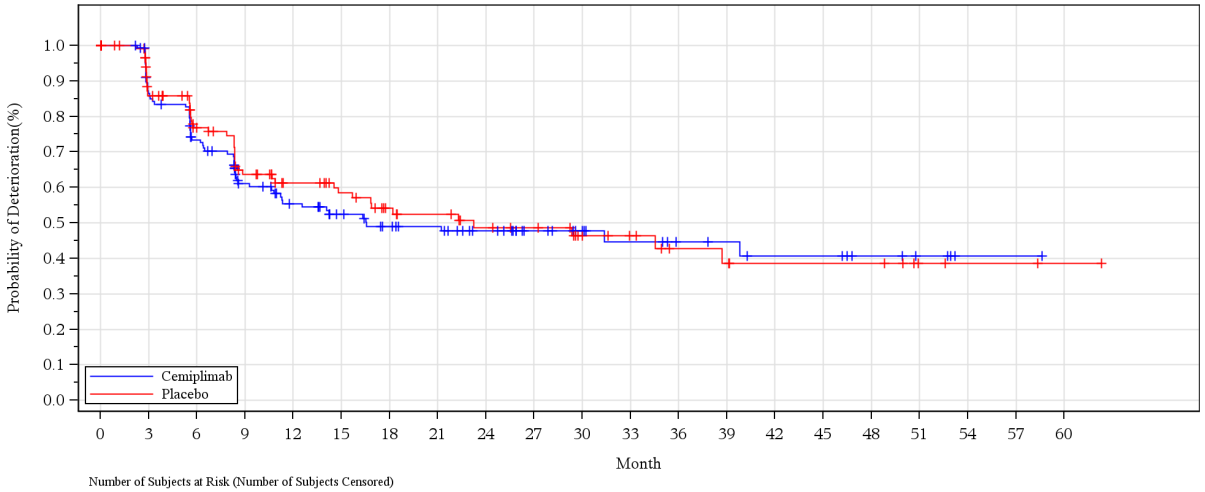
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	37 (9)	28 (11)	23 (11)	21 (13)	16 (14)	13 (17)	13 (17)	10 (20)	10 (20)	8 (22)	6 (24)	3 (27)	3 (27)	3 (27)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)
Placebo	65 (0)	42 (7)	34 (13)	26 (15)	21 (19)	18 (21)	13 (25)	12 (26)	9 (28)	7 (30)	7 (30)	7 (30)	4 (32)	3 (33)	3 (33)	2 (34)	2 (34)	0 (36)	0 (36)	0 (36)	0 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



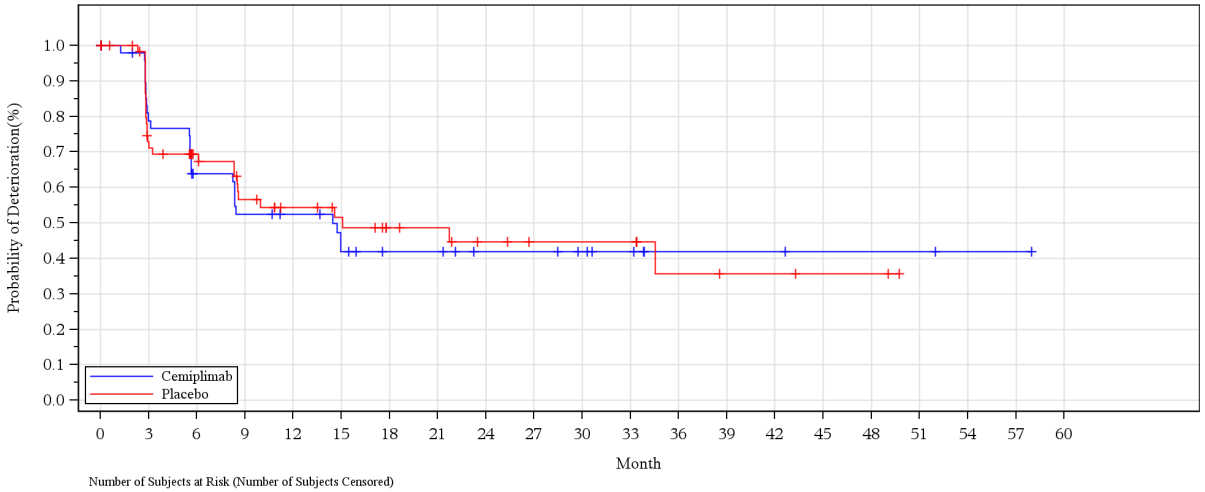
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	114 (21)	93 (25)	68 (35)	57 (40)	48 (46)	41 (50)	38 (53)	31 (59)	23 (67)	18 (72)	15 (74)	12 (77)	11 (78)	9 (79)	9 (79)	6 (82)	4 (84)	1 (87)	1 (87)	0 (88)
Placebo	141 (0)	94 (31)	73 (43)	57 (47)	47 (55)	41 (59)	33 (64)	30 (66)	25 (69)	23 (71)	16 (77)	14 (79)	10 (82)	9 (82)	7 (84)	7 (84)	7 (84)	3 (88)	2 (89)	2 (89)	1 (90)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



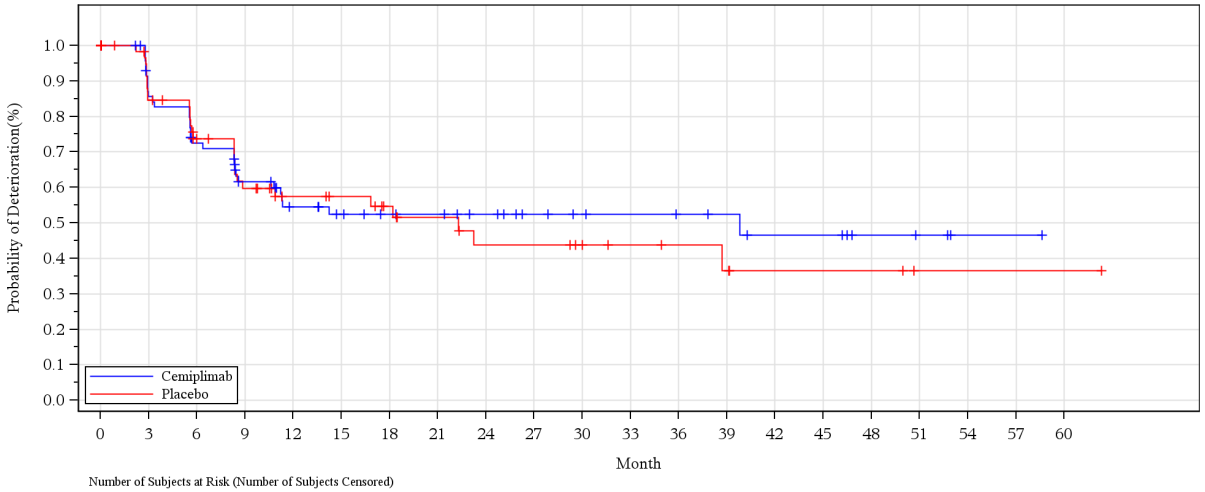
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	37 (9)	28 (11)	23 (11)	21 (13)	16 (14)	13 (17)	13 (17)	10 (20)	10 (20)	8 (22)	6 (24)	3 (27)	3 (27)	3 (27)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)
Placebo	65 (0)	42 (7)	34 (13)	26 (15)	21 (19)	18 (21)	13 (25)	12 (26)	9 (28)	7 (30)	7 (30)	7 (30)	4 (32)	3 (33)	3 (33)	2 (34)	2 (34)	0 (36)	0 (36)	0 (36)	0 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



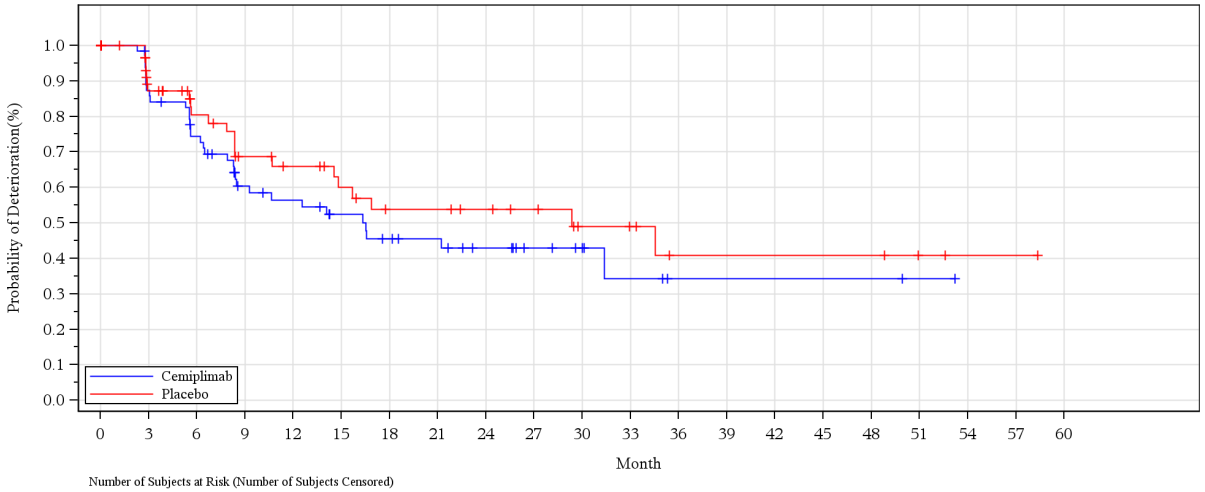
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	59 (11)	48 (13)	37 (17)	29 (21)	25 (24)	22 (27)	21 (28)	18 (31)	14 (35)	12 (37)	11 (38)	10 (39)	9 (40)	7 (41)	7 (41)	4 (44)	3 (45)	1 (47)	1 (47)	0 (48)
Placebo	69 (0)	49 (11)	38 (16)	30 (17)	23 (23)	21 (25)	17 (28)	14 (30)	11 (31)	11 (31)	8 (34)	7 (35)	6 (36)	5 (36)	3 (38)	3 (38)	3 (38)	1 (40)	1 (40)	1 (40)	1 (40)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	55 (10)	45 (12)	31 (18)	28 (19)	23 (22)	19 (23)	17 (25)	13 (28)	9 (32)	6 (35)	4 (36)	2 (38)	2 (38)	2 (38)	2 (38)	2 (38)	1 (39)	0 (40)	0 (40)	0 (40)
Placebo	72 (0)	45 (20)	35 (27)	27 (30)	24 (32)	20 (34)	16 (36)	16 (36)	14 (38)	12 (40)	8 (43)	7 (44)	4 (46)	4 (46)	4 (46)	4 (46)	4 (46)	2 (48)	1 (49)	1 (49)	0 (50)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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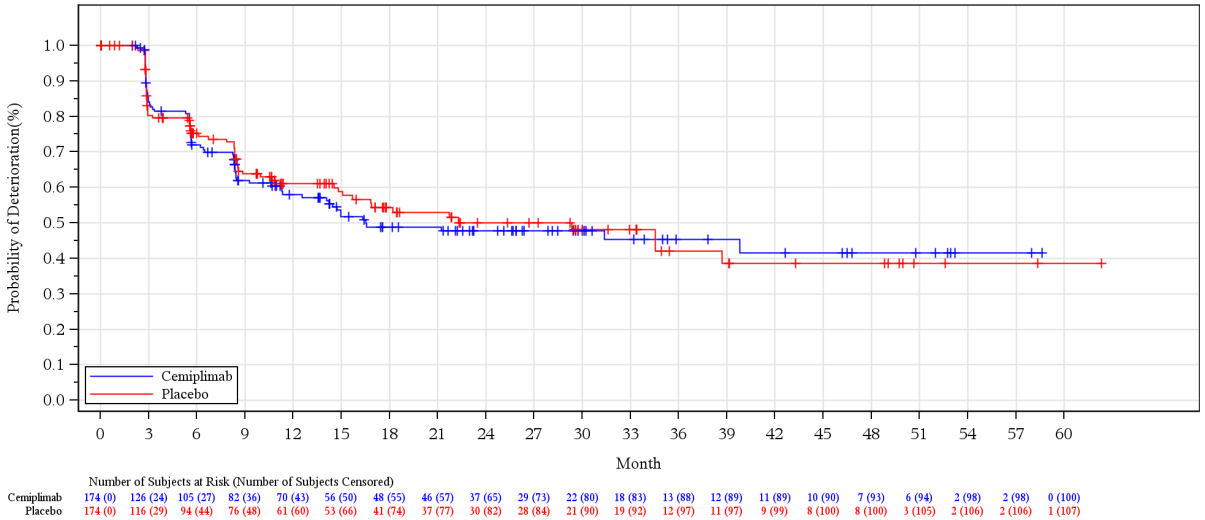
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Gender group: Male



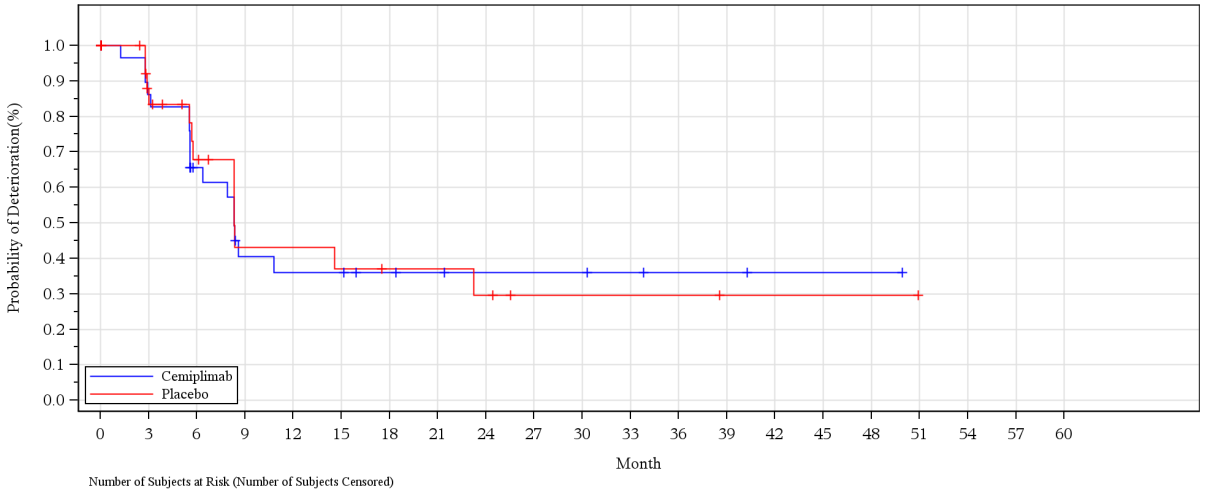
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	126 (24)	105 (27)	82 (36)	70 (43)	56 (50)	48 (55)	46 (57)	37 (65)	29 (73)	22 (80)	18 (83)	13 (88)	12 (89)	11 (89)	10 (90)	7 (93)	6 (94)	2 (98)	2 (98)	0 (100)
Placebo	174 (0)	116 (29)	94 (44)	76 (48)	61 (60)	53 (66)	41 (74)	37 (77)	30 (82)	28 (84)	21 (90)	19 (92)	12 (97)	11 (97)	9 (99)	8 (100)	8 (100)	3 (105)	2 (106)	2 (106)	1 (107)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Gender group: Female



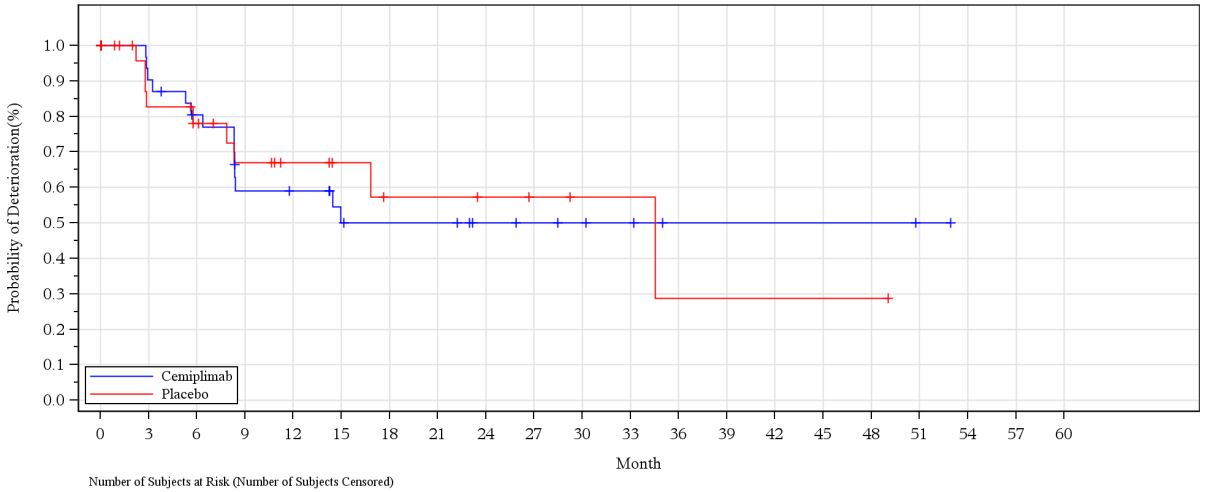
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	25 (6)	16 (9)	9 (10)	8 (10)	8 (10)	6 (12)	5 (13)	4 (14)	4 (14)	4 (14)	3 (15)	2 (16)	2 (16)	1 (17)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	32 (0)	20 (9)	13 (12)	7 (14)	7 (14)	6 (14)	5 (15)	5 (15)	4 (15)	2 (17)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



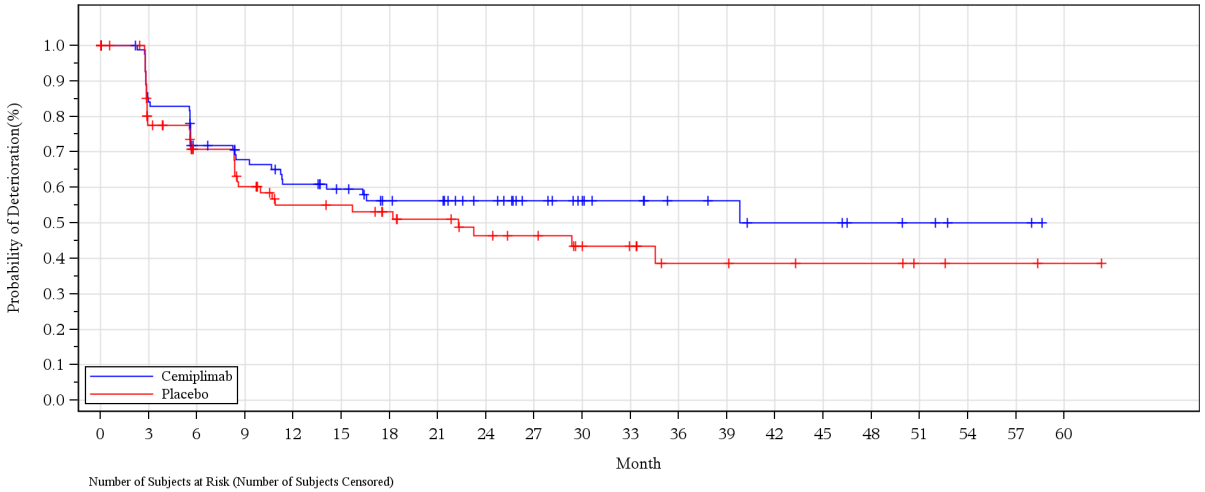
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	28 (6)	23 (8)	16 (9)	15 (10)	11 (12)	10 (13)	10 (13)	7 (16)	6 (17)	5 (18)	4 (19)	2 (21)	2 (21)	2 (21)	2 (21)	2 (21)	1 (22)	0 (23)	0 (23)	0 (23)
Placebo	31 (0)	19 (8)	16 (10)	12 (12)	9 (15)	7 (17)	5 (18)	5 (18)	4 (19)	3 (20)	2 (21)	2 (21)	1 (21)	1 (21)	1 (21)	1 (21)	1 (21)	0 (22)	0 (22)	0 (22)	0 (22)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



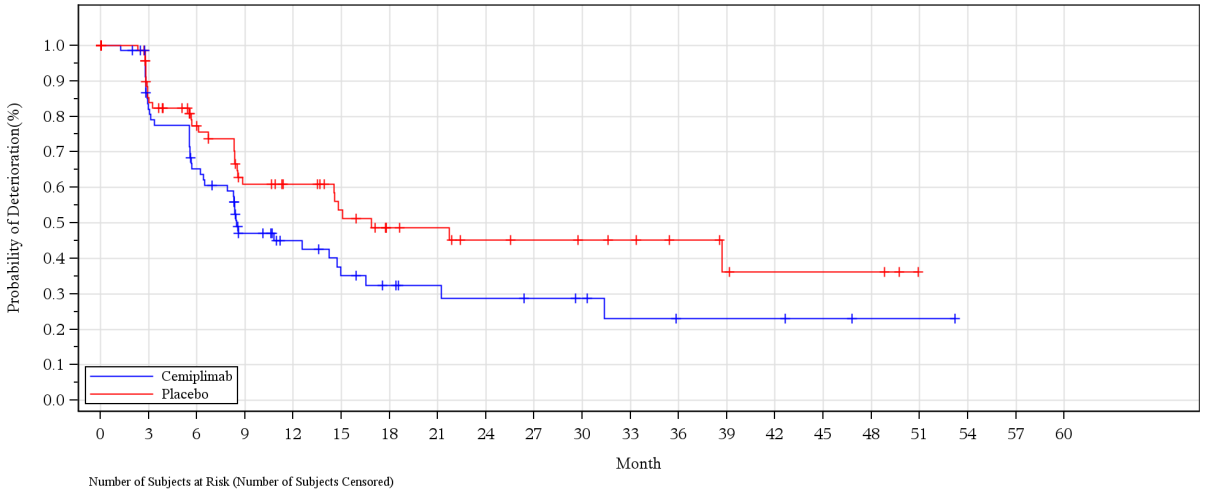
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	69 (8)	56 (11)	50 (14)	44 (15)	39 (19)	33 (23)	32 (24)	26 (30)	20 (36)	15 (41)	13 (43)	10 (46)	9 (47)	7 (48)	7 (48)	5 (50)	4 (51)	2 (53)	2 (53)	0 (55)
Placebo	90 (0)	60 (12)	47 (20)	39 (21)	31 (26)	30 (27)	26 (30)	23 (32)	19 (34)	17 (36)	12 (40)	11 (41)	7 (44)	7 (44)	6 (45)	5 (46)	5 (46)	3 (48)	2 (49)	2 (49)	1 (50)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



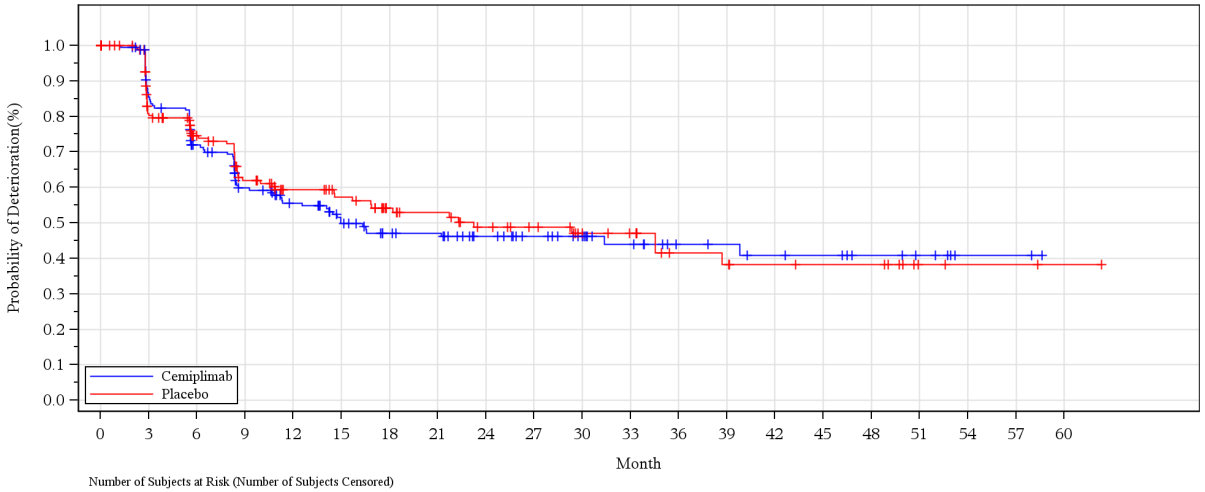
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	54 (16)	42 (17)	25 (23)	19 (28)	14 (29)	11 (31)	9 (33)	8 (33)	7 (34)	6 (35)	4 (36)	3 (37)	3 (37)	3 (37)	2 (38)	1 (39)	1 (39)	0 (40)	0 (40)	0 (40)
Placebo	85 (0)	57 (18)	44 (26)	32 (29)	28 (33)	22 (36)	15 (41)	14 (42)	11 (44)	10 (45)	9 (46)	8 (47)	6 (49)	4 (50)	3 (51)	3 (51)	3 (51)	0 (54)	0 (54)	0 (54)	0 (54)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	140 (25)	112 (31)	86 (39)	73 (46)	59 (53)	49 (60)	47 (62)	38 (70)	32 (76)	26 (82)	21 (86)	15 (92)	14 (93)	12 (94)	11 (95)	8 (98)	6 (100)	2 (104)	2 (104)	0 (106)
Placebo	189 (0)	123 (36)	97 (53)	76 (58)	62 (69)	56 (73)	44 (82)	40 (85)	33 (89)	29 (93)	22 (99)	20 (101)	13 (106)	12 (106)	10 (108)	9 (109)	9 (109)	3 (115)	2 (116)	2 (116)	1 (117)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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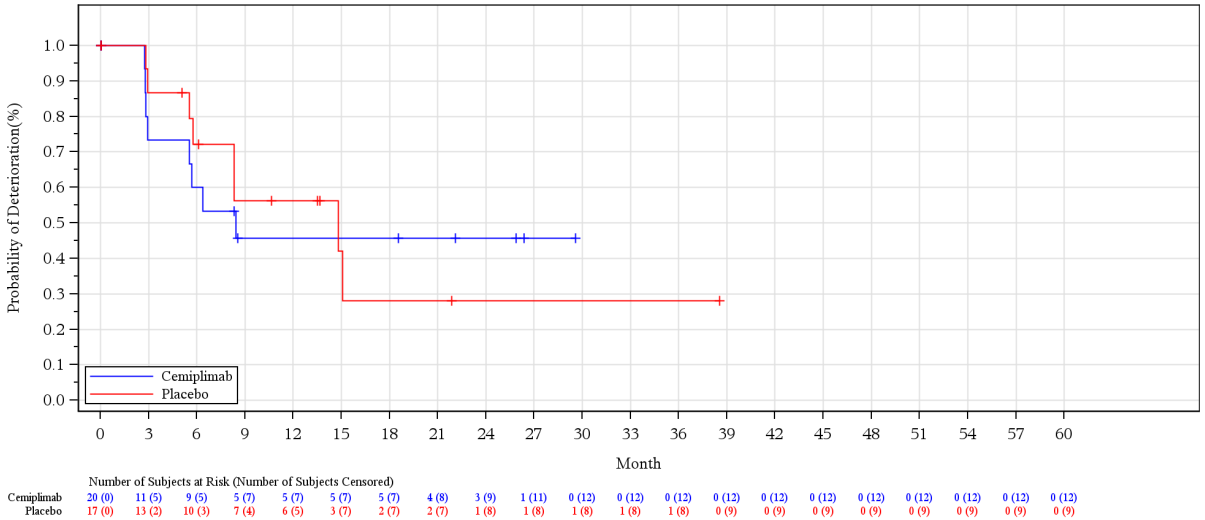
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (5)	9 (5)	5 (7)	5 (7)	5 (7)	5 (7)	4 (8)	3 (9)	1 (11)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)
Placebo	17 (0)	13 (2)	10 (3)	7 (4)	6 (5)	3 (7)	2 (7)	2 (7)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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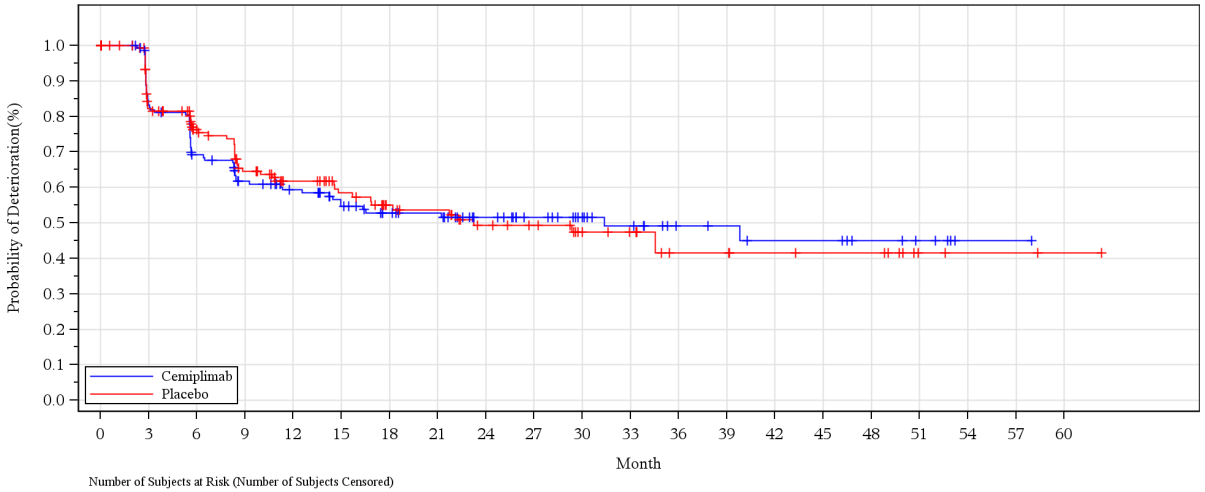
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	119 (23)	96 (26)	79 (33)	70 (39)	59 (45)	50 (52)	47 (55)	37 (64)	30 (71)	23 (78)	19 (81)	13 (87)	12 (88)	10 (89)	10 (89)	7 (92)	5 (94)	1 (98)	1 (98)	0 (99)
Placebo	177 (0)	118 (33)	94 (49)	75 (54)	61 (65)	52 (71)	42 (78)	39 (80)	31 (85)	28 (88)	21 (94)	19 (96)	12 (101)	12 (101)	10 (103)	9 (104)	9 (104)	3 (110)	2 (111)	2 (111)	1 (112)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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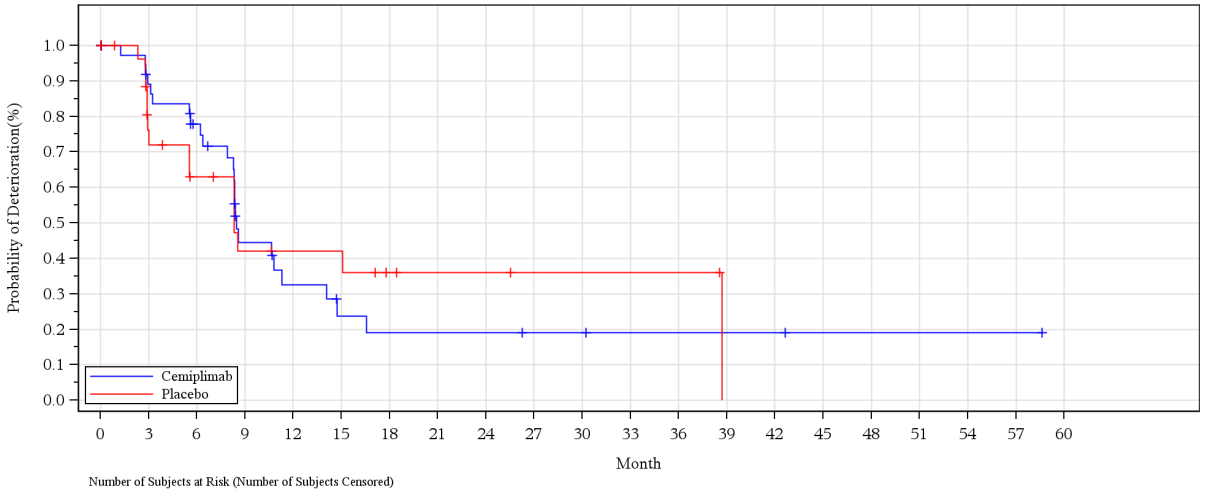
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	32 (7)	25 (10)	12 (13)	8 (14)	5 (15)	4 (15)	4 (15)	4 (15)	3 (16)	3 (16)	2 (17)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)
Placebo	29 (0)	18 (5)	13 (7)	8 (8)	7 (9)	7 (9)	4 (11)	3 (12)	3 (12)	2 (13)	2 (13)	2 (13)	2 (13)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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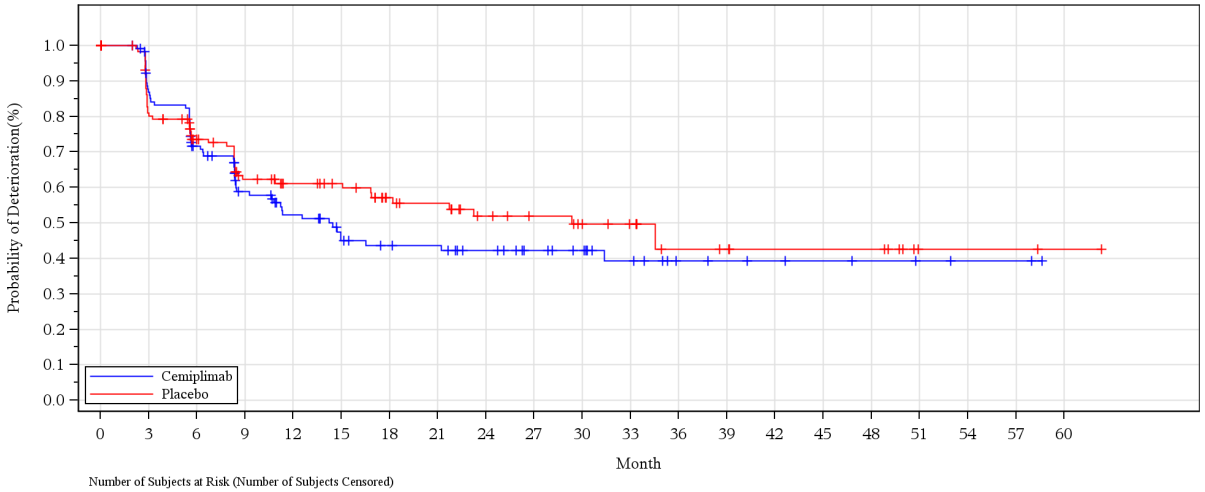
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



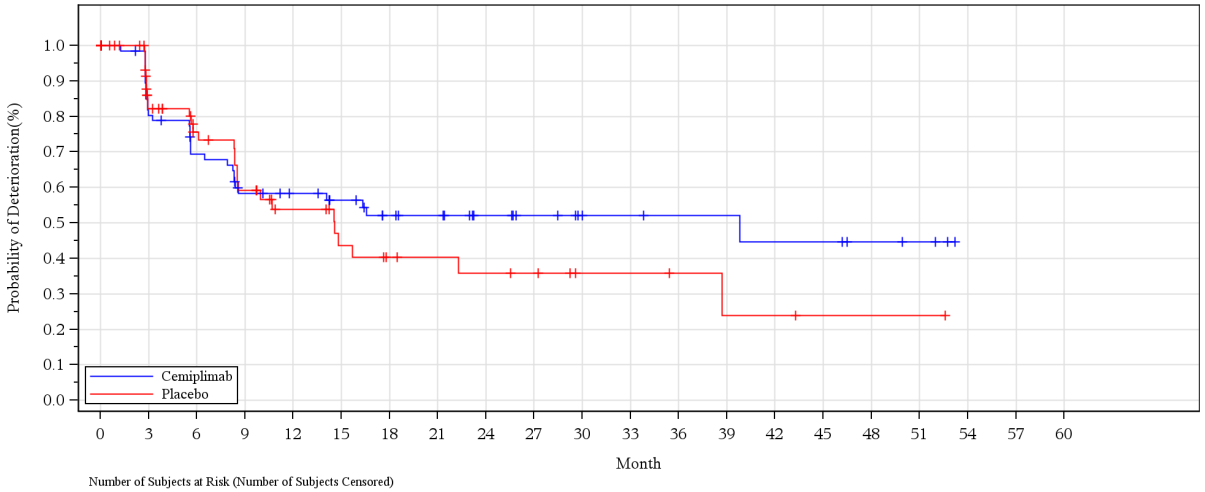
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	98 (20)	77 (24)	56 (32)	46 (36)	36 (40)	32 (43)	31 (44)	26 (48)	21 (53)	18 (56)	13 (60)	8 (65)	7 (66)	6 (67)	5 (68)	4 (69)	3 (70)	2 (71)	2 (71)	0 (73)
Placebo	131 (0)	93 (16)	74 (27)	58 (32)	50 (39)	46 (43)	36 (50)	33 (52)	26 (57)	23 (60)	19 (63)	17 (65)	11 (69)	10 (70)	8 (72)	8 (72)	8 (72)	2 (78)	2 (78)	2 (78)	1 (79)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



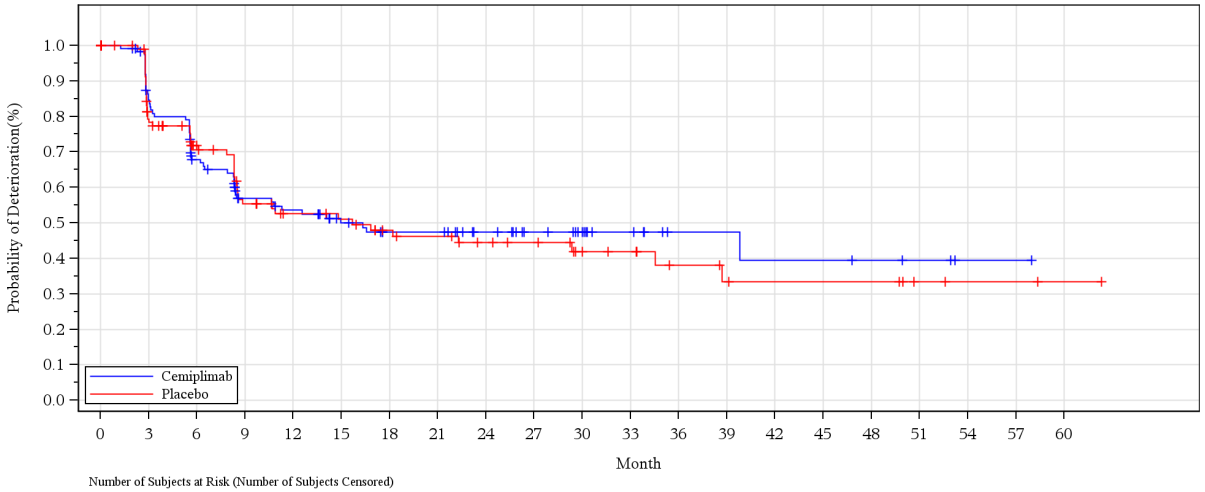
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	53 (10)	44 (12)	35 (14)	32 (17)	28 (20)	22 (24)	20 (26)	15 (31)	12 (34)	8 (38)	8 (38)	7 (39)	7 (39)	6 (39)	6 (39)	4 (41)	3 (42)	0 (45)	0 (45)	0 (45)
Placebo	75 (0)	43 (22)	33 (29)	25 (30)	18 (35)	13 (37)	10 (39)	9 (40)	8 (40)	7 (41)	4 (44)	4 (44)	3 (45)	2 (45)	2 (45)	1 (46)	1 (46)	1 (46)	0 (47)	0 (47)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	92 (16)	70 (20)	52 (27)	48 (28)	39 (34)	33 (38)	33 (38)	26 (45)	20 (51)	15 (56)	11 (60)	6 (65)	6 (65)	5 (65)	5 (65)	4 (66)	3 (67)	1 (69)	1 (69)	0 (70)
Placebo	117 (0)	78 (18)	59 (30)	43 (33)	36 (38)	34 (39)	28 (43)	26 (44)	22 (47)	20 (49)	14 (54)	13 (55)	9 (58)	7 (59)	6 (60)	6 (60)	6 (60)	3 (63)	2 (64)	2 (64)	1 (65)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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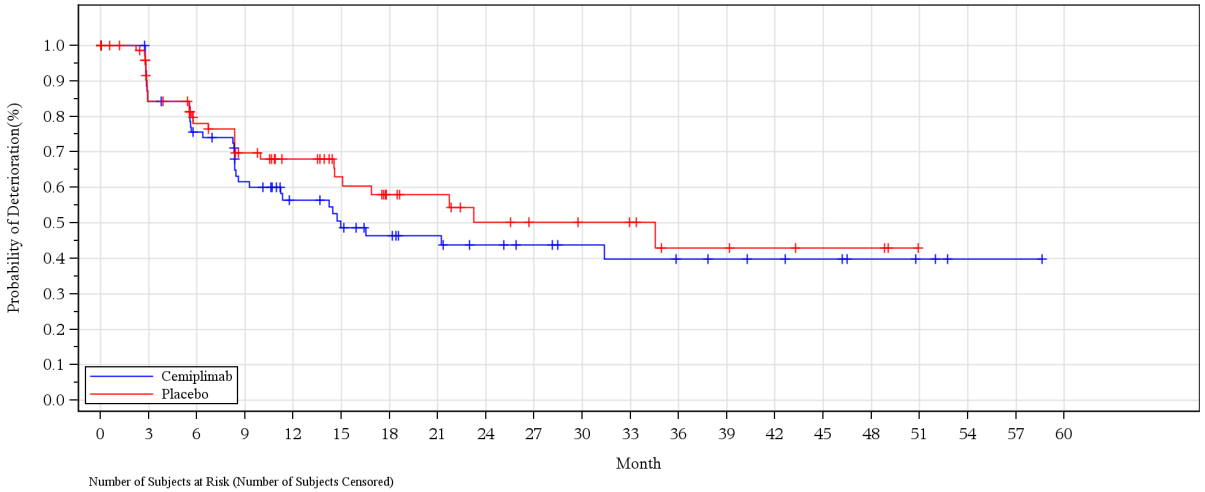
Figure 14.2.8.1.12 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Insomnia Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



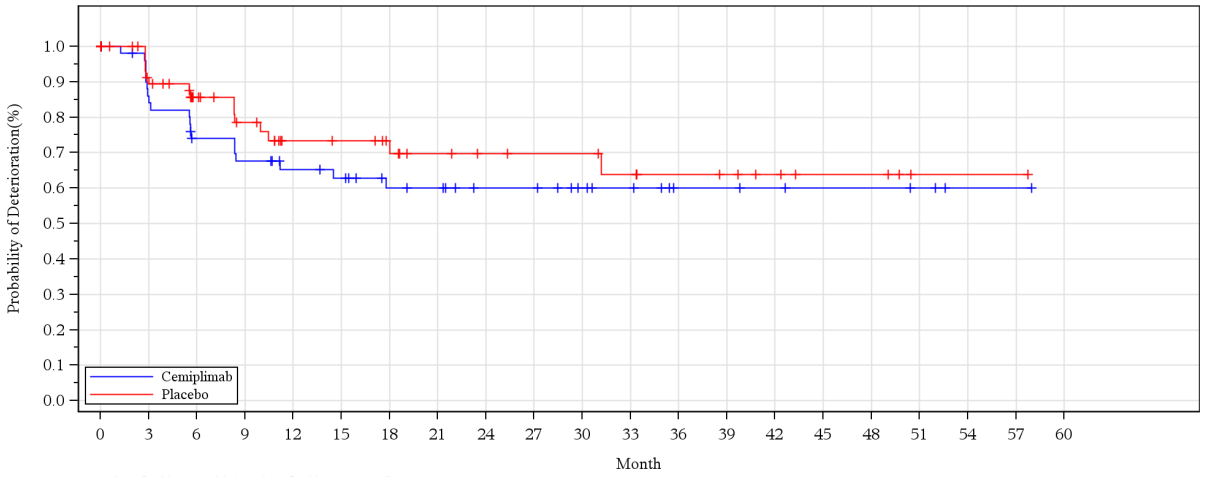
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	59 (14)	51 (16)	39 (19)	30 (25)	25 (26)	21 (29)	18 (32)	15 (34)	13 (36)	11 (38)	10 (38)	9 (39)	8 (40)	7 (41)	6 (42)	4 (44)	3 (45)	1 (47)	1 (47)	0 (48)
Placebo	89 (0)	58 (20)	48 (26)	40 (29)	32 (36)	25 (41)	18 (46)	16 (48)	12 (50)	10 (52)	9 (53)	8 (54)	5 (56)	5 (56)	4 (57)	3 (58)	3 (58)	0 (61)	0 (61)	0 (61)	0 (61)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



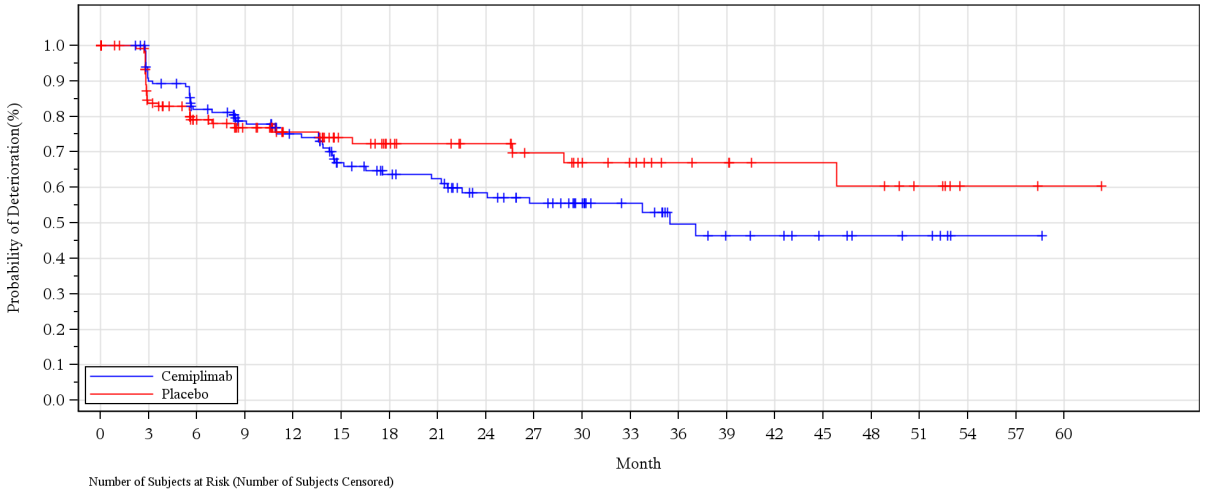
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	43 (6)	35 (8)	32 (8)	28 (11)	26 (12)	21 (16)	20 (17)	16 (21)	16 (21)	12 (25)	10 (27)	6 (31)	6 (31)	5 (32)	4 (33)	4 (33)	3 (34)	1 (36)	1 (36)	0 (37)
Placebo	65 (0)	51 (9)	39 (18)	32 (22)	24 (28)	23 (29)	20 (32)	16 (35)	14 (37)	13 (38)	13 (38)	11 (39)	9 (41)	8 (42)	6 (44)	4 (46)	4 (46)	1 (49)	1 (49)	1 (49)	0 (50)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	116 (24)	101 (29)	89 (37)	79 (43)	62 (52)	54 (57)	51 (59)	41 (66)	35 (70)	27 (78)	22 (83)	15 (88)	12 (90)	11 (91)	8 (94)	6 (96)	5 (97)	1 (101)	1 (101)	0 (102)
Placebo	141 (0)	95 (27)	77 (40)	66 (49)	53 (61)	43 (70)	36 (76)	33 (79)	30 (82)	25 (86)	20 (90)	18 (92)	14 (96)	13 (97)	10 (100)	10 (100)	9 (100)	6 (103)	2 (107)	2 (107)	1 (108)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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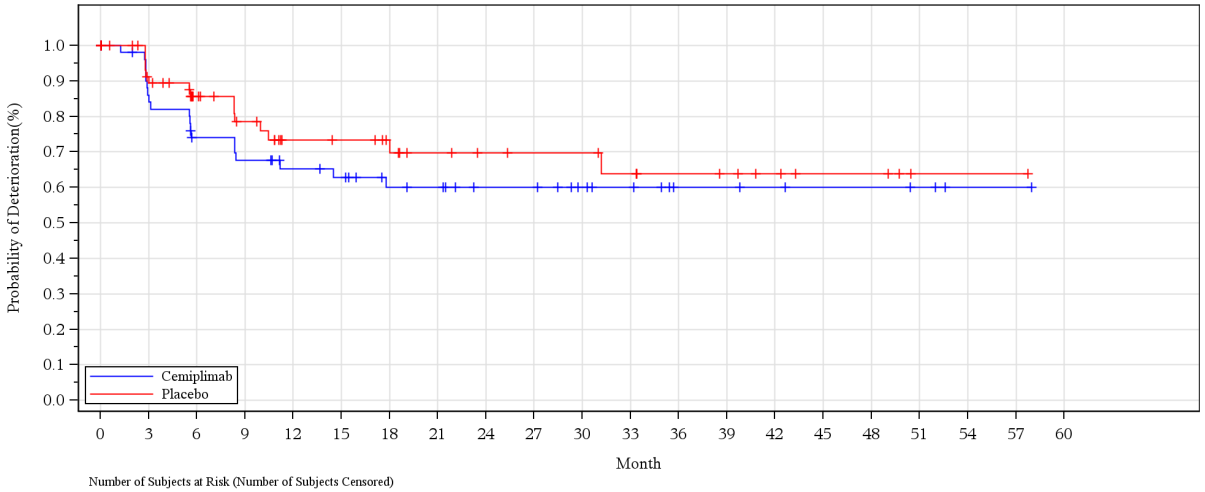
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



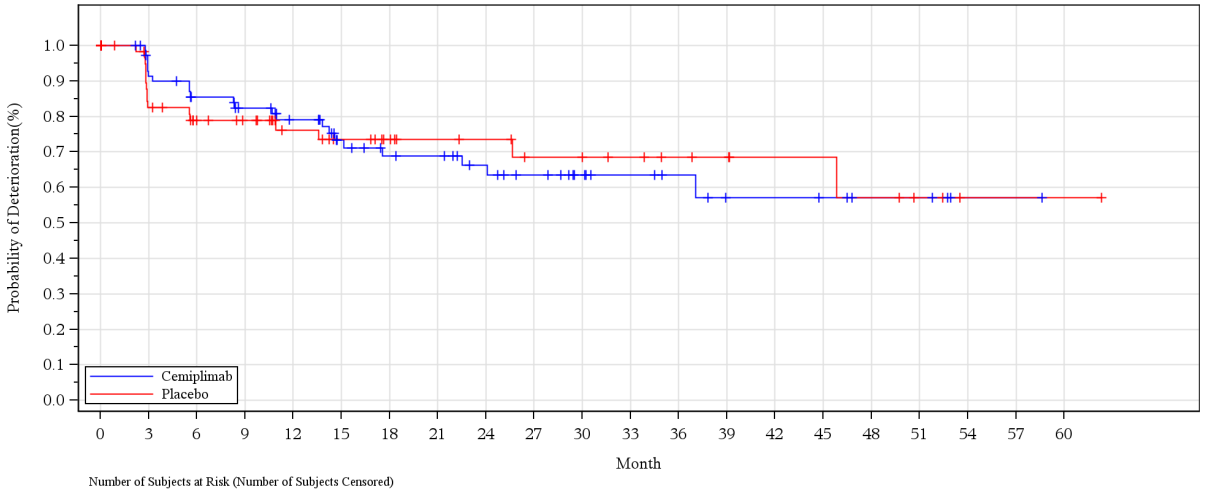
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	43 (6)	35 (8)	32 (8)	28 (11)	26 (12)	21 (16)	20 (17)	16 (21)	16 (21)	12 (25)	10 (27)	6 (31)	6 (31)	5 (32)	4 (33)	4 (33)	3 (34)	1 (36)	1 (36)	0 (37)
Placebo	65 (0)	51 (9)	39 (18)	32 (22)	24 (28)	23 (29)	20 (32)	16 (35)	14 (37)	13 (38)	13 (38)	11 (39)	9 (41)	8 (42)	6 (44)	4 (46)	4 (46)	1 (49)	1 (49)	1 (49)	0 (50)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



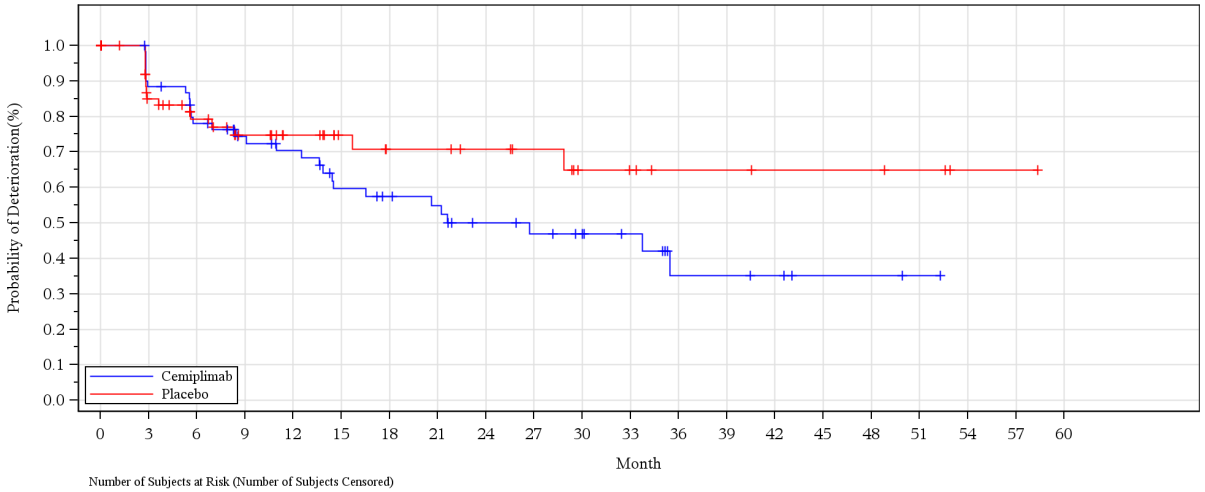
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	63 (11)	56 (14)	51 (17)	45 (21)	35 (28)	30 (31)	29 (32)	24 (36)	20 (39)	15 (44)	12 (47)	10 (49)	7 (51)	7 (51)	6 (52)	4 (54)	4 (54)	1 (57)	1 (57)	0 (58)
Placebo	69 (0)	47 (12)	39 (18)	36 (21)	28 (28)	24 (31)	20 (35)	17 (38)	16 (39)	13 (41)	12 (42)	11 (43)	9 (45)	8 (46)	6 (48)	6 (48)	5 (48)	3 (50)	1 (52)	1 (52)	1 (52)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	53 (13)	45 (15)	38 (20)	34 (22)	27 (24)	24 (26)	22 (27)	17 (30)	15 (31)	12 (34)	10 (36)	5 (39)	5 (39)	4 (40)	2 (42)	2 (42)	1 (43)	0 (44)	0 (44)	0 (44)
Placebo	72 (0)	48 (15)	38 (22)	30 (28)	25 (33)	19 (39)	16 (41)	16 (41)	14 (43)	12 (45)	8 (48)	7 (49)	5 (51)	5 (51)	4 (52)	4 (52)	4 (52)	3 (53)	1 (55)	1 (55)	0 (56)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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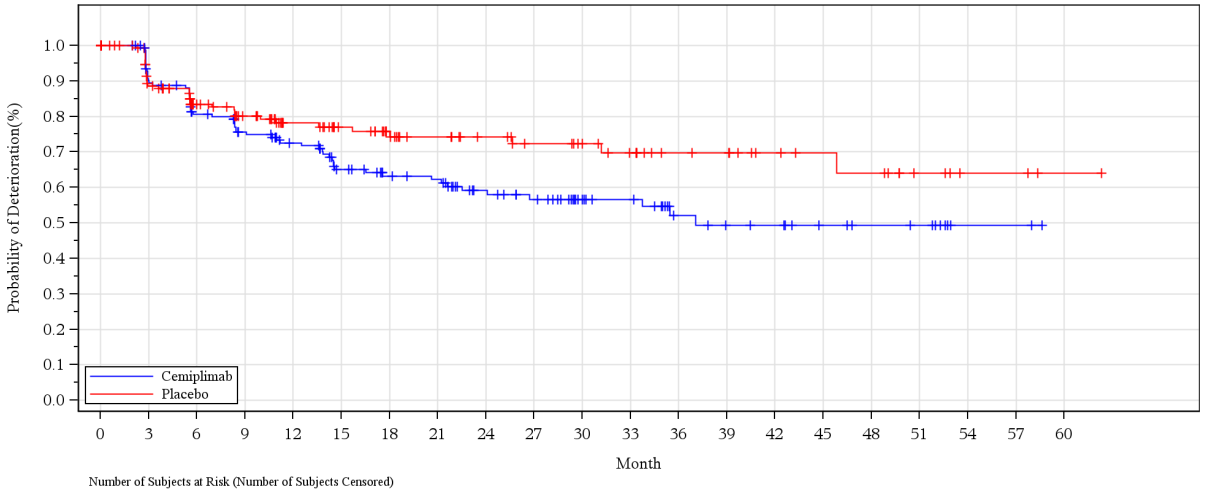
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	135 (24)	116 (29)	103 (35)	92 (42)	75 (50)	66 (57)	63 (59)	50 (69)	44 (73)	32 (85)	29 (88)	19 (96)	16 (98)	15 (99)	11 (103)	9 (105)	8 (106)	2 (112)	2 (112)	0 (114)
Placebo	174 (0)	129 (28)	103 (47)	89 (57)	70 (74)	60 (83)	51 (91)	44 (97)	39 (102)	34 (106)	30 (110)	26 (113)	20 (119)	19 (120)	14 (125)	12 (127)	11 (127)	6 (132)	3 (135)	3 (135)	1 (137)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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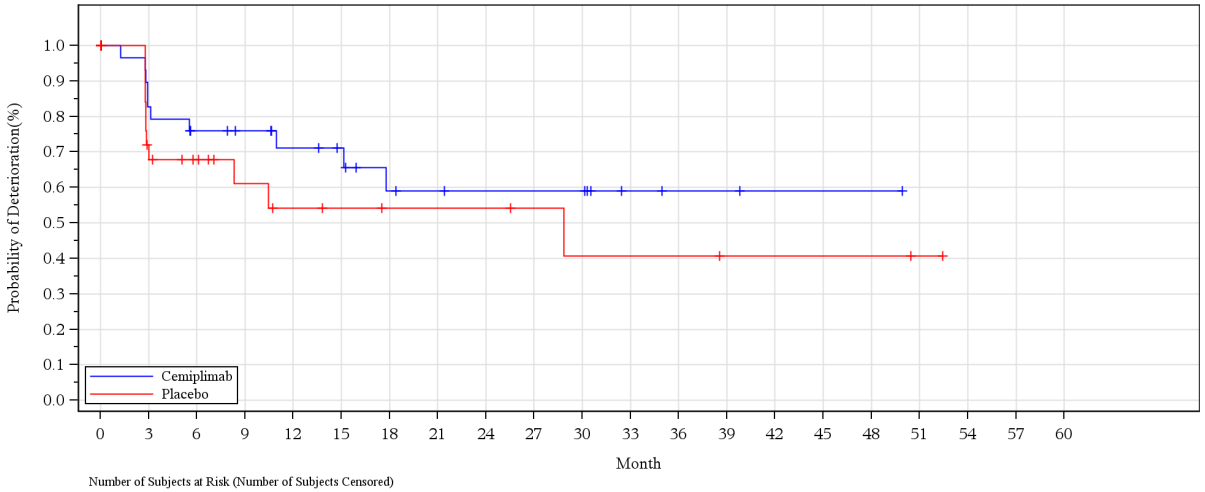
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	24 (6)	20 (8)	18 (10)	15 (12)	13 (14)	9 (16)	8 (17)	7 (18)	7 (18)	7 (18)	3 (22)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)	0 (25)	0 (25)	0 (25)
Placebo	32 (0)	17 (8)	13 (11)	9 (14)	7 (15)	6 (16)	5 (17)	5 (17)	5 (17)	4 (18)	3 (18)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	0 (21)	0 (21)	0 (21)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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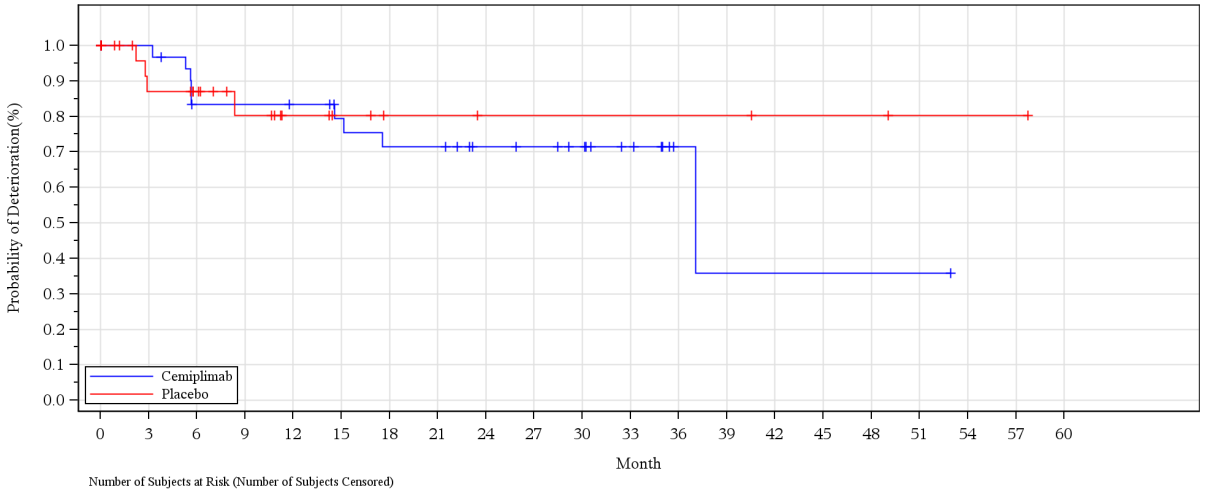
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	31 (6)	24 (8)	24 (8)	23 (9)	20 (11)	18 (11)	18 (11)	14 (15)	13 (16)	11 (18)	7 (22)	2 (27)	1 (27)	1 (27)	1 (27)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)
Placebo	31 (0)	20 (8)	17 (11)	12 (15)	8 (19)	6 (21)	4 (23)	4 (23)	3 (24)	3 (24)	3 (24)	3 (24)	3 (24)	3 (24)	2 (25)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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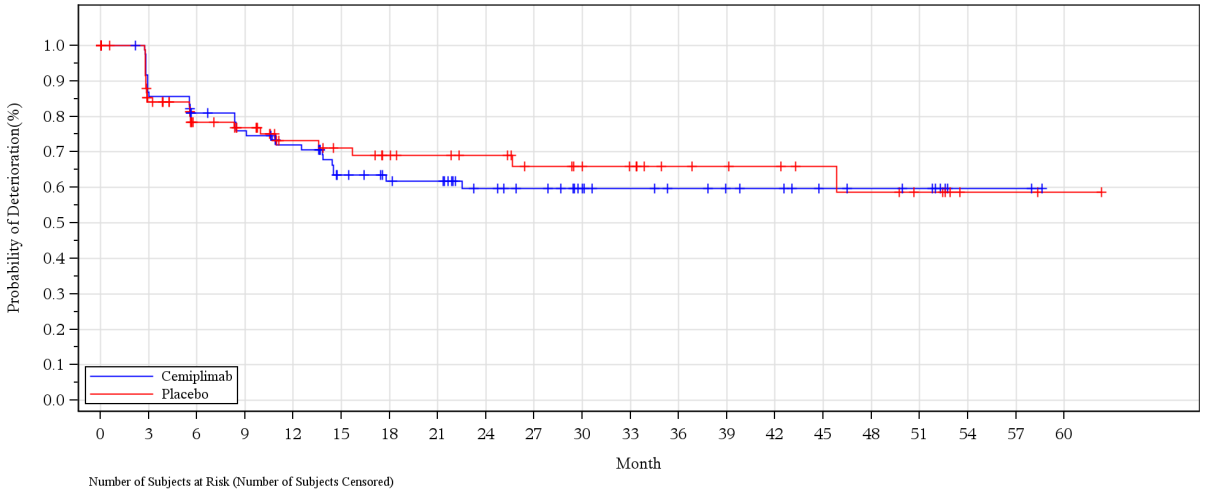
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	73 (6)	65 (9)	60 (10)	54 (13)	42 (19)	37 (23)	36 (24)	28 (31)	25 (34)	19 (40)	17 (42)	15 (44)	13 (46)	12 (47)	9 (50)	8 (51)	7 (52)	2 (57)	2 (57)	0 (59)
Placebo	90 (0)	66 (11)	51 (22)	46 (26)	36 (34)	33 (36)	29 (39)	27 (41)	25 (43)	21 (46)	18 (49)	17 (50)	13 (54)	12 (55)	11 (56)	9 (58)	8 (58)	6 (60)	2 (64)	2 (64)	1 (65)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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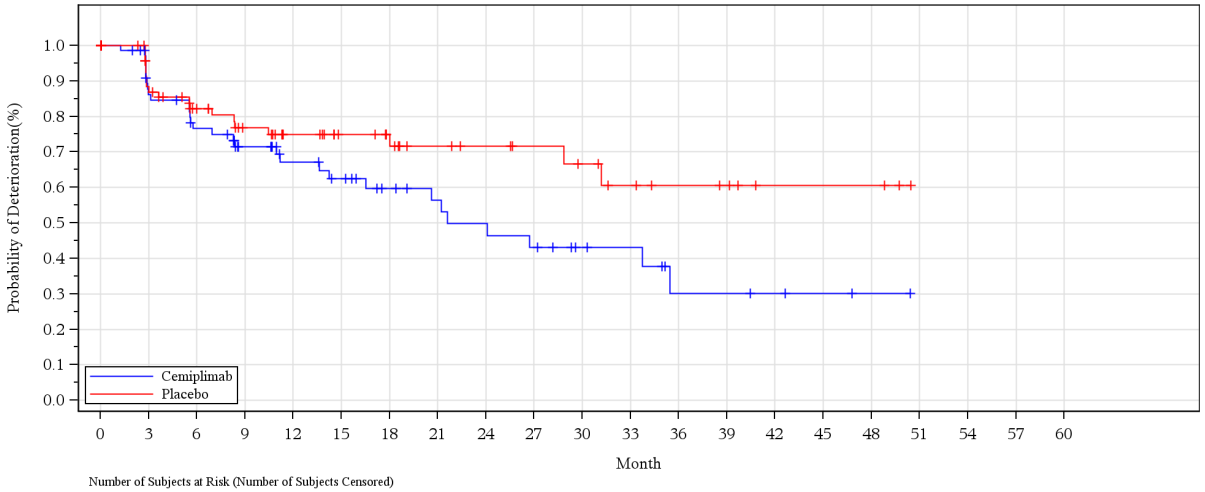
Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



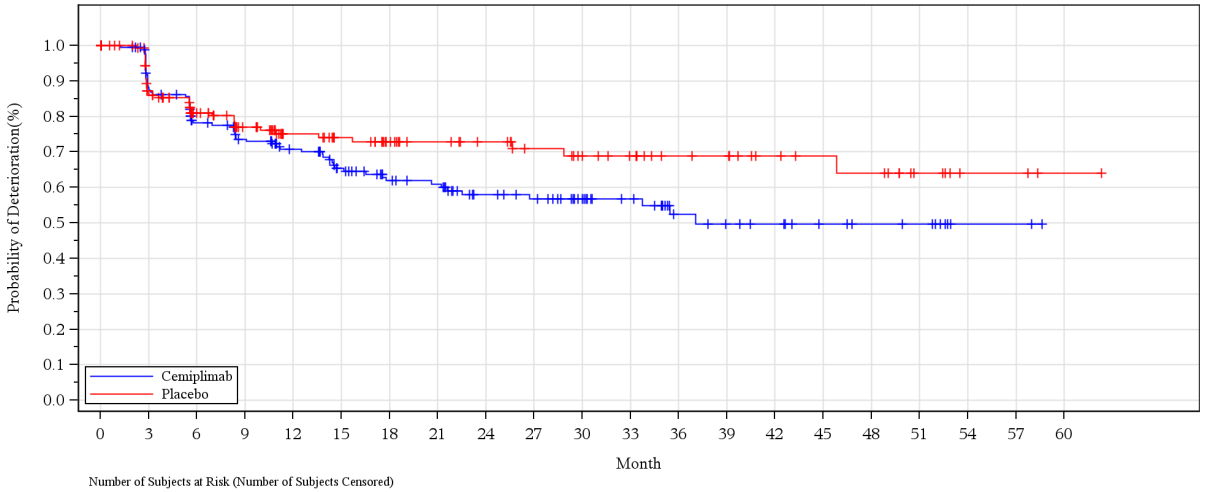
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	55 (18)	47 (20)	37 (27)	30 (32)	26 (34)	20 (39)	17 (41)	15 (41)	13 (41)	9 (45)	8 (46)	4 (48)	4 (48)	3 (49)	2 (50)	1 (51)	0 (52)	0 (52)	0 (52)	0 (52)
Placebo	85 (0)	60 (17)	48 (25)	40 (30)	33 (36)	27 (42)	23 (46)	18 (50)	16 (52)	14 (54)	12 (55)	9 (57)	7 (59)	6 (60)	3 (63)	3 (63)	3 (63)	0 (66)	0 (66)	0 (66)	0 (66)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Race: White



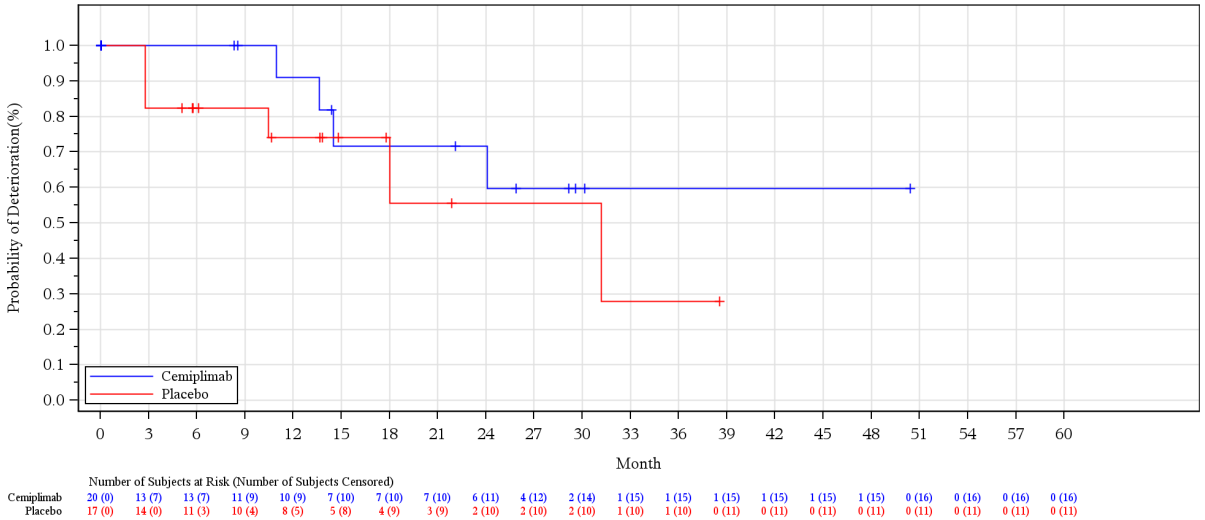
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	146 (23)	123 (30)	110 (36)	97 (45)	81 (54)	68 (63)	64 (66)	51 (76)	47 (79)	37 (89)	31 (95)	20 (104)	17 (106)	15 (108)	11 (112)	9 (114)	8 (115)	2 (121)	2 (121)	0 (123)
Placebo	189 (0)	132 (36)	105 (55)	88 (67)	69 (84)	61 (91)	52 (99)	46 (105)	42 (109)	36 (114)	31 (118)	28 (121)	22 (127)	21 (128)	16 (133)	14 (135)	13 (135)	7 (141)	3 (145)	3 (145)	1 (147)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Race: Non-white



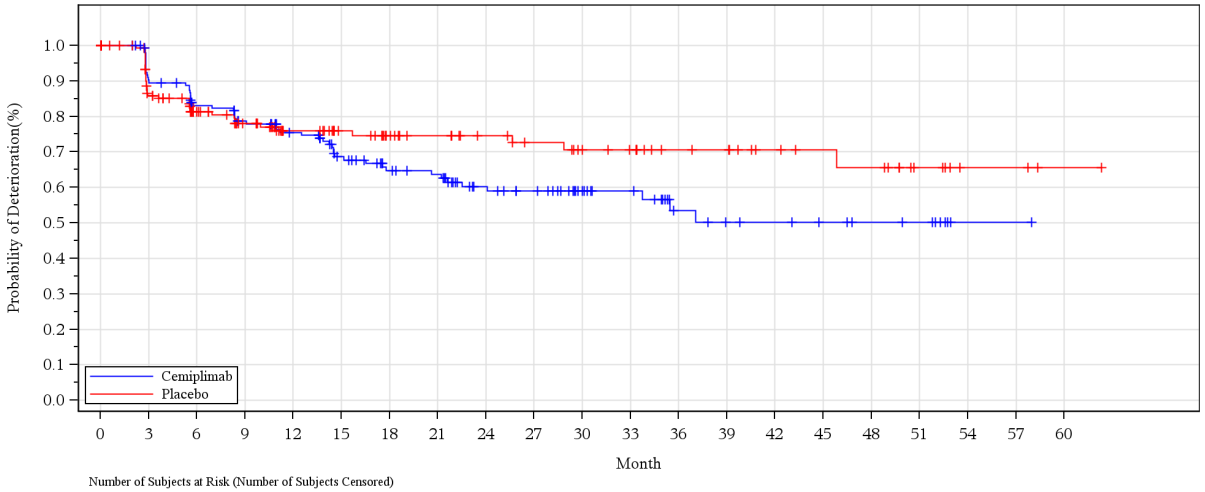
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	13 (7)	13 (7)	11 (9)	10 (9)	7 (10)	7 (10)	7 (10)	6 (11)	4 (12)	2 (14)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	17 (0)	14 (0)	11 (3)	10 (4)	8 (5)	5 (8)	4 (9)	3 (9)	2 (10)	2 (10)	2 (10)	1 (10)	1 (10)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



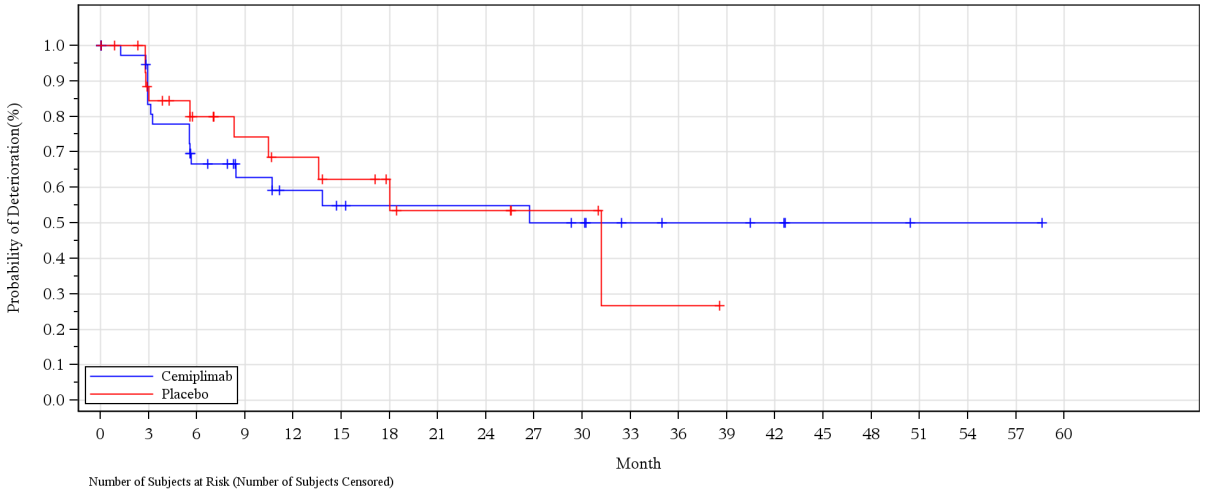
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	129 (23)	114 (28)	104 (32)	93 (39)	76 (48)	64 (56)	60 (59)	46 (70)	41 (74)	30 (85)	26 (89)	16 (97)	13 (99)	12 (100)	10 (102)	8 (104)	7 (105)	1 (111)	1 (111)	0 (112)
Placebo	177 (0)	124 (32)	100 (50)	85 (61)	66 (78)	57 (87)	49 (94)	44 (99)	39 (104)	35 (107)	30 (111)	28 (113)	22 (119)	21 (120)	16 (125)	14 (127)	13 (127)	7 (133)	3 (137)	3 (137)	1 (139)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



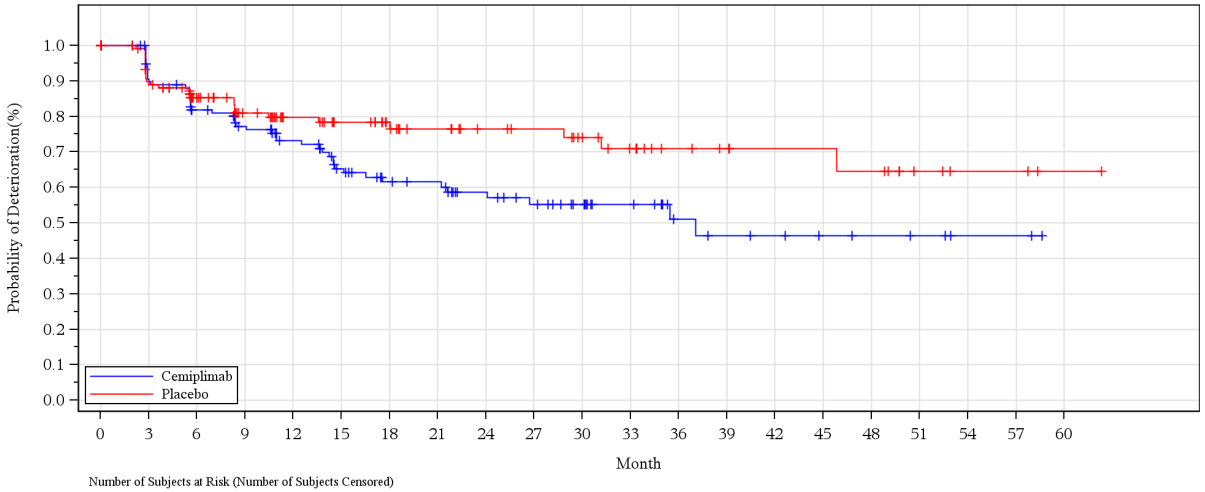
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	30 (7)	22 (9)	17 (13)	14 (15)	12 (16)	11 (17)	11 (17)	11 (17)	10 (17)	9 (18)	6 (21)	5 (22)	5 (22)	4 (23)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)
Placebo	29 (0)	22 (4)	16 (8)	13 (10)	11 (11)	9 (12)	7 (14)	5 (15)	5 (15)	3 (17)	3 (17)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



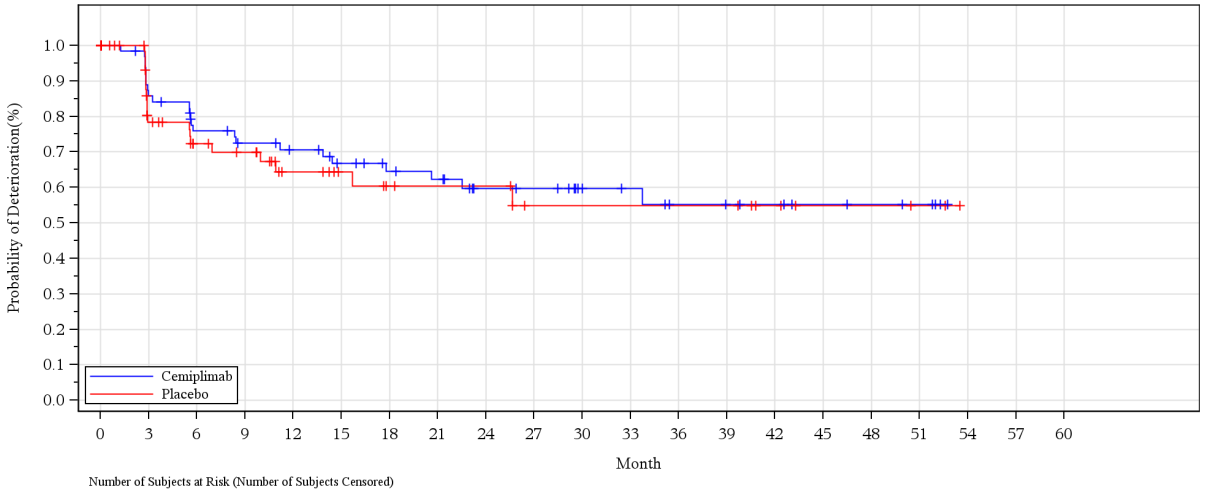
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	105 (17)	91 (21)	80 (27)	69 (34)	55 (41)	46 (47)	44 (49)	36 (55)	31 (58)	25 (64)	19 (70)	11 (77)	9 (78)	8 (79)	6 (81)	5 (82)	4 (83)	2 (85)	2 (85)	0 (87)
Placebo	131 (0)	105 (14)	84 (30)	69 (41)	57 (52)	50 (58)	43 (65)	37 (70)	32 (75)	30 (77)	25 (81)	21 (84)	15 (90)	13 (92)	11 (94)	11 (94)	10 (94)	5 (99)	3 (101)	3 (101)	1 (103)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



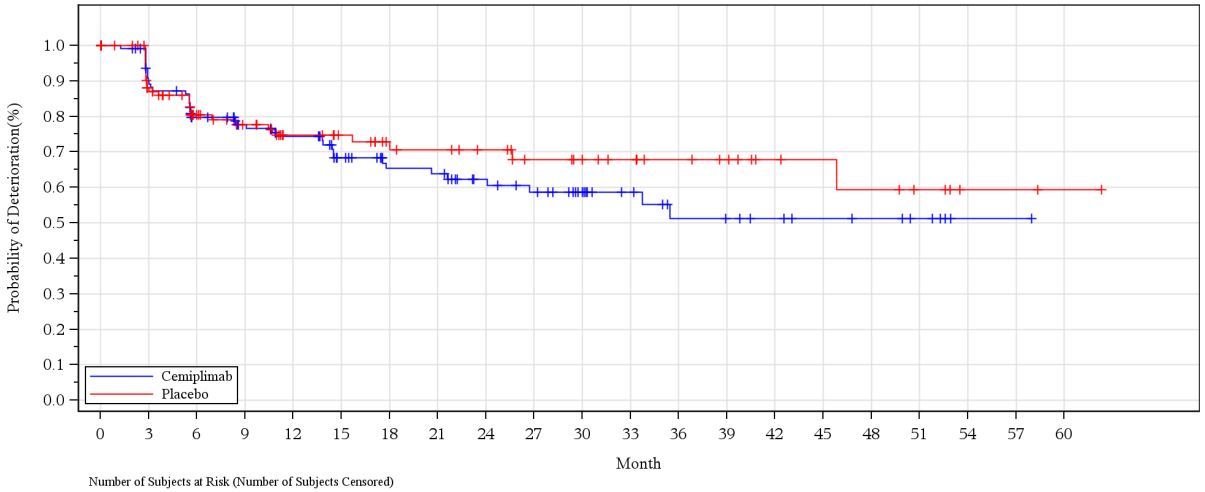
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	54 (13)	45 (16)	41 (18)	38 (20)	33 (23)	29 (26)	27 (27)	21 (32)	20 (33)	14 (39)	13 (40)	10 (42)	9 (43)	8 (44)	6 (46)	5 (47)	4 (48)	0 (52)	0 (52)	0 (52)
Placebo	75 (0)	41 (22)	32 (28)	29 (30)	20 (37)	16 (41)	13 (43)	12 (44)	12 (44)	8 (47)	8 (47)	8 (47)	8 (47)	8 (47)	5 (50)	3 (52)	3 (52)	2 (53)	0 (55)	0 (55)	0 (55)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



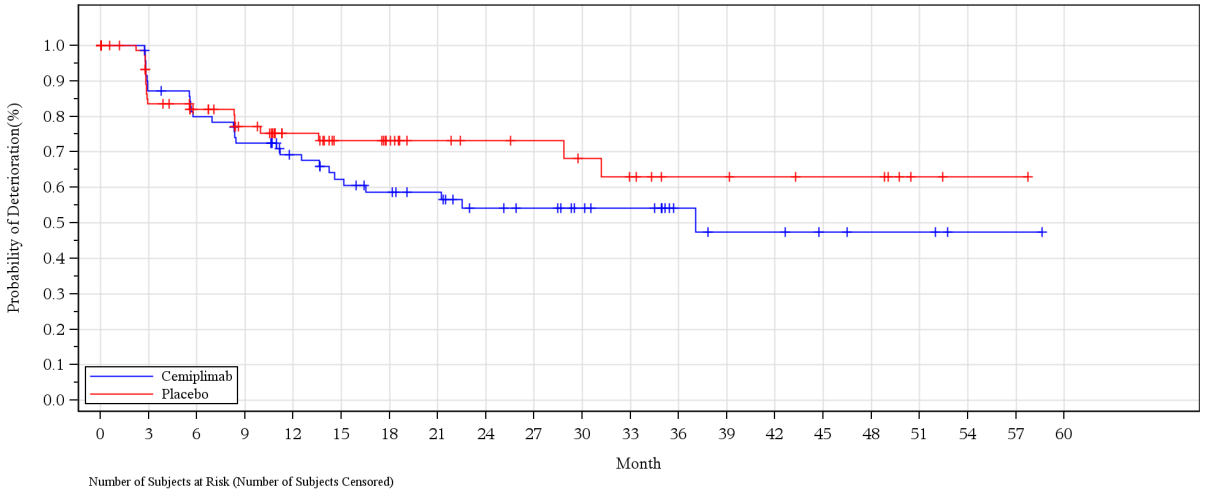
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	98 (16)	81 (22)	72 (29)	66 (32)	53 (40)	44 (47)	43 (47)	35 (54)	31 (56)	23 (64)	18 (69)	13 (72)	12 (73)	10 (75)	8 (77)	7 (78)	5 (80)	1 (84)	1 (84)	0 (85)
Placebo	117 (0)	86 (19)	63 (35)	54 (42)	43 (51)	39 (55)	33 (60)	31 (61)	28 (64)	23 (68)	20 (71)	18 (73)	15 (76)	13 (78)	9 (82)	8 (83)	7 (83)	5 (85)	2 (88)	2 (88)	1 (89)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.13 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Appetite Loss Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



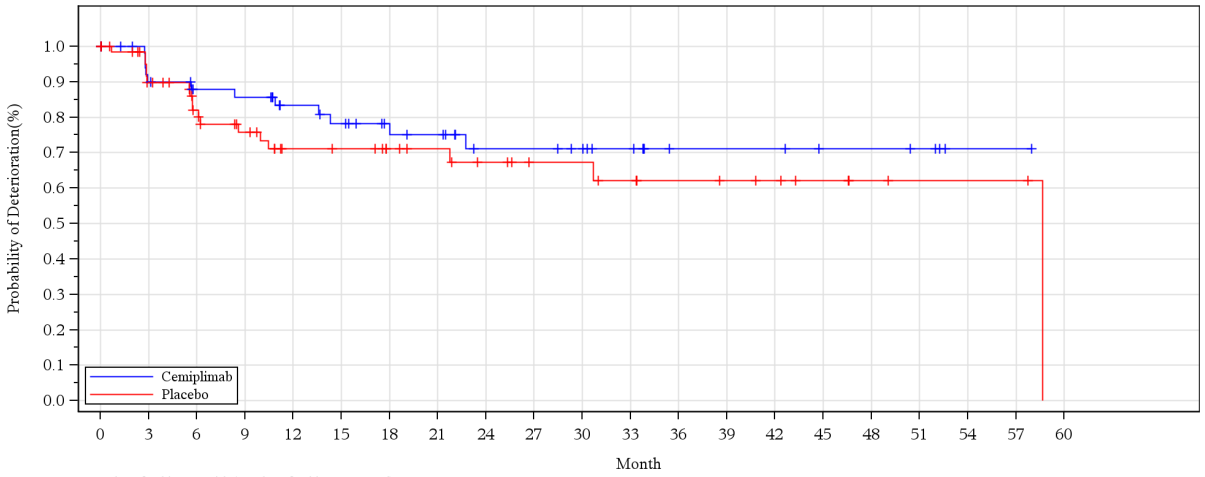
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	61 (14)	55 (15)	49 (16)	41 (22)	35 (24)	31 (26)	28 (29)	22 (33)	20 (35)	16 (39)	14 (41)	8 (47)	6 (48)	6 (48)	4 (50)	3 (51)	3 (51)	1 (53)	1 (53)	0 (54)
Placebo	89 (0)	60 (17)	53 (23)	44 (29)	34 (38)	27 (44)	23 (48)	18 (53)	16 (55)	15 (56)	13 (57)	11 (58)	8 (61)	8 (61)	7 (62)	6 (63)	6 (63)	2 (67)	1 (68)	1 (68)	0 (69)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



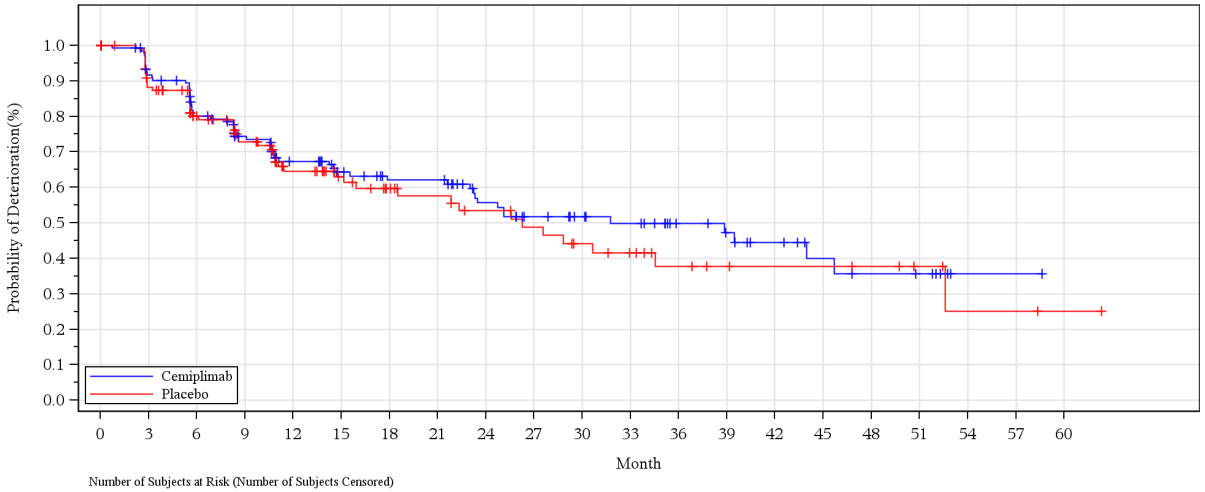
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	45 (6)	40 (10)	39 (10)	33 (15)	30 (16)	25 (21)	23 (22)	17 (27)	17 (27)	15 (29)	12 (32)	7 (37)	7 (37)	7 (37)	5 (39)	5 (39)	4 (40)	1 (43)	1 (43)	0 (44)
Placebo	65 (0)	51 (8)	41 (14)	34 (18)	26 (24)	25 (25)	21 (29)	19 (31)	16 (33)	13 (36)	13 (36)	11 (37)	9 (39)	8 (40)	7 (41)	5 (43)	3 (45)	2 (46)	2 (46)	2 (46)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	121 (21)	102 (25)	86 (34)	72 (40)	61 (48)	54 (53)	54 (53)	42 (60)	35 (64)	31 (68)	28 (70)	20 (78)	17 (80)	13 (83)	9 (86)	7 (87)	6 (88)	1 (93)	1 (93)	0 (94)
Placebo	141 (0)	104 (23)	82 (36)	68 (43)	49 (55)	39 (64)	32 (69)	28 (72)	24 (74)	21 (75)	17 (77)	14 (79)	10 (82)	8 (84)	7 (85)	7 (85)	6 (86)	4 (88)	2 (89)	2 (89)	1 (90)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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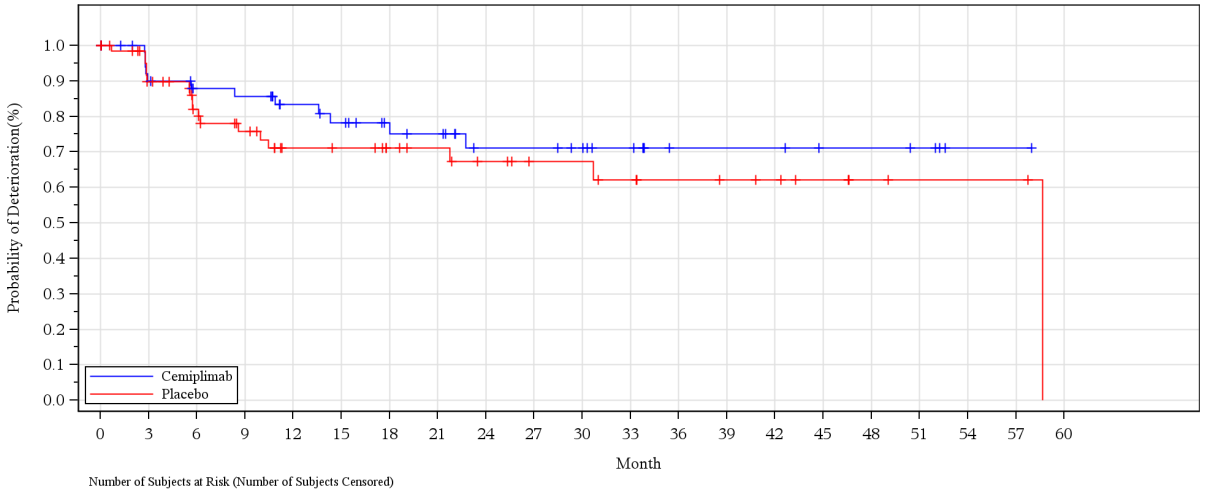
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



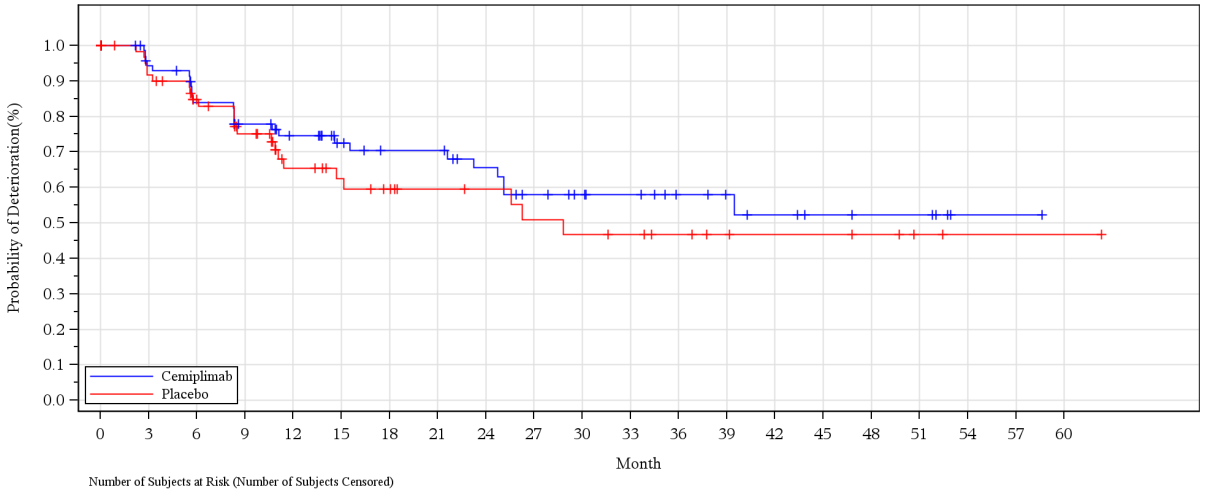
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	45 (6)	40 (10)	39 (10)	33 (15)	30 (16)	25 (21)	23 (22)	17 (27)	17 (27)	15 (29)	12 (32)	7 (37)	7 (37)	7 (37)	5 (39)	5 (39)	4 (40)	1 (43)	1 (43)	0 (44)
Placebo	65 (0)	51 (8)	41 (14)	34 (18)	26 (24)	25 (25)	21 (29)	19 (31)	16 (33)	13 (36)	13 (36)	11 (37)	9 (39)	8 (40)	7 (41)	5 (43)	3 (45)	2 (46)	2 (46)	2 (46)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



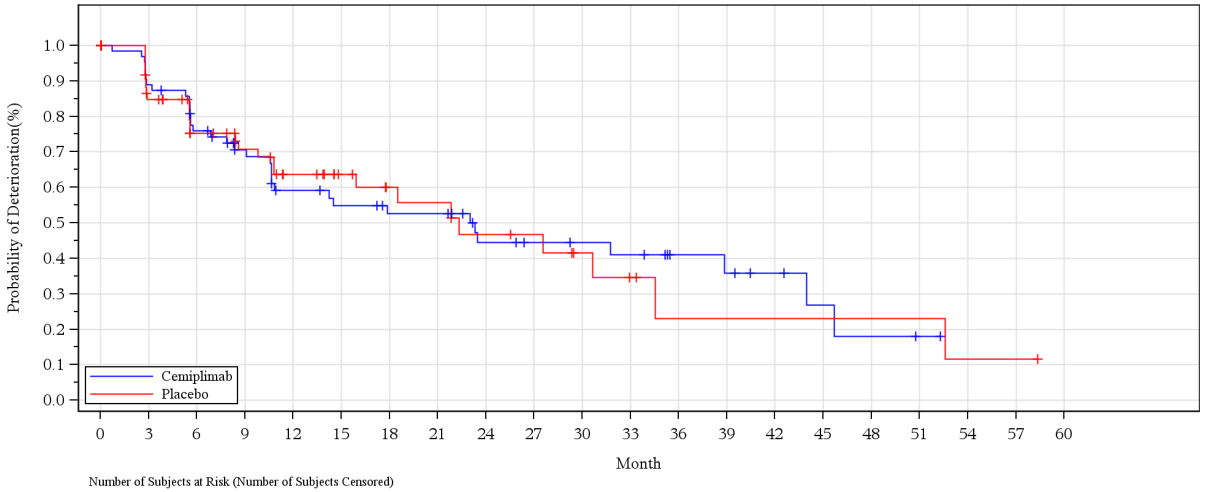
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	65 (11)	56 (13)	49 (16)	43 (20)	35 (27)	31 (30)	31 (30)	26 (33)	21 (35)	18 (38)	16 (40)	12 (44)	10 (46)	8 (47)	6 (49)	5 (50)	5 (50)	1 (54)	1 (54)	0 (55)
Placebo	69 (0)	55 (9)	45 (15)	37 (18)	25 (26)	21 (29)	18 (31)	15 (34)	14 (35)	12 (35)	11 (35)	10 (36)	8 (38)	6 (40)	5 (41)	5 (41)	4 (42)	2 (44)	1 (45)	1 (45)	1 (45)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



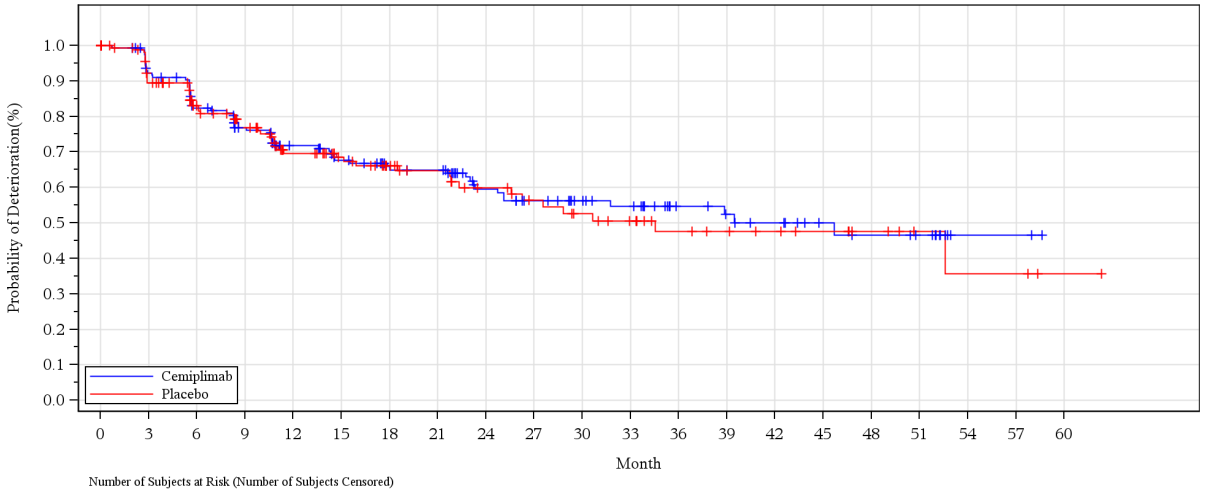
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	56 (10)	46 (12)	37 (18)	29 (20)	26 (21)	23 (23)	23 (23)	16 (27)	14 (29)	13 (30)	12 (30)	8 (34)	7 (34)	5 (36)	3 (37)	2 (37)	1 (38)	0 (39)	0 (39)	0 (39)
Placebo	72 (0)	49 (14)	37 (21)	31 (25)	24 (29)	18 (35)	14 (38)	13 (38)	10 (39)	9 (40)	6 (42)	4 (43)	2 (44)	2 (44)	2 (44)	2 (44)	2 (44)	2 (44)	1 (44)	1 (44)	0 (45)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Gender group: Male



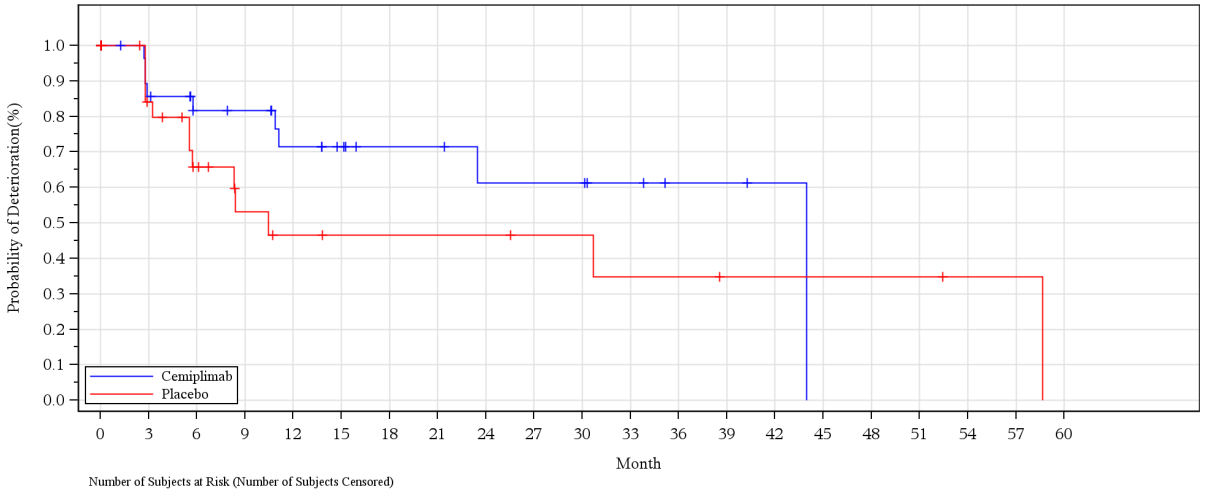
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	142 (20)	123 (24)	107 (32)	91 (41)	80 (47)	71 (54)	69 (55)	53 (66)	46 (70)	40 (76)	36 (79)	25 (90)	22 (92)	19 (94)	14 (99)	12 (100)	10 (102)	2 (110)	2 (110)	0 (112)
Placebo	174 (0)	135 (23)	110 (39)	94 (47)	69 (64)	59 (73)	48 (82)	42 (87)	35 (91)	30 (94)	26 (96)	22 (99)	16 (104)	14 (106)	12 (108)	10 (110)	7 (113)	4 (116)	3 (116)	3 (116)	1 (118)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Gender group: Female



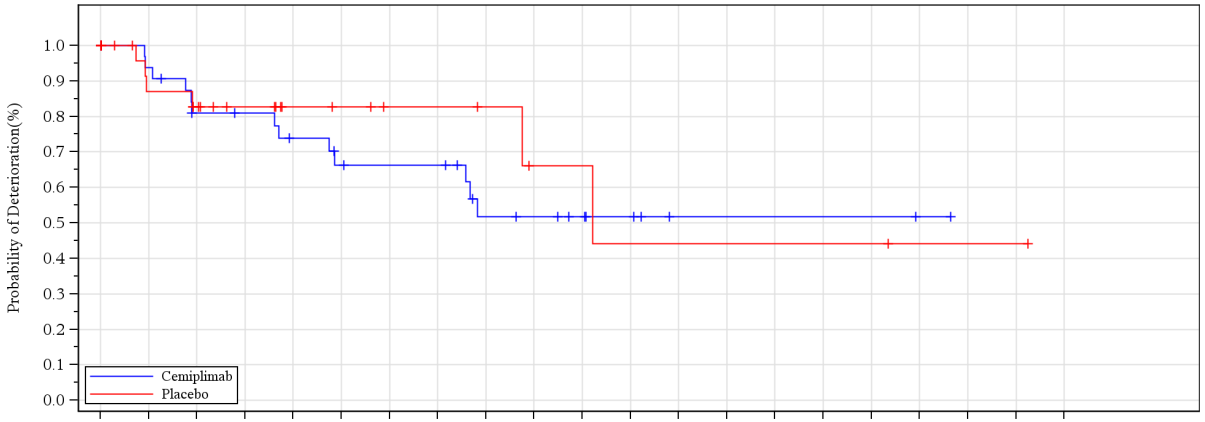
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	24 (7)	19 (11)	18 (12)	14 (14)	11 (17)	8 (20)	8 (20)	6 (21)	6 (21)	6 (21)	4 (23)	2 (25)	2 (25)	1 (26)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	32 (0)	20 (8)	13 (11)	8 (14)	6 (15)	5 (16)	5 (16)	5 (16)	5 (16)	4 (17)	4 (17)	3 (17)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	1 (19)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



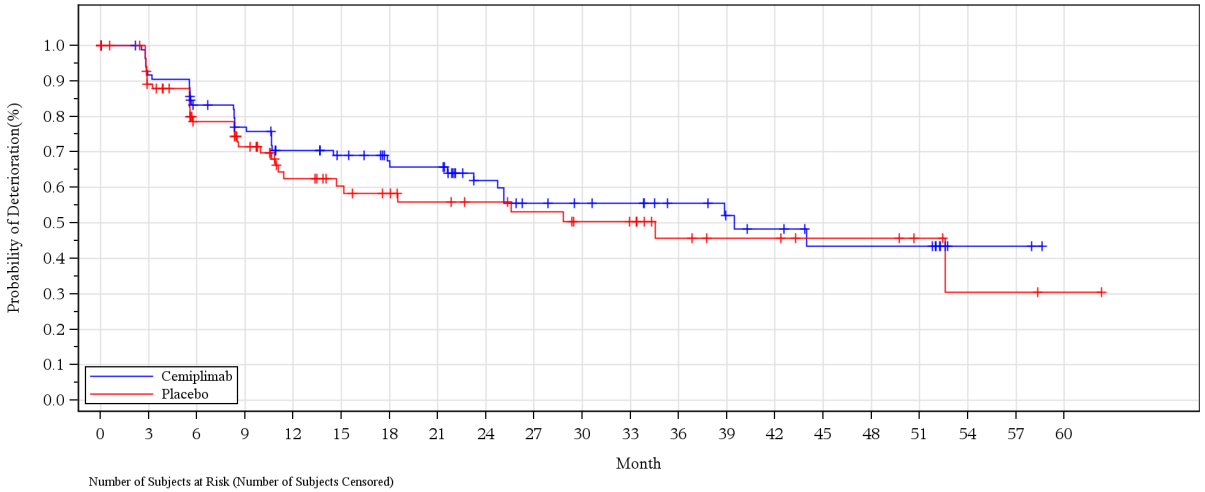
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (5)	24 (7)	23 (8)	20 (9)	17 (10)	16 (11)	16 (11)	10 (14)	9 (15)	7 (17)	5 (19)	2 (22)	2 (22)	2 (22)	2 (22)	2 (22)	1 (23)	0 (24)	0 (24)	0 (24)
Placebo	31 (0)	20 (8)	17 (10)	13 (14)	9 (18)	8 (19)	6 (21)	6 (21)	5 (22)	3 (23)	3 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



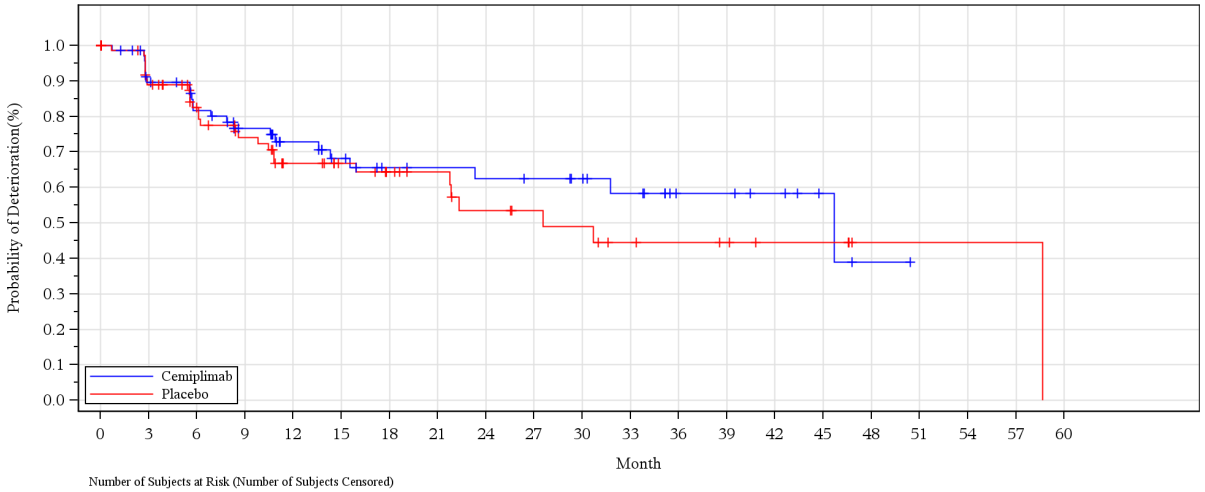
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	77 (6)	67 (9)	60 (11)	52 (14)	47 (18)	41 (23)	40 (23)	29 (32)	24 (34)	22 (36)	21 (37)	17 (41)	14 (43)	12 (44)	9 (46)	9 (46)	9 (46)	2 (53)	2 (53)	0 (55)
Placebo	90 (0)	72 (9)	56 (17)	47 (21)	34 (29)	29 (33)	26 (35)	23 (37)	21 (39)	19 (40)	16 (42)	15 (43)	10 (47)	8 (49)	8 (49)	6 (51)	6 (51)	4 (53)	2 (54)	2 (54)	1 (55)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



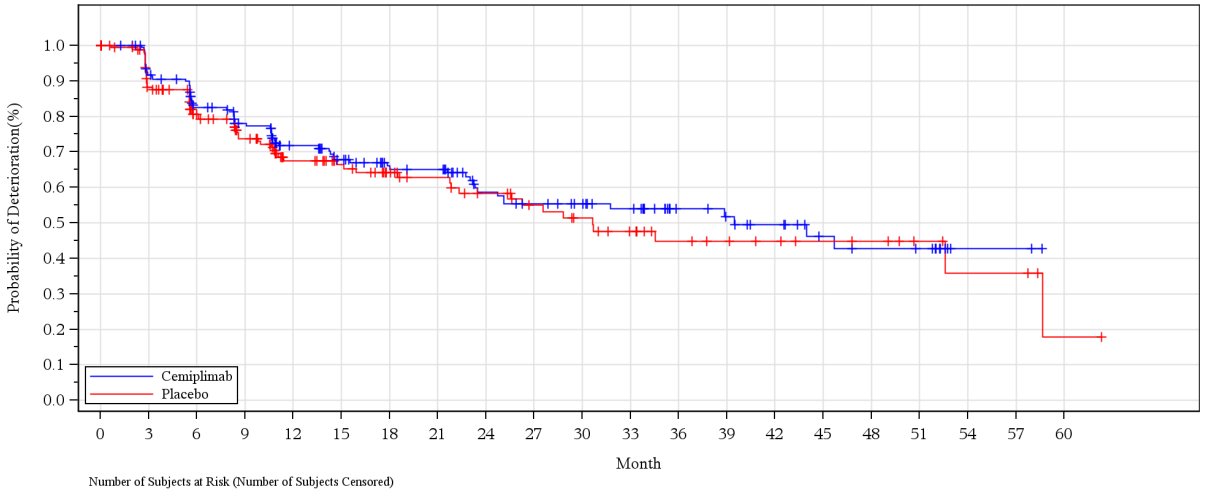
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	59 (16)	51 (19)	42 (25)	33 (32)	27 (36)	22 (40)	21 (41)	20 (41)	19 (42)	17 (44)	14 (46)	8 (52)	8 (52)	6 (54)	3 (57)	1 (58)	0 (59)	0 (59)	0 (59)	0 (59)
Placebo	85 (0)	63 (14)	50 (23)	42 (26)	32 (32)	27 (37)	21 (42)	18 (45)	14 (46)	12 (48)	11 (48)	8 (50)	7 (51)	6 (52)	4 (54)	4 (54)	1 (57)	1 (57)	1 (57)	1 (57)	0 (57)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Race: White



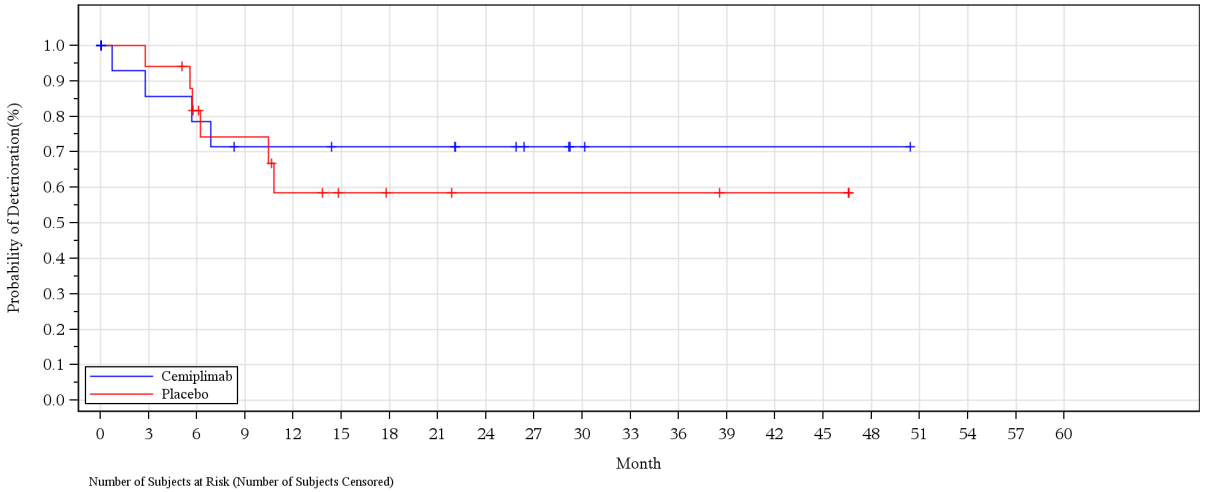
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	154 (21)	131 (29)	116 (37)	96 (48)	83 (56)	71 (66)	69 (67)	53 (77)	48 (79)	44 (83)	39 (87)	26 (100)	23 (102)	19 (105)	13 (110)	11 (111)	10 (112)	2 (120)	2 (120)	0 (122)
Placebo	189 (0)	139 (31)	111 (48)	92 (58)	68 (75)	59 (83)	49 (91)	43 (96)	37 (99)	31 (103)	27 (105)	22 (108)	16 (113)	14 (115)	12 (117)	10 (119)	9 (120)	6 (123)	4 (124)	4 (124)	1 (126)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	12 (6)	11 (6)	9 (7)	9 (7)	8 (8)	8 (8)	8 (8)	6 (10)	4 (12)	2 (14)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	17 (0)	16 (0)	12 (2)	10 (3)	7 (4)	5 (6)	4 (7)	4 (7)	3 (8)	3 (8)	3 (8)	3 (8)	3 (8)	2 (9)	2 (9)	2 (9)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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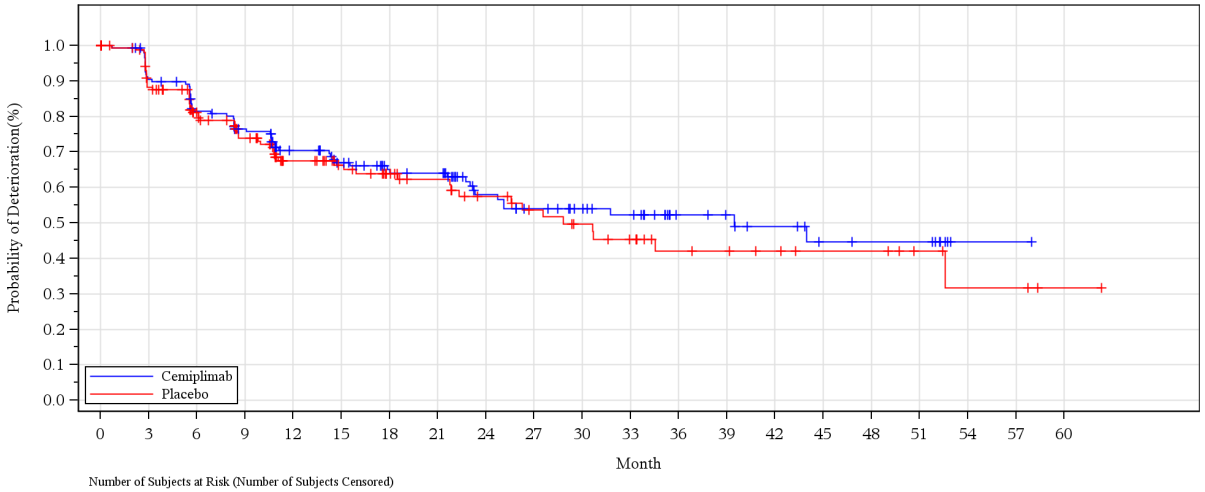
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	133 (19)	116 (23)	103 (29)	86 (38)	75 (45)	64 (54)	62 (55)	45 (67)	39 (70)	34 (75)	30 (78)	18 (90)	16 (92)	13 (94)	9 (97)	8 (98)	8 (98)	1 (105)	1 (105)	0 (106)
Placebo	177 (0)	133 (26)	107 (42)	88 (52)	64 (69)	54 (78)	45 (85)	39 (90)	32 (94)	27 (97)	23 (99)	19 (101)	13 (106)	12 (107)	10 (109)	8 (111)	8 (111)	5 (114)	3 (115)	3 (115)	1 (117)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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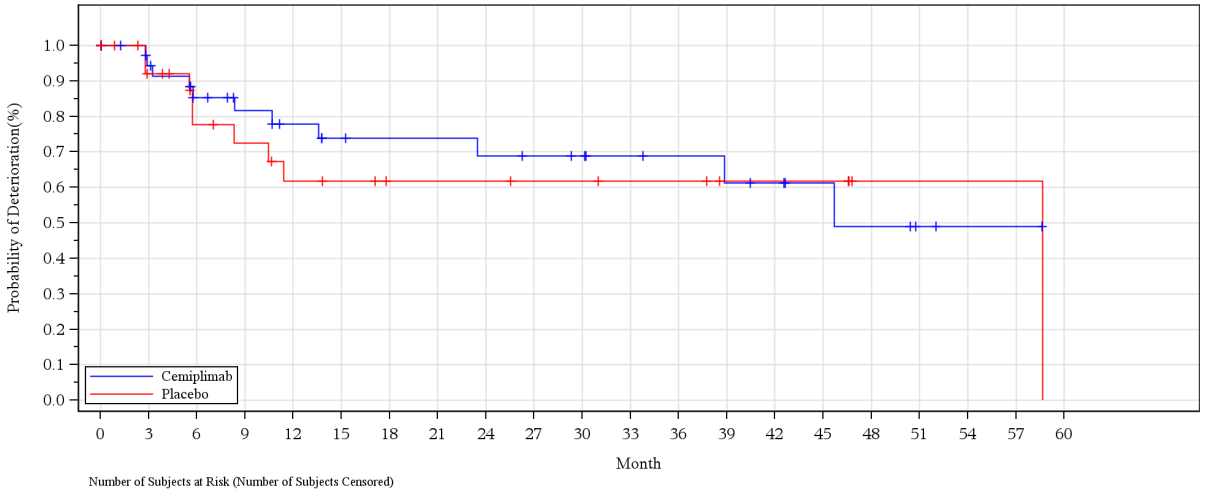
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	33 (8)	26 (12)	22 (15)	19 (17)	16 (19)	15 (20)	15 (20)	14 (20)	13 (21)	12 (22)	10 (24)	9 (25)	8 (25)	7 (26)	5 (28)	4 (28)	2 (30)	1 (31)	1 (31)	0 (32)
Placebo	29 (0)	22 (5)	16 (8)	14 (9)	11 (10)	10 (11)	8 (13)	8 (13)	8 (13)	7 (14)	7 (14)	6 (15)	6 (15)	4 (17)	4 (17)	4 (17)	1 (20)	1 (20)	1 (20)	1 (20)	0 (20)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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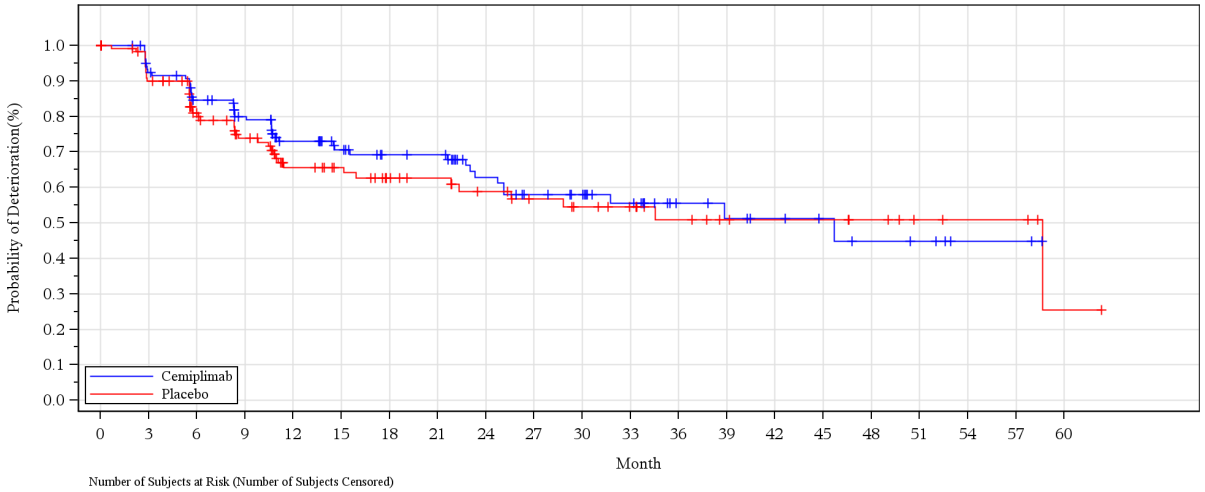
Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



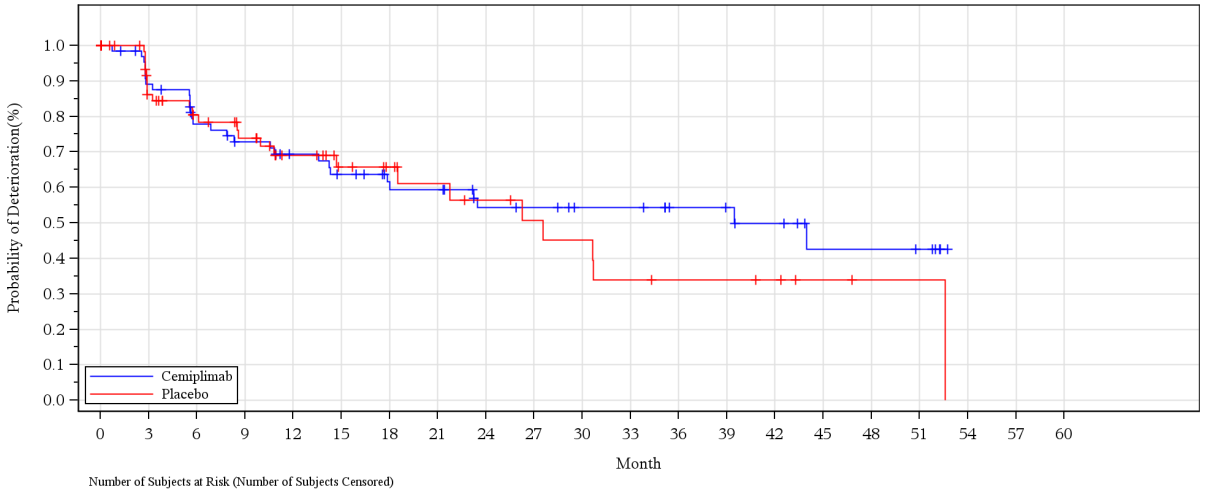
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	109 (15)	95 (20)	83 (27)	68 (35)	58 (43)	51 (49)	50 (50)	38 (58)	32 (61)	29 (64)	23 (69)	14 (78)	12 (79)	10 (81)	8 (83)	6 (84)	5 (85)	2 (88)	2 (88)	0 (90)
Placebo	131 (0)	107 (12)	84 (25)	69 (33)	50 (45)	45 (50)	37 (56)	34 (59)	29 (62)	25 (65)	22 (67)	19 (70)	14 (74)	11 (77)	10 (78)	10 (78)	8 (80)	5 (83)	4 (84)	4 (84)	1 (86)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



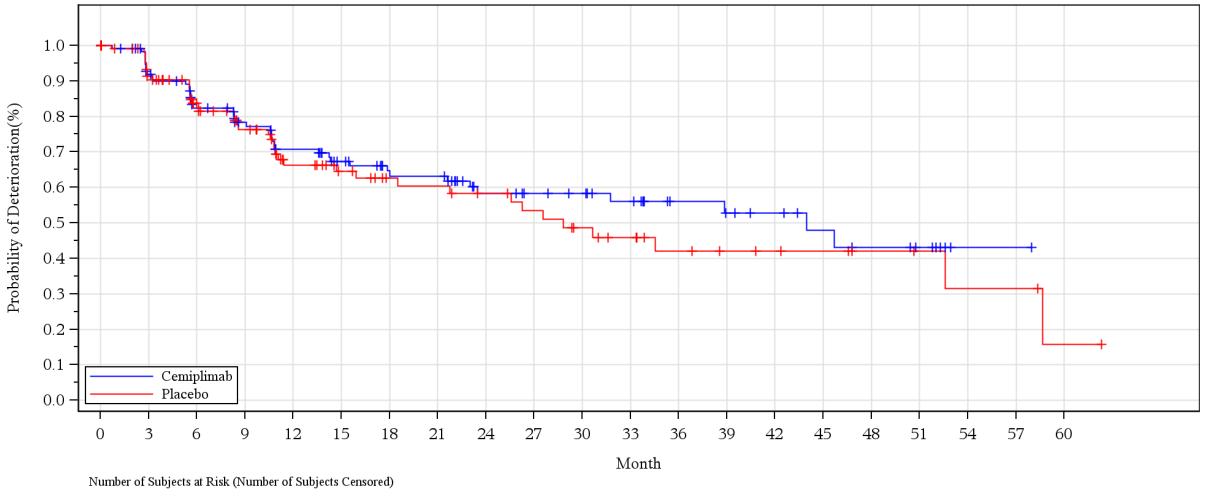
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	57 (12)	47 (15)	42 (17)	37 (20)	33 (21)	28 (25)	27 (25)	21 (29)	20 (30)	17 (33)	17 (33)	13 (37)	12 (38)	10 (39)	6 (42)	6 (42)	5 (43)	0 (48)	0 (48)	0 (48)
Placebo	75 (0)	48 (19)	39 (25)	33 (28)	25 (34)	19 (39)	16 (42)	13 (44)	11 (45)	9 (46)	8 (46)	6 (46)	5 (47)	5 (47)	4 (48)	2 (50)	1 (51)	1 (51)	0 (51)	0 (51)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



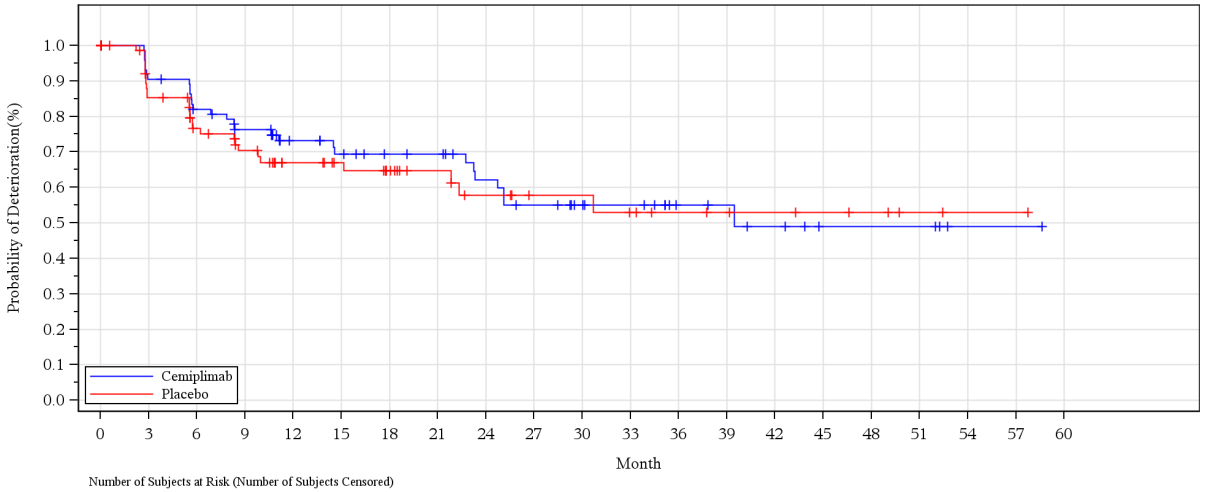
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	100 (16)	84 (22)	74 (28)	64 (31)	54 (38)	46 (44)	45 (44)	33 (53)	30 (56)	28 (58)	24 (61)	17 (68)	15 (69)	13 (71)	10 (73)	8 (74)	6 (76)	1 (81)	1 (81)	0 (82)
Placebo	117 (0)	92 (16)	72 (29)	59 (36)	42 (46)	35 (52)	29 (57)	28 (57)	25 (59)	22 (60)	18 (62)	15 (64)	11 (67)	9 (69)	8 (70)	7 (71)	5 (73)	4 (74)	3 (74)	3 (74)	1 (75)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.14 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Constipation Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



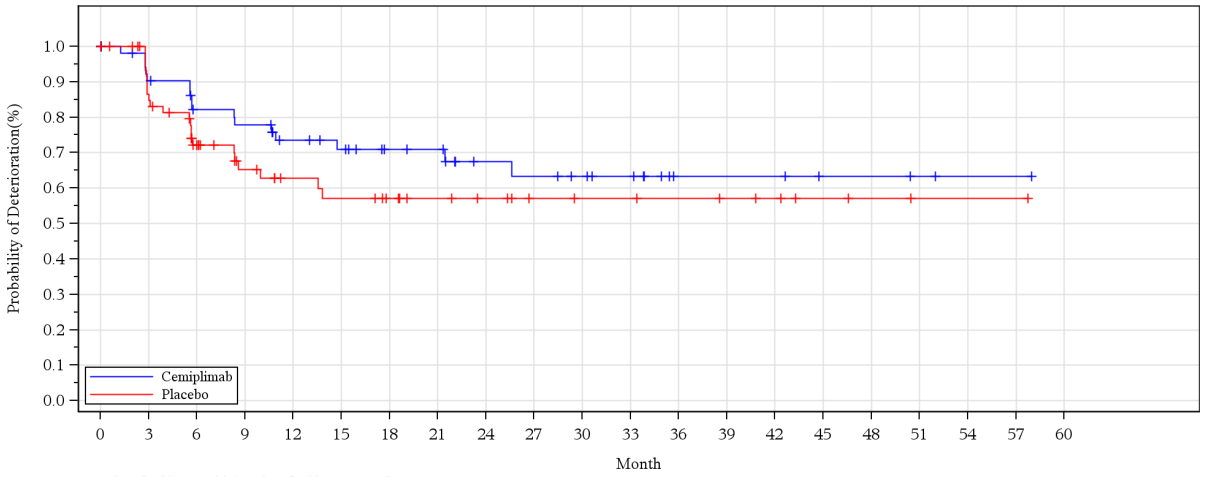
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	66 (11)	58 (13)	51 (16)	41 (24)	37 (26)	33 (30)	32 (31)	26 (34)	22 (35)	18 (39)	16 (41)	10 (47)	9 (48)	7 (49)	4 (52)	4 (52)	4 (52)	1 (55)	1 (55)	0 (56)
Placebo	89 (0)	63 (15)	51 (21)	43 (25)	33 (33)	29 (37)	24 (41)	19 (46)	15 (48)	12 (51)	12 (51)	10 (52)	8 (54)	7 (55)	6 (56)	5 (57)	4 (58)	2 (60)	1 (61)	1 (61)	0 (62)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



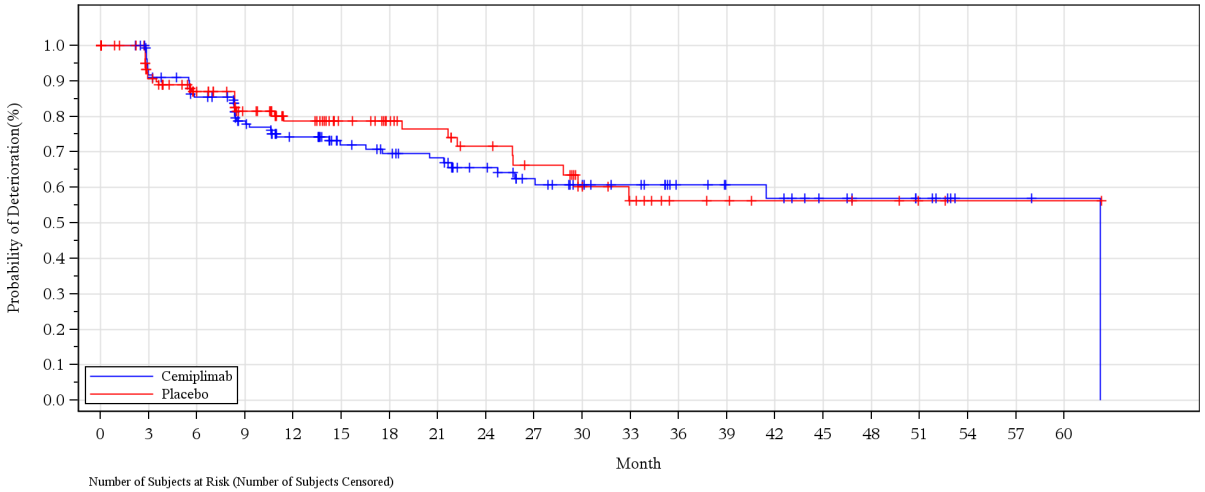
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	46 (5)	39 (8)	37 (8)	31 (12)	28 (14)	23 (19)	22 (20)	16 (25)	15 (25)	13 (27)	11 (29)	5 (35)	5 (35)	5 (35)	3 (37)	3 (37)	2 (38)	1 (39)	1 (39)	0 (40)
Placebo	65 (0)	51 (6)	37 (12)	27 (19)	22 (23)	20 (23)	17 (26)	14 (29)	12 (31)	9 (34)	8 (35)	8 (35)	7 (36)	6 (37)	5 (38)	3 (40)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



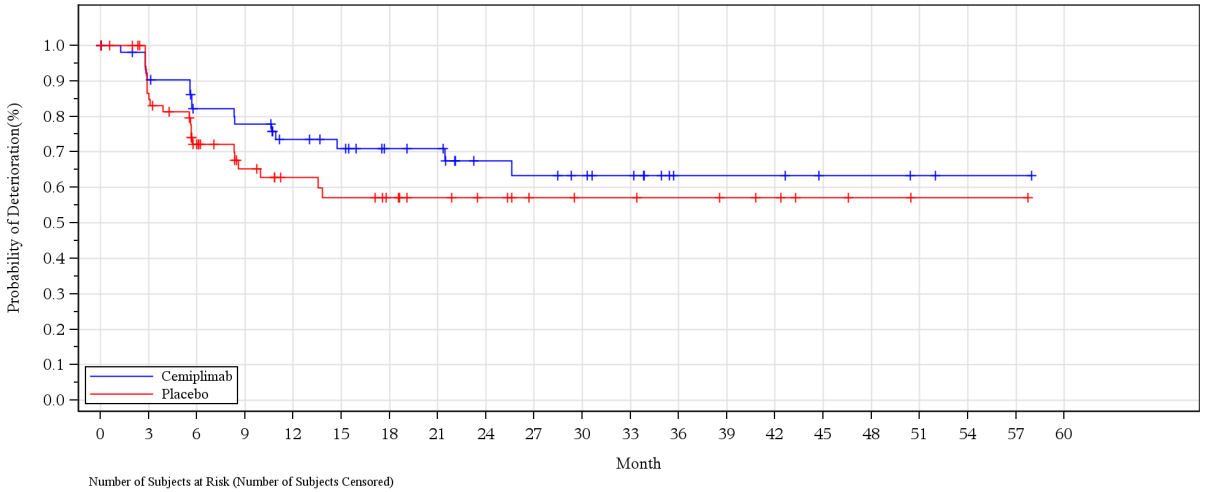
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	121 (21)	108 (26)	89 (37)	76 (45)	62 (57)	57 (60)	53 (63)	44 (70)	36 (76)	29 (82)	26 (85)	19 (92)	16 (95)	15 (95)	11 (99)	9 (101)	7 (103)	2 (108)	2 (108)	1 (109)
Placebo	141 (0)	104 (26)	85 (41)	69 (52)	55 (64)	44 (75)	37 (82)	33 (85)	28 (88)	24 (90)	16 (96)	13 (98)	8 (103)	7 (104)	5 (106)	5 (106)	4 (107)	2 (109)	1 (110)	1 (110)	1 (110)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



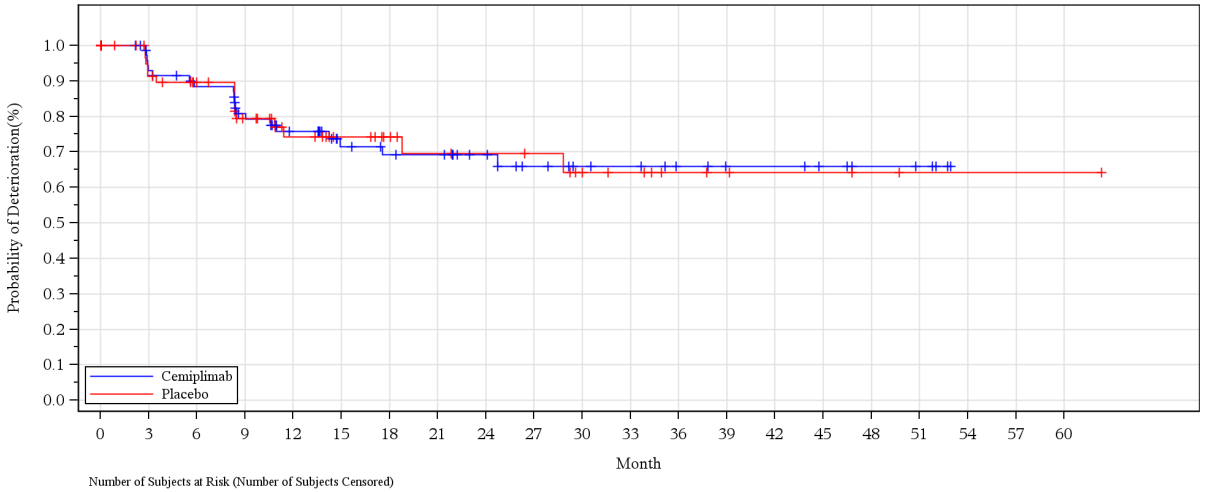
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	46 (5)	39 (8)	37 (8)	31 (12)	28 (14)	23 (19)	22 (20)	16 (25)	15 (25)	13 (27)	11 (29)	5 (35)	5 (35)	5 (35)	3 (37)	3 (37)	2 (38)	1 (39)	1 (39)	0 (40)
Placebo	65 (0)	51 (6)	37 (12)	27 (19)	22 (23)	20 (23)	17 (26)	14 (29)	12 (31)	9 (34)	8 (35)	8 (35)	7 (36)	6 (37)	5 (38)	3 (40)	2 (41)	1 (42)	1 (42)	1 (42)	0 (43)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



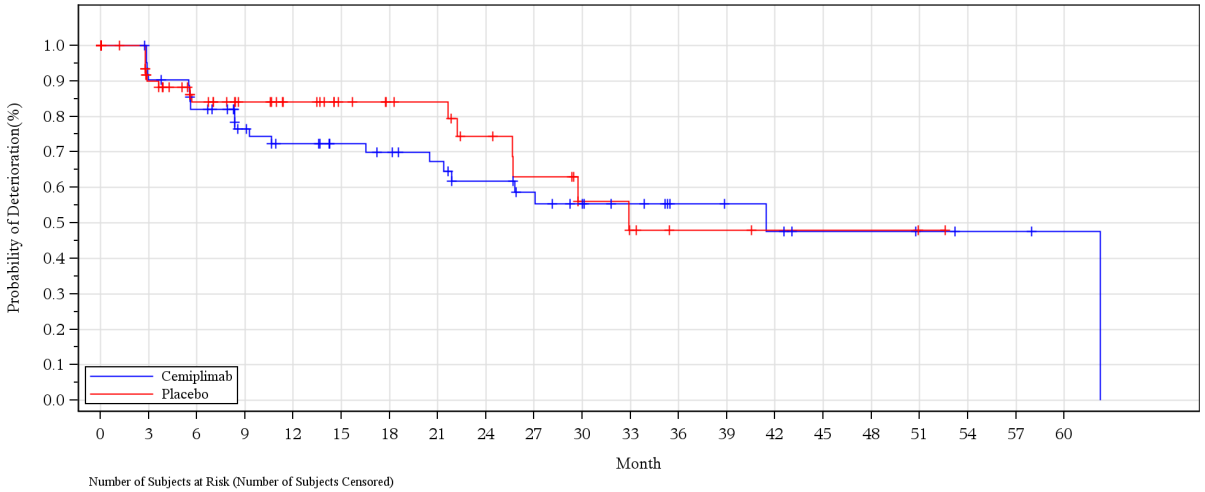
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	65 (10)	59 (13)	50 (17)	42 (22)	32 (30)	29 (32)	28 (33)	23 (38)	18 (42)	15 (45)	14 (46)	11 (49)	9 (51)	9 (51)	7 (53)	5 (55)	4 (56)	0 (60)	0 (60)	0 (60)
Placebo	69 (0)	53 (11)	45 (18)	36 (22)	27 (29)	22 (34)	18 (38)	15 (40)	14 (41)	13 (42)	9 (45)	8 (46)	5 (49)	4 (50)	3 (51)	3 (51)	2 (52)	1 (53)	1 (53)	1 (53)	1 (53)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



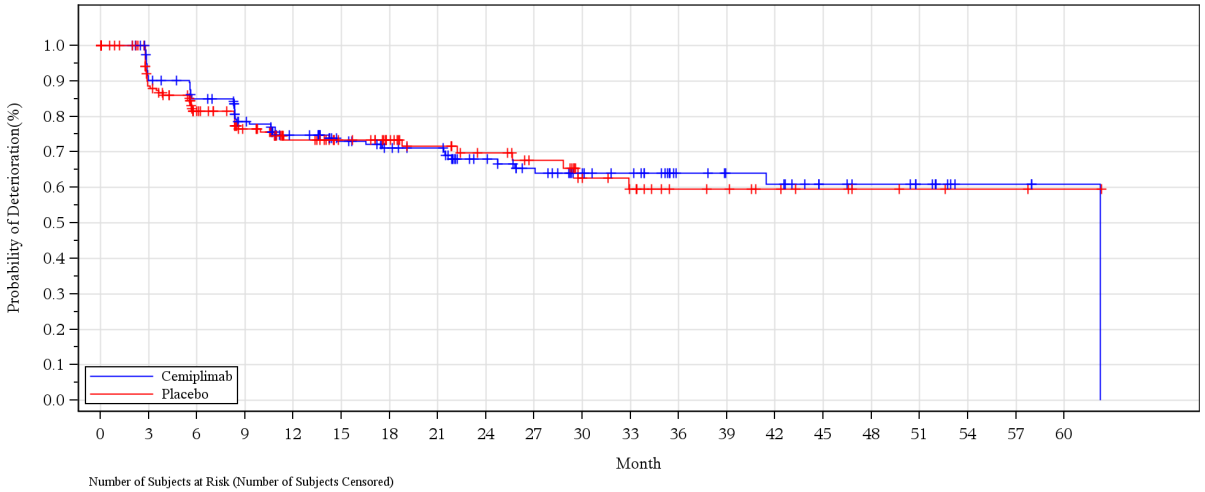
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	56 (11)	49 (13)	39 (20)	34 (23)	30 (27)	28 (28)	25 (30)	21 (32)	18 (34)	14 (37)	12 (39)	8 (43)	7 (44)	6 (44)	4 (46)	4 (46)	3 (47)	2 (48)	2 (48)	1 (49)
Placebo	72 (0)	51 (15)	40 (23)	33 (30)	28 (35)	22 (41)	19 (44)	18 (45)	14 (47)	11 (48)	7 (51)	5 (52)	3 (54)	3 (54)	2 (55)	2 (55)	2 (55)	1 (56)	0 (57)	0 (57)	0 (57)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Gender group: Male



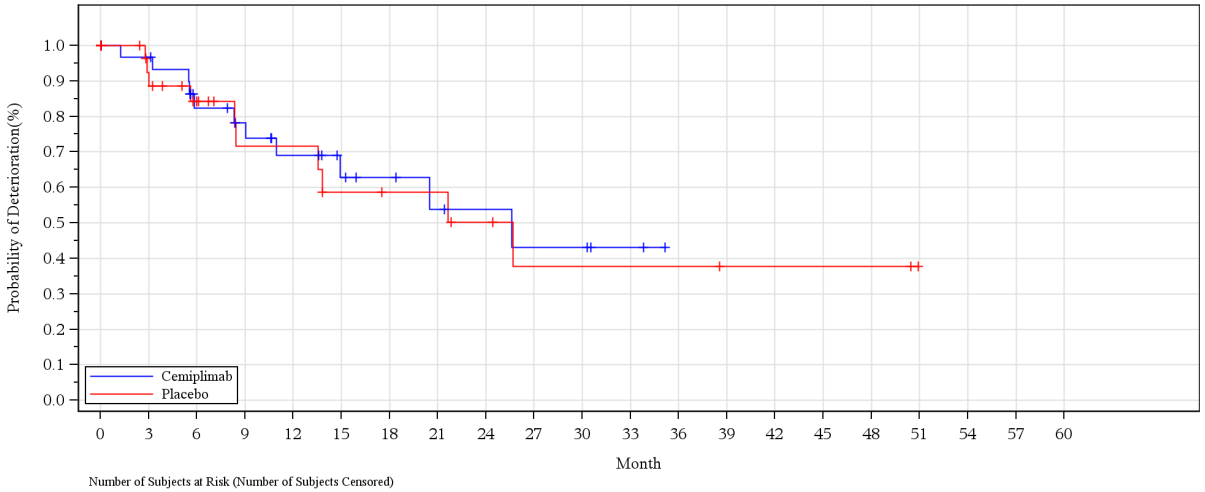
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	138 (21)	126 (25)	108 (34)	93 (44)	80 (55)	72 (61)	69 (64)	55 (75)	47 (81)	38 (89)	35 (92)	24 (103)	21 (106)	20 (106)	14 (112)	12 (114)	9 (117)	3 (123)	3 (123)	1 (125)
Placebo	174 (0)	131 (26)	104 (43)	85 (56)	66 (72)	56 (82)	47 (91)	40 (97)	35 (101)	30 (105)	21 (112)	18 (114)	12 (120)	11 (121)	8 (124)	6 (126)	4 (128)	3 (129)	2 (130)	2 (130)	1 (131)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Gender group: Female



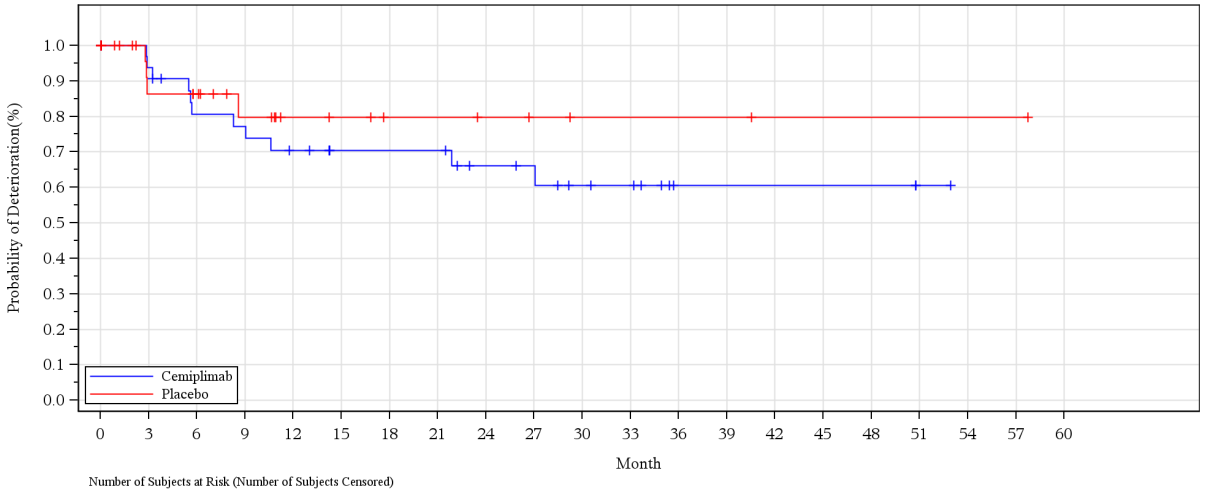
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	29 (5)	21 (9)	18 (11)	14 (13)	10 (16)	8 (18)	6 (19)	5 (20)	4 (20)	4 (20)	2 (22)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)
Placebo	32 (0)	24 (6)	18 (10)	11 (15)	11 (15)	8 (16)	7 (17)	7 (17)	5 (18)	3 (19)	3 (19)	3 (19)	3 (19)	2 (20)	2 (20)	2 (20)	2 (20)	0 (22)	0 (22)	0 (22)	0 (22)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (5)	24 (7)	23 (7)	20 (8)	17 (11)	17 (11)	17 (11)	13 (14)	12 (15)	9 (17)	8 (18)	3 (23)	3 (23)	3 (23)	3 (23)	3 (23)	1 (25)	0 (26)	0 (26)	0 (26)
Placebo	31 (0)	19 (9)	17 (11)	12 (15)	8 (19)	7 (20)	5 (22)	5 (22)	4 (23)	3 (24)	2 (25)	2 (25)	2 (25)	2 (25)	1 (26)	1 (26)	1 (26)	1 (26)	1 (26)	1 (26)	0 (27)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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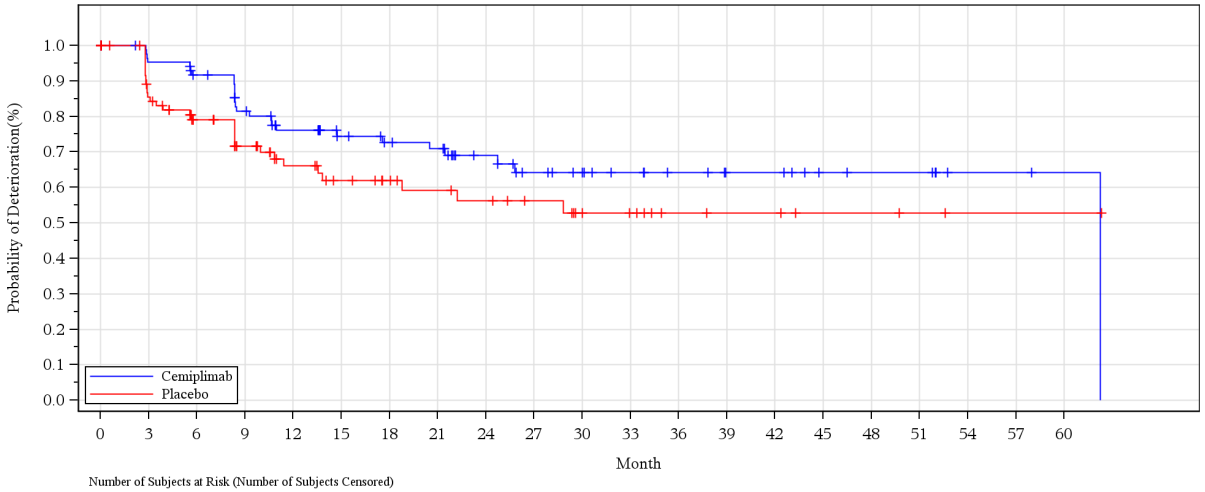
Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



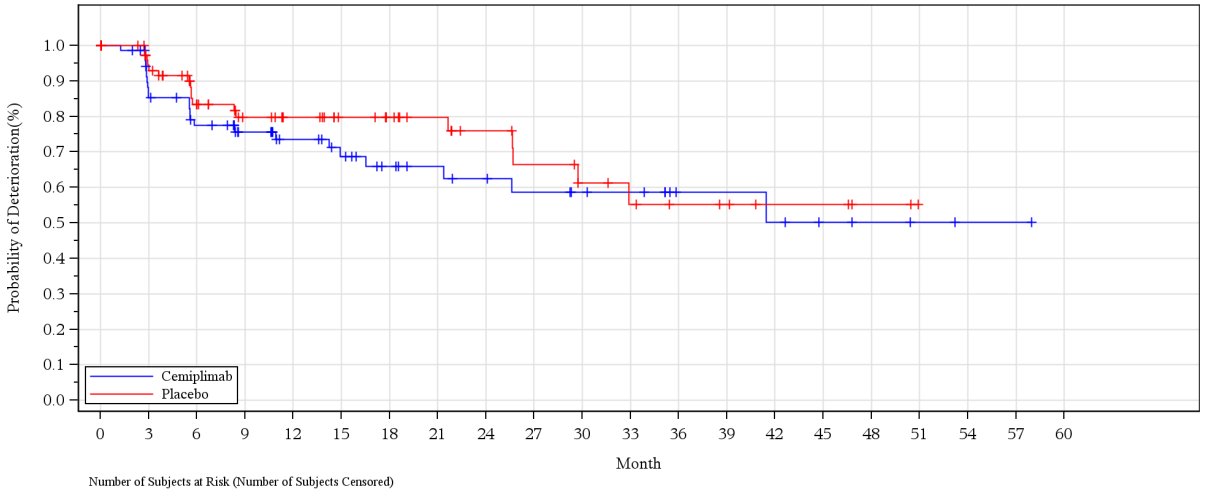
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	80 (6)	74 (9)	63 (12)	54 (17)	45 (25)	41 (28)	39 (29)	30 (37)	24 (41)	20 (45)	17 (48)	14 (51)	11 (54)	11 (54)	7 (58)	6 (59)	6 (59)	2 (63)	2 (63)	1 (64)
Placebo	90 (0)	70 (8)	55 (18)	44 (24)	34 (31)	28 (35)	24 (39)	21 (41)	19 (42)	16 (45)	11 (49)	10 (50)	6 (54)	5 (55)	5 (55)	3 (57)	3 (57)	2 (58)	1 (59)	1 (59)	1 (59)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



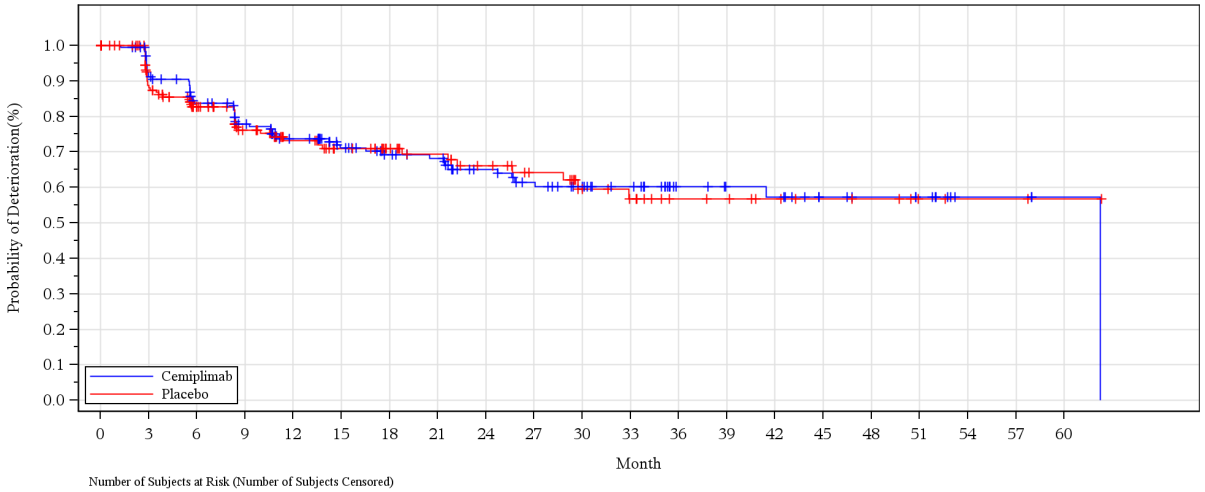
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	57 (15)	49 (18)	40 (26)	33 (32)	28 (35)	22 (40)	19 (43)	17 (44)	15 (45)	13 (47)	12 (48)	7 (53)	7 (53)	6 (53)	4 (55)	3 (56)	2 (57)	1 (58)	1 (58)	0 (59)
Placebo	85 (0)	66 (15)	50 (24)	40 (32)	35 (37)	29 (43)	25 (47)	21 (51)	17 (54)	14 (55)	11 (57)	9 (58)	7 (60)	6 (61)	4 (63)	4 (63)	2 (65)	0 (67)	0 (67)	0 (67)	0 (67)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Race: White



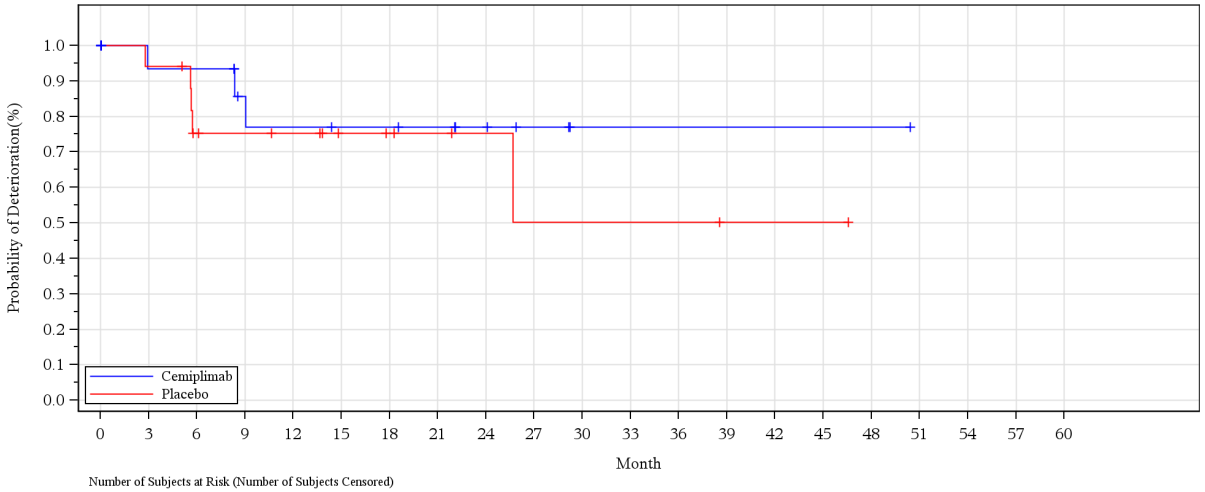
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	153 (21)	133 (29)	116 (37)	98 (49)	82 (62)	72 (70)	68 (73)	55 (83)	48 (87)	41 (93)	36 (98)	23 (111)	20 (114)	19 (114)	13 (120)	11 (122)	9 (124)	3 (130)	3 (130)	1 (132)
Placebo	189 (0)	139 (32)	111 (51)	86 (68)	68 (83)	58 (91)	49 (100)	43 (105)	37 (109)	31 (114)	22 (121)	19 (123)	13 (129)	12 (130)	9 (133)	7 (135)	6 (136)	3 (139)	2 (140)	2 (140)	1 (141)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Race: Non-white



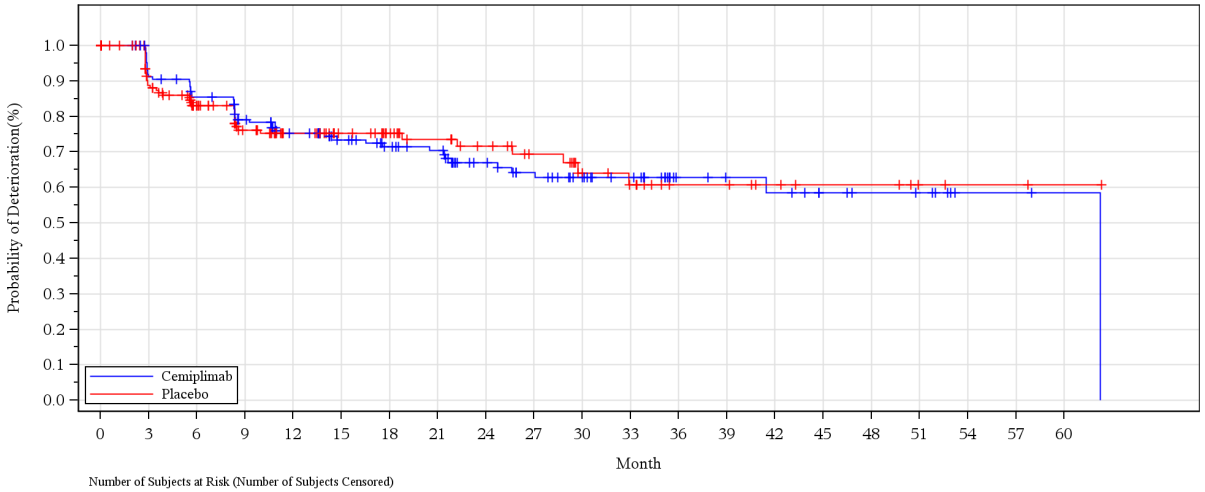
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	14 (5)	14 (5)	10 (8)	9 (8)	8 (9)	8 (9)	7 (10)	5 (12)	3 (14)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	17 (0)	16 (0)	11 (2)	10 (3)	9 (4)	6 (7)	5 (8)	4 (9)	3 (10)	2 (10)	2 (10)	2 (10)	2 (10)	1 (11)	1 (11)	1 (11)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



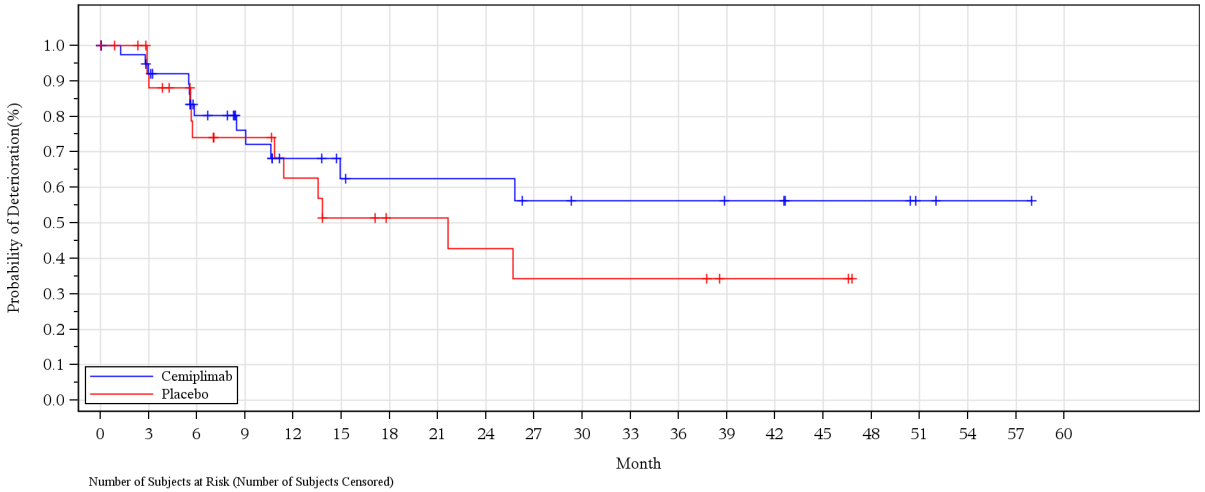
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	133 (20)	122 (23)	107 (29)	93 (38)	79 (50)	70 (57)	65 (61)	50 (73)	43 (78)	35 (85)	30 (90)	17 (103)	15 (105)	14 (105)	10 (109)	8 (111)	7 (112)	2 (117)	2 (117)	1 (118)
Placebo	177 (0)	132 (28)	106 (46)	82 (62)	66 (77)	56 (87)	48 (95)	41 (101)	35 (106)	29 (111)	20 (118)	17 (120)	11 (126)	11 (126)	8 (129)	6 (131)	6 (131)	3 (134)	2 (135)	2 (135)	1 (136)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



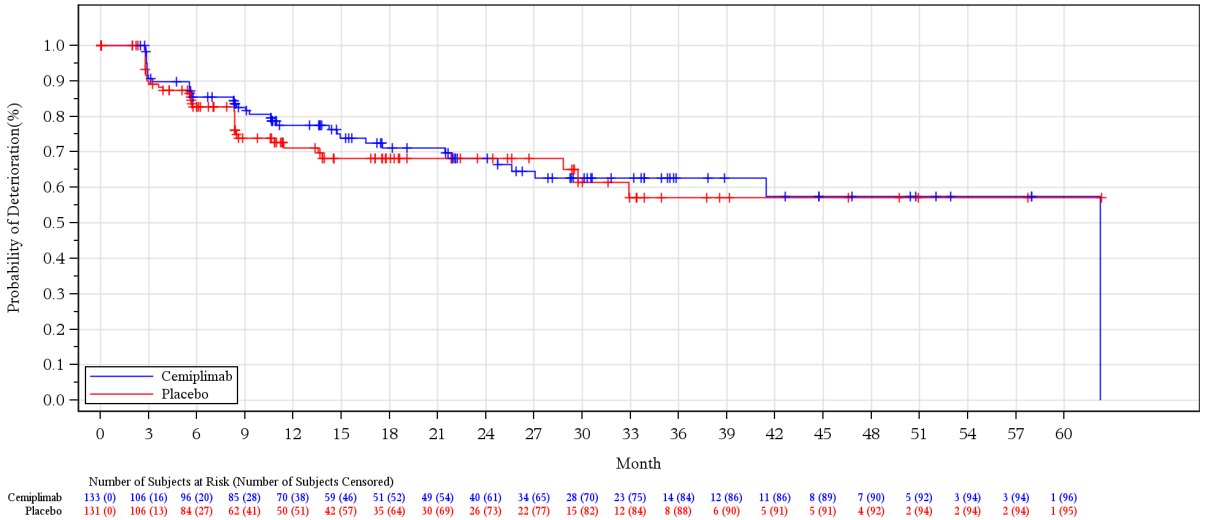
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	34 (6)	25 (11)	19 (16)	14 (19)	11 (21)	10 (22)	10 (22)	10 (22)	8 (23)	7 (24)	7 (24)	7 (24)	6 (25)	6 (25)	4 (27)	4 (27)	2 (29)	1 (30)	1 (30)	0 (31)
Placebo	29 (0)	23 (4)	16 (7)	14 (9)	11 (10)	8 (11)	6 (13)	6 (13)	5 (13)	4 (13)	4 (13)	4 (13)	4 (13)	2 (15)	2 (15)	2 (15)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



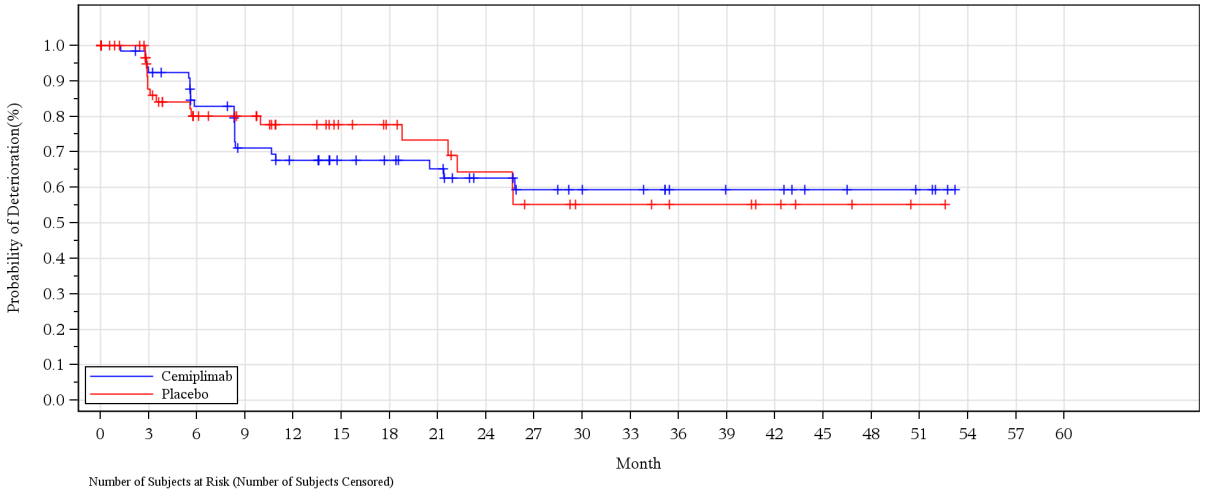
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	106 (16)	96 (20)	85 (28)	70 (38)	59 (46)	51 (52)	49 (54)	40 (61)	34 (65)	28 (70)	23 (75)	14 (84)	12 (86)	11 (86)	8 (89)	7 (90)	5 (92)	3 (94)	3 (94)	1 (96)
Placebo	131 (0)	106 (13)	84 (27)	62 (41)	50 (51)	42 (57)	35 (64)	30 (69)	26 (73)	22 (77)	15 (82)	12 (84)	8 (88)	6 (90)	5 (91)	5 (91)	4 (92)	2 (94)	2 (94)	2 (94)	1 (95)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



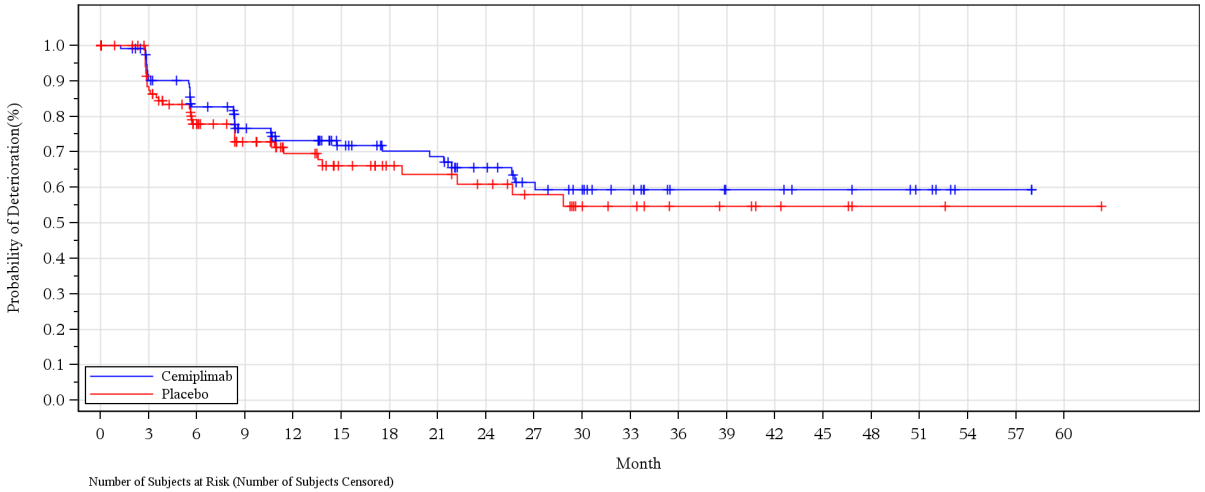
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	61 (10)	51 (14)	41 (17)	37 (19)	31 (25)	29 (27)	26 (29)	20 (34)	17 (36)	14 (39)	14 (39)	10 (43)	9 (44)	9 (44)	6 (47)	5 (48)	4 (49)	0 (53)	0 (53)	0 (53)
Placebo	75 (0)	49 (19)	38 (26)	34 (30)	27 (36)	22 (41)	19 (44)	17 (45)	14 (46)	11 (47)	9 (49)	9 (49)	7 (51)	7 (51)	5 (53)	3 (55)	2 (56)	1 (57)	0 (58)	0 (58)	0 (58)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



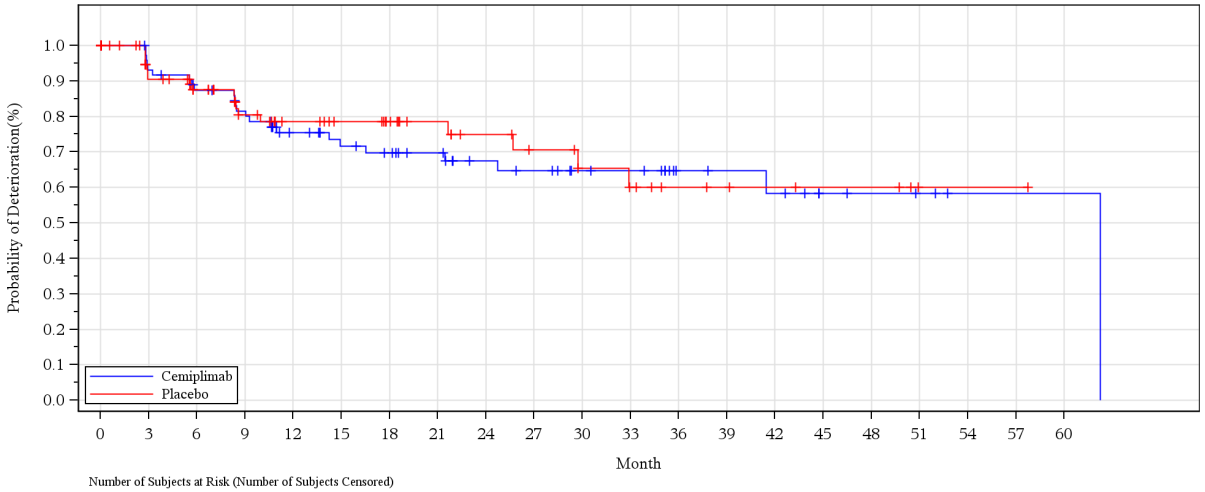
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	100 (14)	86 (20)	71 (29)	63 (34)	52 (44)	45 (50)	44 (50)	35 (57)	28 (62)	23 (66)	19 (70)	13 (76)	11 (78)	11 (78)	9 (80)	8 (81)	6 (83)	2 (87)	2 (87)	0 (89)
Placebo	117 (0)	90 (15)	67 (28)	53 (38)	42 (47)	33 (54)	27 (60)	25 (61)	22 (63)	18 (66)	12 (71)	11 (72)	8 (75)	7 (76)	5 (78)	4 (79)	2 (81)	2 (81)	1 (82)	1 (82)	1 (82)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.15 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Diarrhoea Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



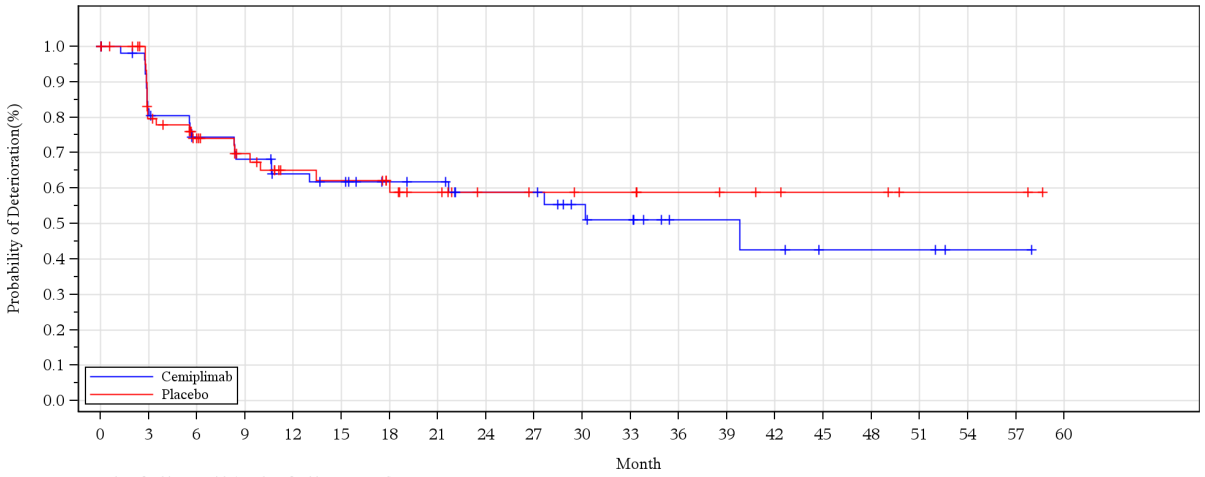
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	67 (12)	61 (14)	55 (16)	44 (23)	38 (27)	35 (29)	31 (33)	25 (38)	23 (39)	19 (43)	18 (44)	11 (51)	10 (52)	9 (52)	5 (56)	4 (57)	3 (58)	1 (60)	1 (60)	1 (60)
Placebo	89 (0)	65 (17)	55 (25)	43 (33)	35 (40)	31 (44)	27 (48)	22 (53)	18 (56)	15 (58)	12 (60)	10 (61)	7 (64)	6 (65)	5 (66)	4 (67)	4 (67)	1 (70)	1 (70)	1 (70)	0 (71)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



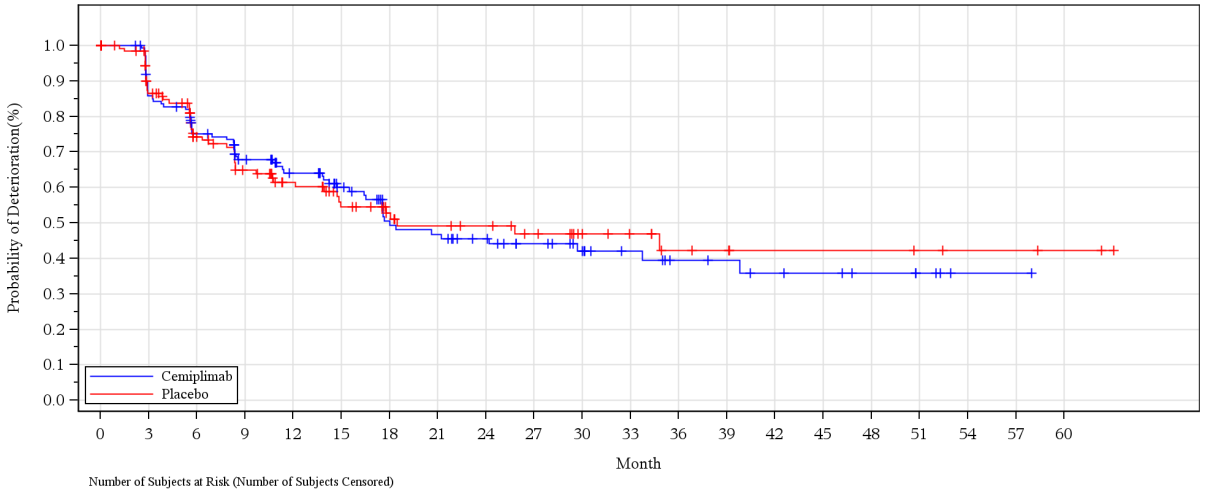
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	42 (5)	36 (7)	33 (7)	29 (9)	27 (10)	23 (14)	22 (15)	18 (18)	18 (18)	13 (22)	11 (23)	6 (28)	6 (28)	5 (28)	3 (30)	3 (30)	3 (30)	1 (32)	1 (32)	0 (33)
Placebo	65 (0)	46 (7)	37 (13)	30 (18)	23 (23)	22 (23)	19 (26)	15 (29)	11 (33)	10 (34)	9 (35)	9 (35)	7 (37)	6 (38)	5 (39)	4 (40)	4 (40)	2 (42)	2 (42)	2 (42)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



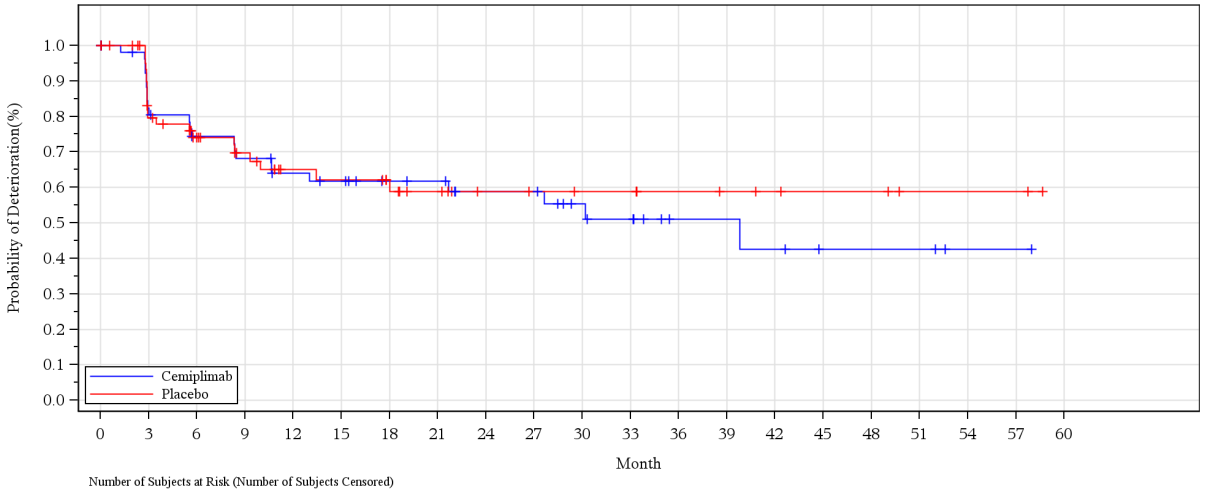
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	114 (20)	96 (24)	80 (31)	68 (39)	55 (48)	41 (54)	38 (54)	32 (59)	26 (64)	20 (69)	16 (73)	12 (76)	11 (77)	9 (78)	8 (79)	6 (81)	4 (83)	1 (86)	1 (86)	0 (87)
Placebo	141 (0)	100 (25)	73 (39)	60 (43)	48 (52)	38 (57)	30 (64)	26 (66)	24 (68)	20 (71)	14 (77)	12 (79)	8 (82)	7 (83)	5 (85)	5 (85)	5 (85)	4 (86)	3 (87)	3 (87)	2 (88)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	42 (5)	36 (7)	33 (7)	29 (9)	27 (10)	23 (14)	22 (15)	18 (18)	18 (18)	13 (22)	11 (23)	6 (28)	6 (28)	5 (28)	3 (30)	3 (30)	3 (30)	1 (32)	1 (32)	0 (33)
Placebo	65 (0)	46 (7)	37 (13)	30 (18)	23 (23)	22 (23)	19 (26)	15 (29)	11 (33)	10 (34)	9 (35)	9 (35)	7 (37)	6 (38)	5 (39)	4 (40)	4 (40)	2 (42)	2 (42)	2 (42)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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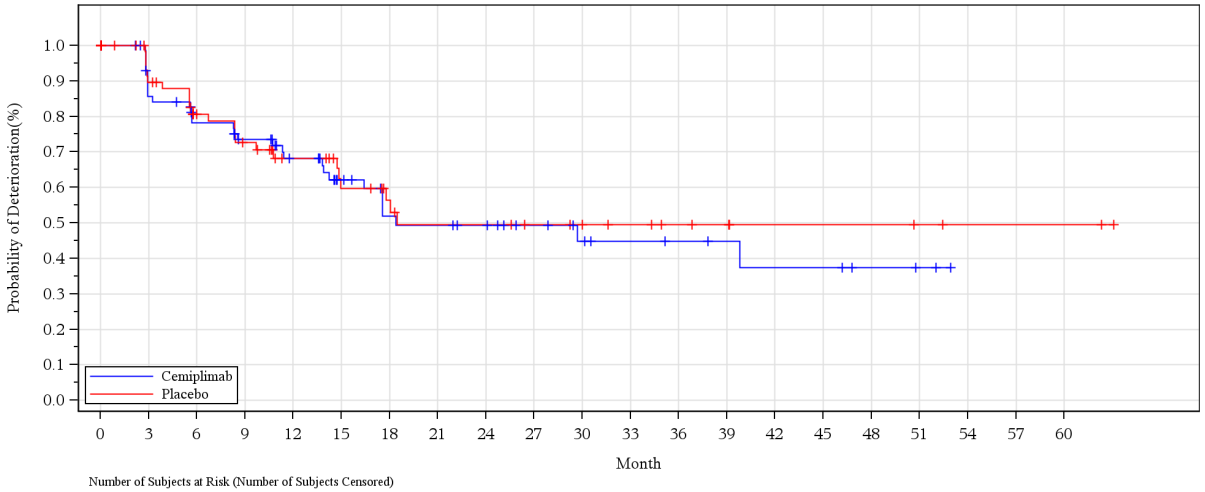
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	59 (11)	51 (14)	45 (17)	37 (22)	27 (29)	20 (32)	19 (32)	17 (34)	13 (38)	10 (40)	8 (42)	7 (43)	6 (44)	5 (44)	5 (44)	3 (46)	2 (47)	0 (49)	0 (49)	0 (49)
Placebo	69 (0)	52 (11)	40 (18)	35 (19)	27 (25)	21 (28)	17 (31)	14 (32)	14 (32)	12 (34)	10 (36)	9 (37)	7 (39)	6 (40)	4 (42)	4 (42)	4 (42)	3 (43)	2 (44)	2 (44)	2 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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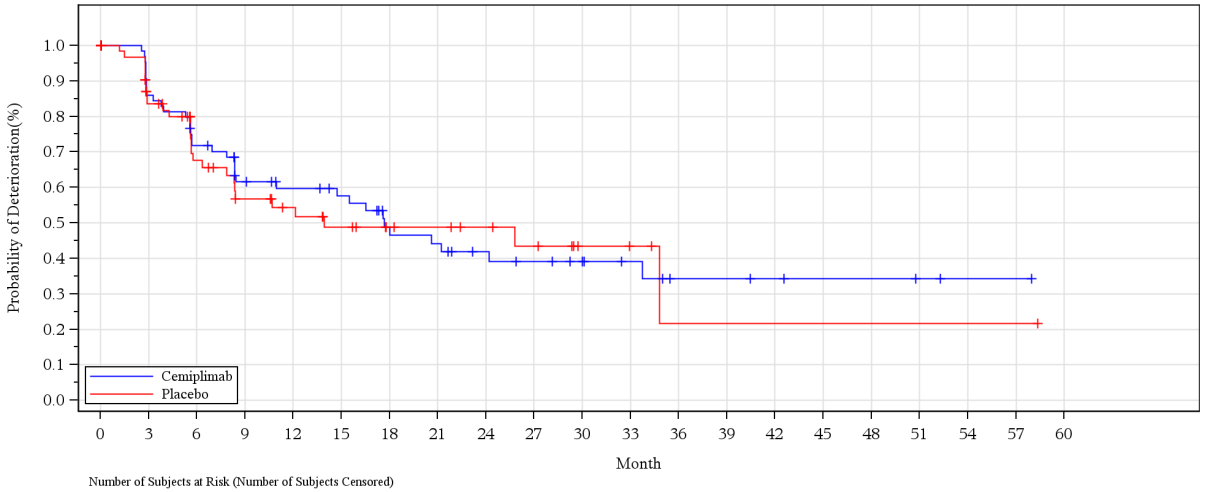
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



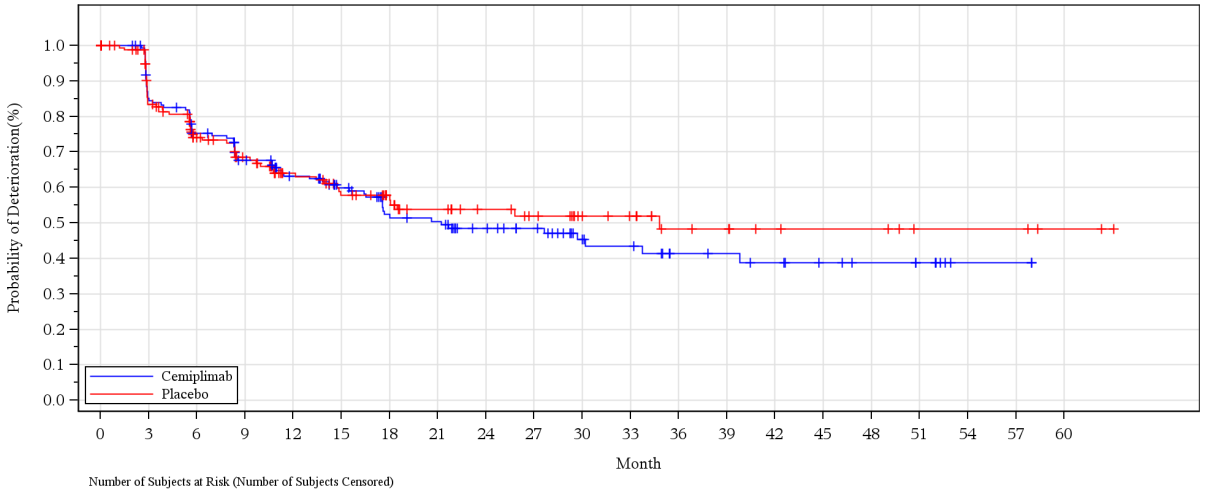
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	55 (9)	45 (10)	35 (14)	31 (17)	28 (19)	21 (22)	19 (22)	15 (25)	13 (26)	10 (29)	8 (31)	5 (33)	5 (33)	4 (34)	3 (35)	3 (35)	2 (36)	1 (37)	1 (37)	0 (38)
Placebo	72 (0)	48 (14)	33 (21)	25 (24)	21 (27)	17 (29)	13 (33)	12 (34)	10 (36)	8 (37)	4 (41)	3 (42)	1 (43)	1 (43)	1 (43)	1 (43)	1 (43)	1 (43)	1 (43)	1 (43)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



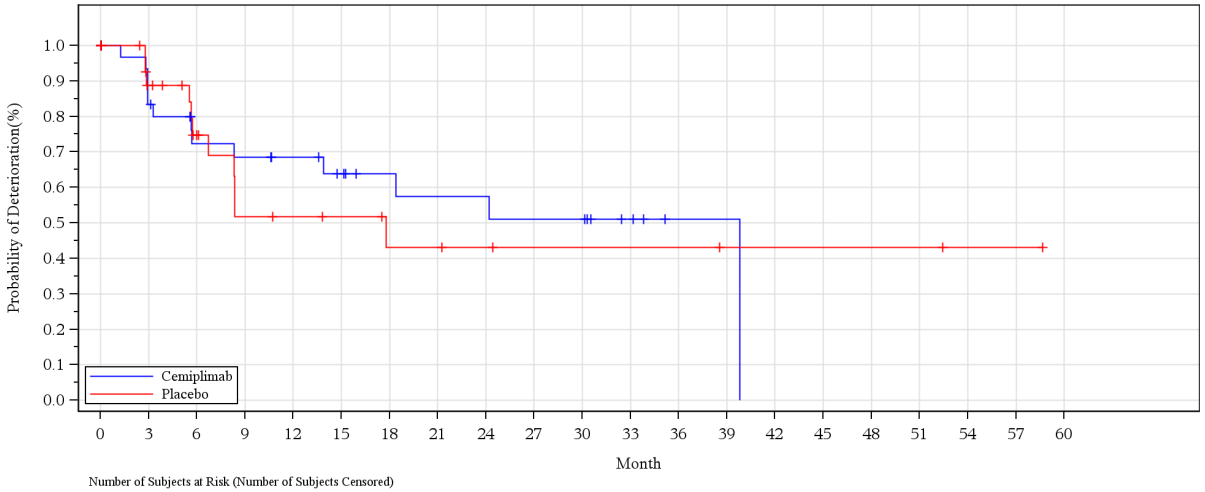
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	131 (20)	113 (23)	95 (30)	81 (38)	69 (46)	54 (53)	51 (54)	41 (62)	36 (67)	25 (76)	23 (77)	17 (82)	16 (83)	14 (84)	11 (87)	9 (89)	7 (91)	2 (96)	2 (96)	0 (98)
Placebo	174 (0)	124 (25)	95 (41)	81 (48)	63 (61)	53 (65)	44 (74)	36 (79)	31 (84)	27 (87)	20 (94)	18 (96)	12 (101)	11 (102)	8 (105)	7 (106)	7 (106)	4 (109)	4 (109)	4 (109)	2 (111)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



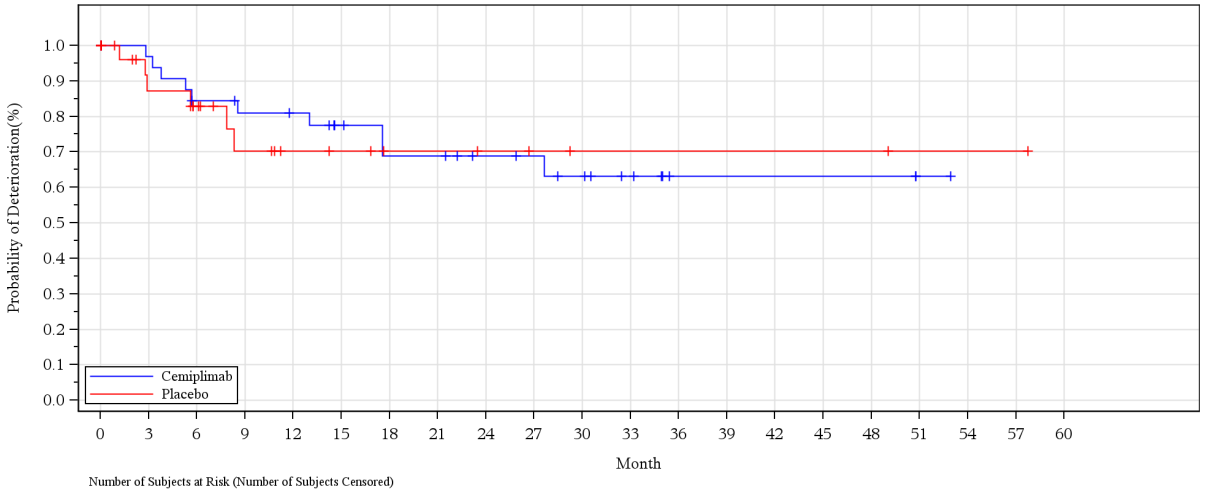
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	25 (5)	19 (8)	18 (8)	16 (10)	13 (12)	10 (15)	9 (15)	9 (15)	8 (15)	8 (15)	4 (19)	1 (22)	1 (22)	0 (22)	0 (22)	0 (22)	0 (22)	0 (22)	0 (22)	0 (22)
Placebo	32 (0)	22 (7)	15 (11)	9 (13)	8 (14)	7 (15)	5 (16)	5 (16)	4 (17)	3 (18)	3 (18)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	1 (20)	0 (21)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



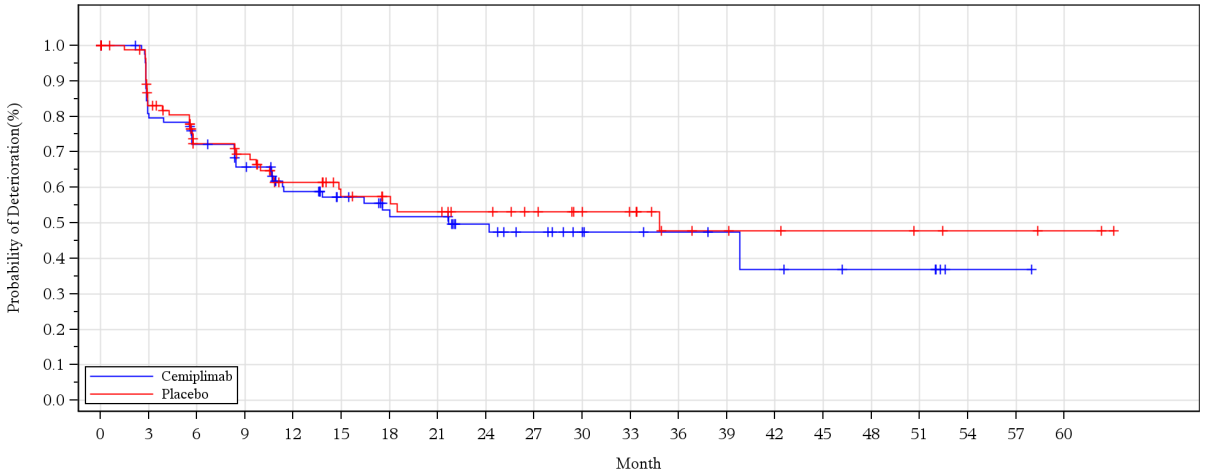
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	31 (5)	26 (6)	24 (7)	23 (8)	19 (11)	16 (12)	16 (12)	13 (15)	12 (16)	10 (17)	7 (20)	3 (24)	3 (24)	3 (24)	3 (24)	3 (24)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	31 (0)	20 (8)	16 (11)	11 (14)	8 (17)	7 (18)	5 (20)	5 (20)	4 (21)	3 (22)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



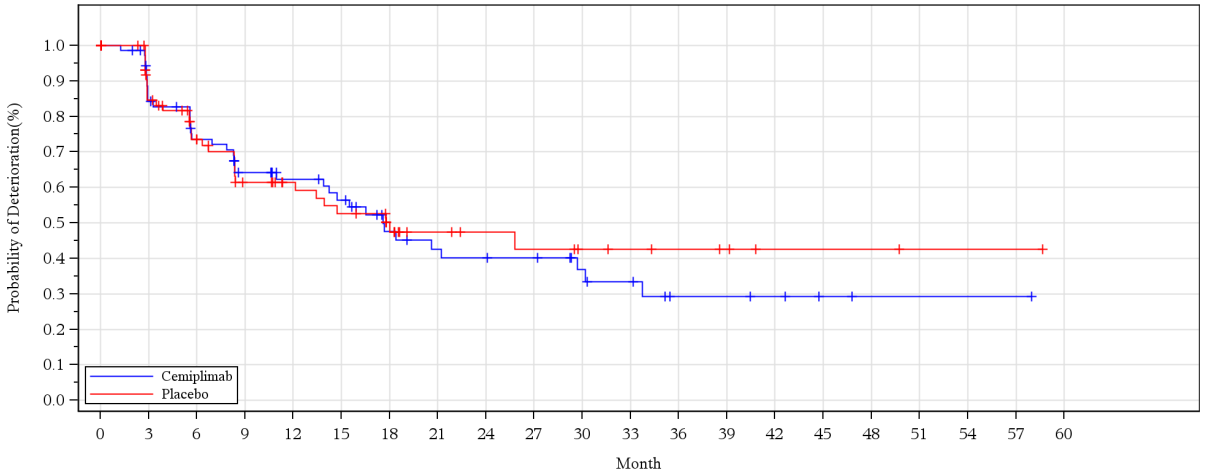
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	67 (7)	58 (9)	51 (11)	41 (16)	34 (22)	28 (26)	27 (26)	21 (31)	17 (34)	12 (39)	11 (40)	10 (41)	9 (42)	7 (42)	6 (43)	5 (44)	5 (44)	1 (48)	1 (48)	0 (49)
Placebo	90 (0)	67 (9)	50 (18)	46 (20)	35 (26)	29 (30)	26 (33)	24 (33)	21 (36)	18 (39)	14 (43)	13 (44)	8 (48)	7 (49)	6 (50)	5 (51)	5 (51)	4 (52)	3 (53)	3 (53)	2 (54)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	58 (13)	48 (16)	38 (20)	33 (24)	29 (25)	20 (30)	17 (31)	16 (31)	15 (32)	11 (35)	9 (36)	5 (39)	5 (39)	4 (40)	2 (42)	1 (43)	1 (43)	1 (43)	1 (43)	0 (44)
Placebo	85 (0)	59 (15)	44 (23)	33 (27)	28 (32)	24 (32)	18 (37)	12 (42)	10 (44)	9 (44)	7 (46)	6 (47)	5 (48)	4 (49)	2 (51)	2 (51)	2 (51)	1 (52)	1 (52)	1 (52)	0 (53)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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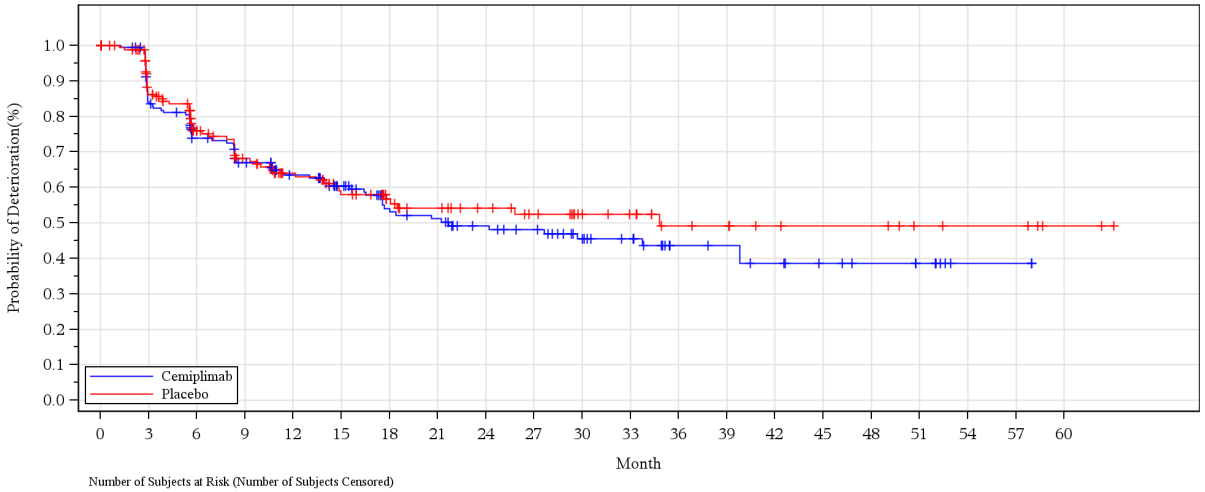
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	142 (20)	119 (26)	103 (31)	88 (41)	74 (51)	57 (61)	53 (62)	45 (68)	41 (71)	31 (79)	27 (83)	18 (91)	17 (92)	14 (93)	11 (96)	9 (98)	7 (100)	2 (105)	2 (105)	0 (107)
Placebo	189 (0)	135 (32)	102 (50)	84 (58)	66 (71)	55 (76)	45 (85)	39 (89)	34 (94)	29 (98)	22 (105)	20 (107)	14 (112)	13 (113)	10 (116)	9 (117)	9 (117)	6 (120)	5 (121)	5 (121)	2 (124)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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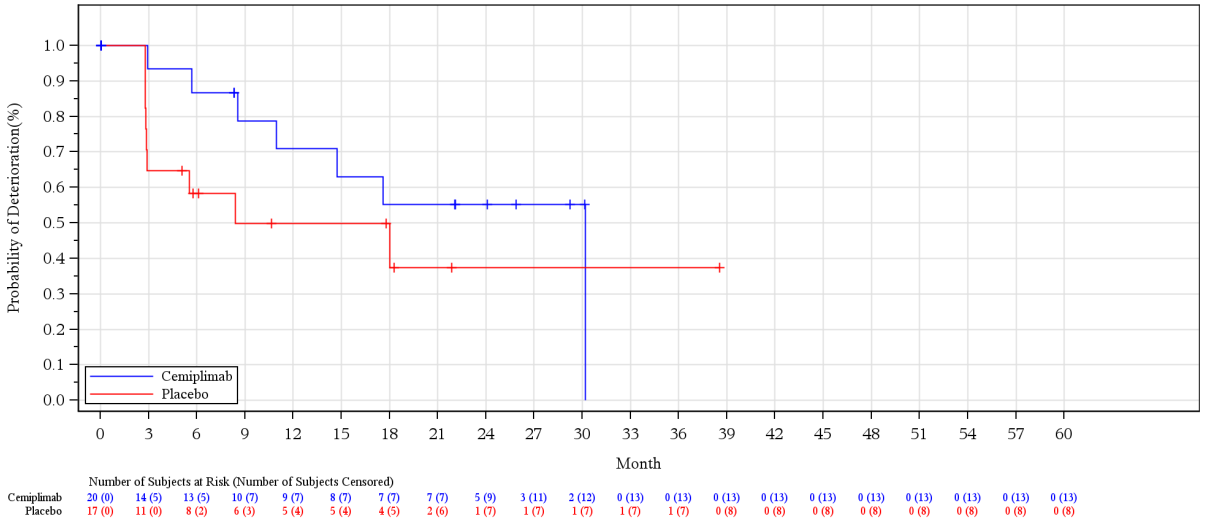
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	14 (5)	13 (5)	10 (7)	9 (7)	8 (7)	7 (7)	7 (7)	5 (9)	3 (11)	2 (12)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)
Placebo	17 (0)	11 (0)	8 (2)	6 (3)	5 (4)	5 (4)	4 (5)	2 (6)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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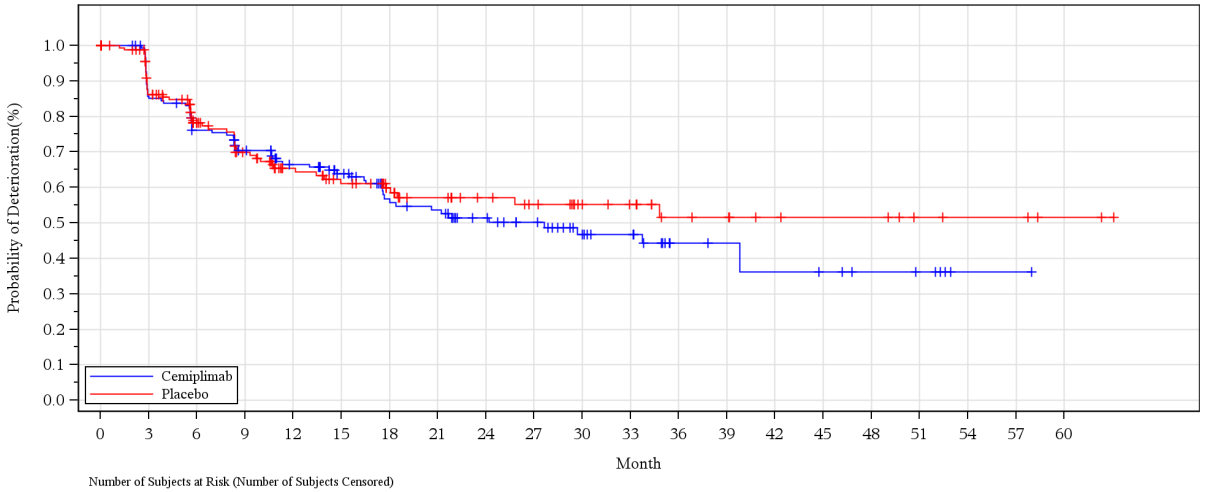
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



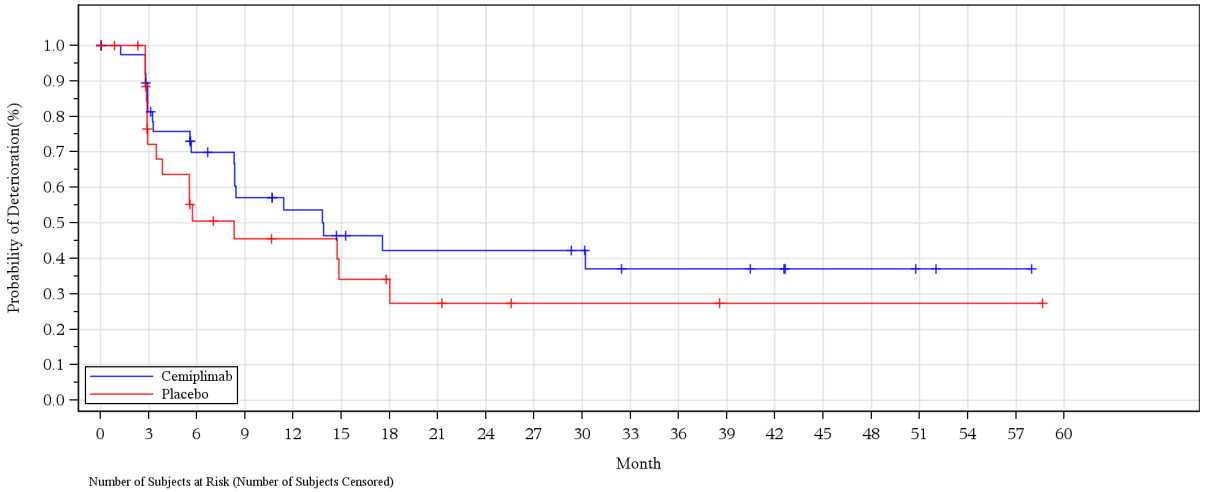
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	126 (19)	109 (22)	95 (28)	82 (36)	70 (45)	54 (54)	50 (55)	40 (63)	34 (68)	24 (76)	21 (79)	12 (87)	11 (88)	9 (88)	8 (89)	6 (91)	5 (92)	1 (96)	1 (96)	0 (97)
Placebo	177 (0)	129 (27)	99 (46)	81 (54)	63 (67)	54 (72)	44 (81)	37 (86)	32 (91)	28 (94)	21 (101)	19 (103)	13 (108)	12 (109)	9 (112)	8 (113)	8 (113)	5 (116)	4 (117)	4 (117)	2 (119)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	30 (6)	23 (9)	18 (10)	15 (12)	12 (13)	10 (14)	10 (14)	10 (14)	10 (14)	9 (15)	6 (17)	6 (17)	6 (17)	5 (18)	3 (20)	3 (20)	2 (21)	1 (22)	1 (22)	0 (23)
Placebo	29 (0)	17 (5)	11 (6)	9 (7)	8 (8)	6 (8)	5 (9)	4 (9)	3 (10)	2 (11)	2 (11)	2 (11)	2 (11)	1 (12)	1 (12)	1 (12)	1 (12)	1 (12)	1 (12)	1 (12)	0 (13)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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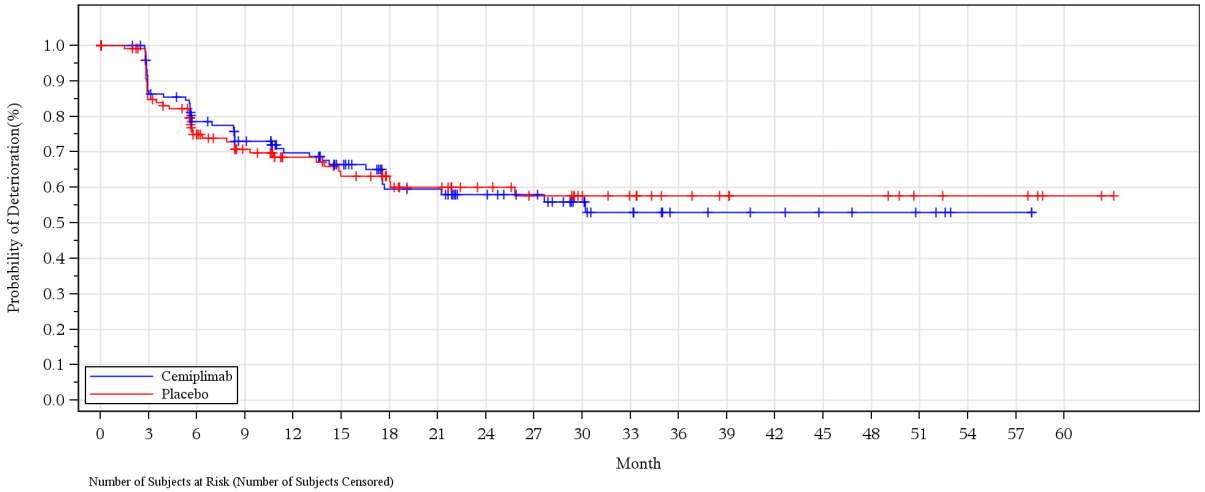
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	102 (16)	87 (21)	76 (26)	65 (34)	55 (41)	42 (49)	41 (50)	33 (57)	29 (61)	21 (68)	16 (72)	11 (77)	10 (78)	9 (79)	7 (81)	6 (82)	5 (83)	2 (86)	2 (86)	0 (88)
Placebo	131 (0)	100 (13)	77 (25)	64 (34)	53 (43)	47 (45)	40 (52)	34 (56)	28 (62)	24 (65)	19 (70)	17 (72)	13 (76)	11 (78)	9 (80)	9 (80)	9 (80)	6 (83)	5 (84)	5 (84)	2 (87)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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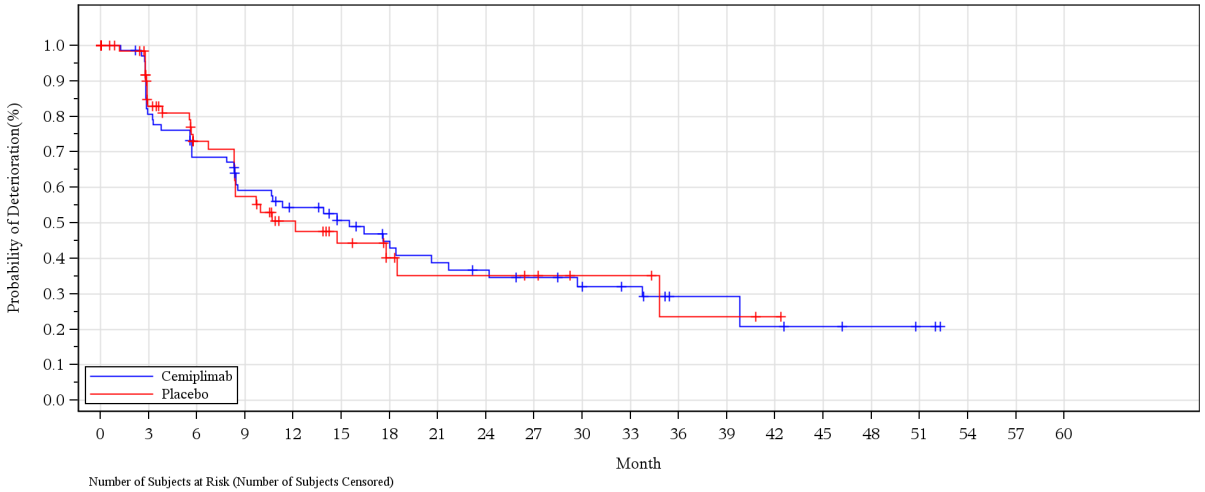
Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



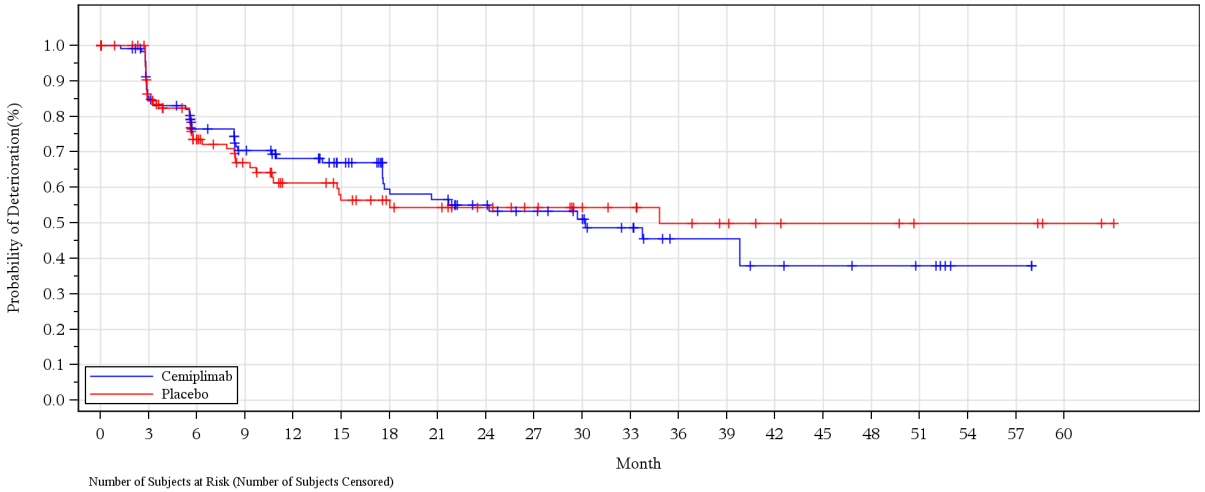
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	54 (9)	45 (10)	37 (12)	32 (14)	27 (17)	22 (19)	19 (19)	17 (20)	15 (21)	12 (23)	11 (24)	7 (27)	7 (27)	5 (27)	4 (28)	3 (29)	2 (30)	0 (32)	0 (32)	0 (32)
Placebo	75 (0)	46 (19)	33 (27)	26 (27)	18 (32)	13 (35)	9 (38)	7 (39)	7 (39)	6 (40)	4 (42)	4 (42)	2 (43)	2 (43)	1 (44)	0 (45)	0 (45)	0 (45)	0 (45)	0 (45)	0 (45)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



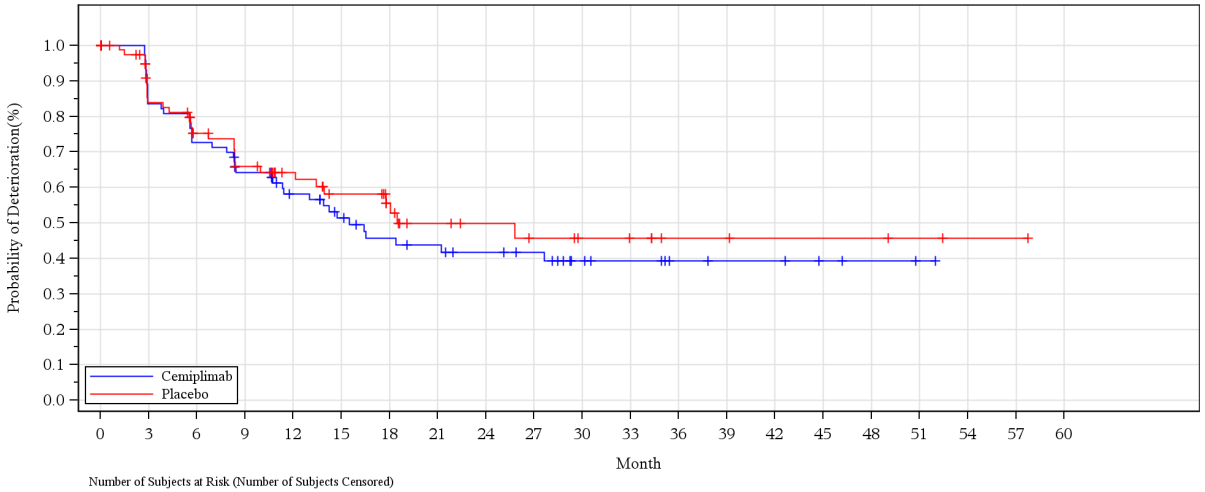
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	95 (14)	79 (20)	68 (25)	61 (30)	53 (37)	40 (45)	38 (45)	31 (51)	27 (54)	22 (58)	18 (61)	12 (66)	12 (66)	9 (67)	8 (68)	7 (69)	6 (70)	2 (74)	2 (74)	0 (76)
Placebo	117 (0)	85 (16)	61 (30)	49 (37)	39 (43)	34 (45)	29 (50)	27 (51)	23 (55)	20 (58)	15 (63)	14 (64)	11 (66)	9 (68)	7 (70)	6 (71)	6 (71)	4 (73)	4 (73)	4 (73)	2 (75)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.2 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Physical Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



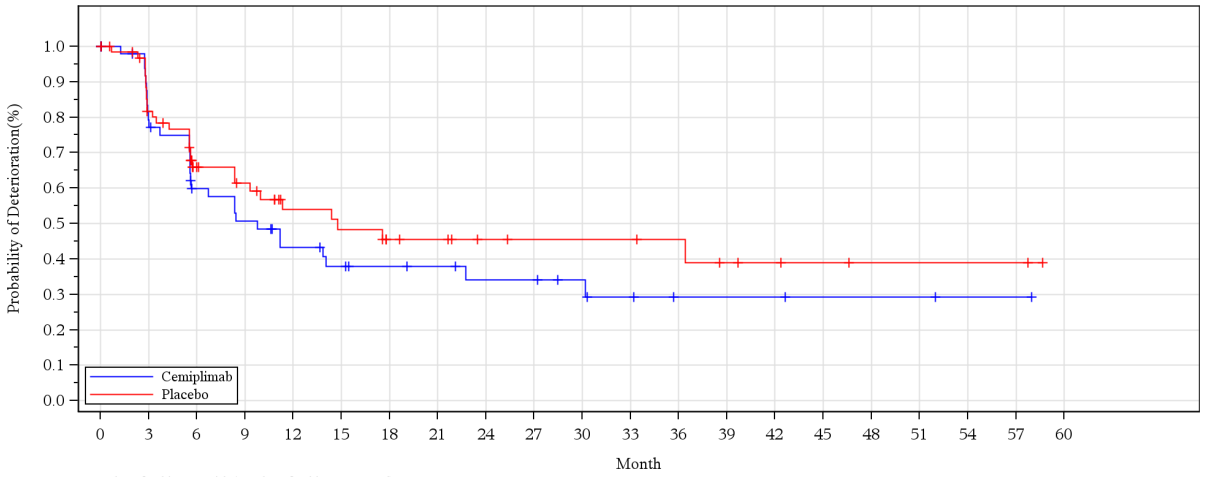
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	61 (11)	53 (11)	45 (13)	36 (18)	29 (21)	24 (23)	22 (24)	19 (26)	17 (28)	11 (33)	9 (35)	6 (38)	5 (39)	5 (39)	3 (41)	2 (42)	1 (43)	0 (44)	0 (44)	0 (44)
Placebo	89 (0)	61 (16)	49 (22)	41 (24)	32 (32)	26 (35)	20 (40)	14 (44)	12 (46)	10 (47)	8 (49)	7 (50)	4 (53)	4 (53)	3 (54)	3 (54)	3 (54)	2 (55)	1 (56)	1 (56)	0 (57)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



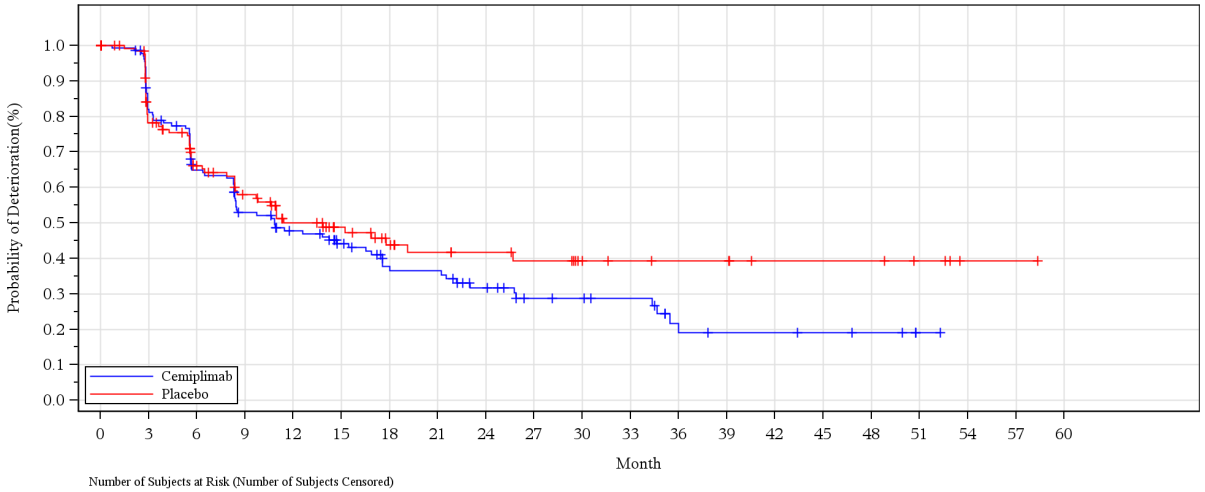
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (8)	26 (11)	22 (11)	17 (13)	14 (14)	12 (16)	11 (17)	9 (18)	9 (18)	7 (20)	5 (21)	3 (23)	3 (23)	3 (23)	2 (24)	2 (24)	2 (24)	1 (25)	1 (25)	0 (26)
Placebo	65 (0)	48 (6)	32 (13)	27 (16)	19 (21)	17 (21)	13 (24)	12 (25)	9 (28)	8 (29)	8 (29)	8 (29)	7 (30)	5 (31)	4 (32)	3 (33)	2 (34)	2 (34)	2 (34)	2 (34)	0 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



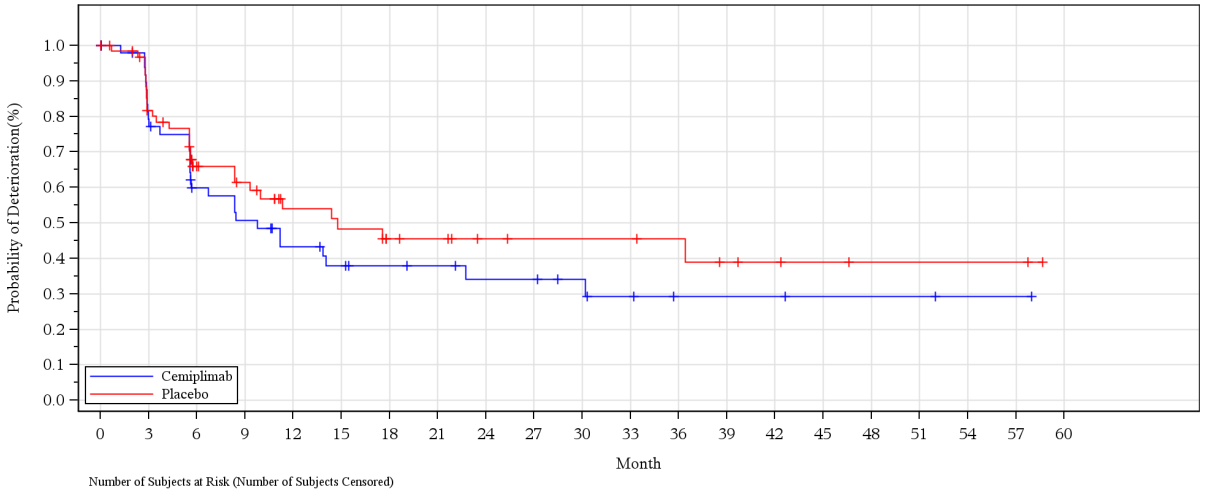
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	108 (21)	82 (25)	64 (28)	54 (32)	44 (38)	33 (43)	32 (43)	24 (47)	17 (52)	16 (53)	14 (55)	7 (58)	6 (59)	6 (59)	5 (60)	4 (61)	1 (64)	0 (65)	0 (65)	0 (65)
Placebo	141 (0)	91 (24)	67 (35)	55 (39)	41 (46)	32 (54)	24 (59)	20 (62)	18 (64)	16 (65)	11 (70)	10 (71)	9 (72)	9 (72)	6 (75)	6 (75)	6 (75)	4 (77)	1 (80)	1 (80)	0 (81)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



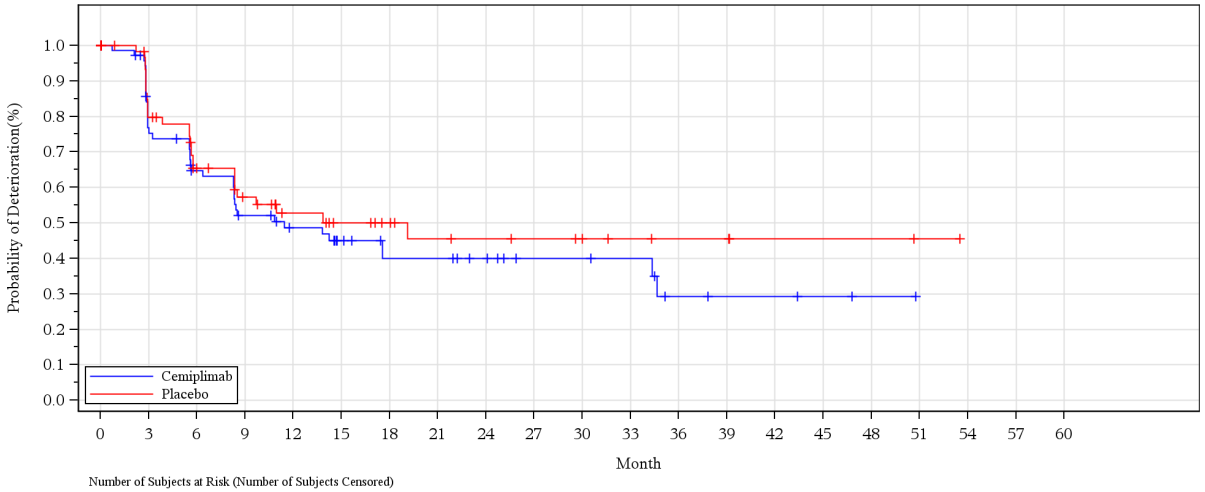
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (8)	26 (11)	22 (11)	17 (13)	14 (14)	12 (16)	11 (17)	9 (18)	9 (18)	7 (20)	5 (21)	3 (23)	3 (23)	3 (23)	2 (24)	2 (24)	2 (24)	1 (25)	1 (25)	0 (26)
Placebo	65 (0)	48 (6)	32 (13)	27 (16)	19 (21)	17 (21)	13 (24)	12 (25)	9 (28)	8 (29)	8 (29)	8 (29)	7 (30)	5 (31)	4 (32)	3 (33)	2 (34)	2 (34)	2 (34)	2 (34)	0 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



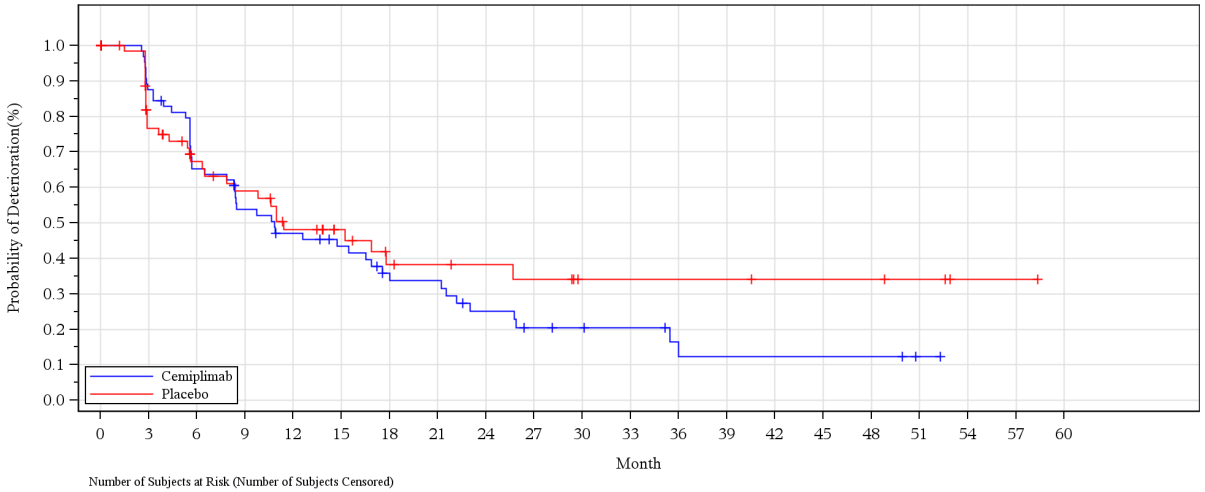
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	52 (12)	41 (15)	32 (16)	27 (19)	21 (23)	16 (26)	16 (26)	13 (29)	9 (33)	9 (33)	8 (34)	4 (36)	3 (37)	3 (37)	2 (38)	1 (39)	0 (40)	0 (40)	0 (40)	0 (40)
Placebo	69 (0)	47 (10)	34 (15)	27 (18)	20 (23)	16 (26)	13 (29)	10 (31)	9 (32)	8 (33)	6 (35)	5 (36)	4 (37)	4 (37)	2 (39)	2 (39)	2 (39)	1 (40)	0 (41)	0 (41)	0 (41)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



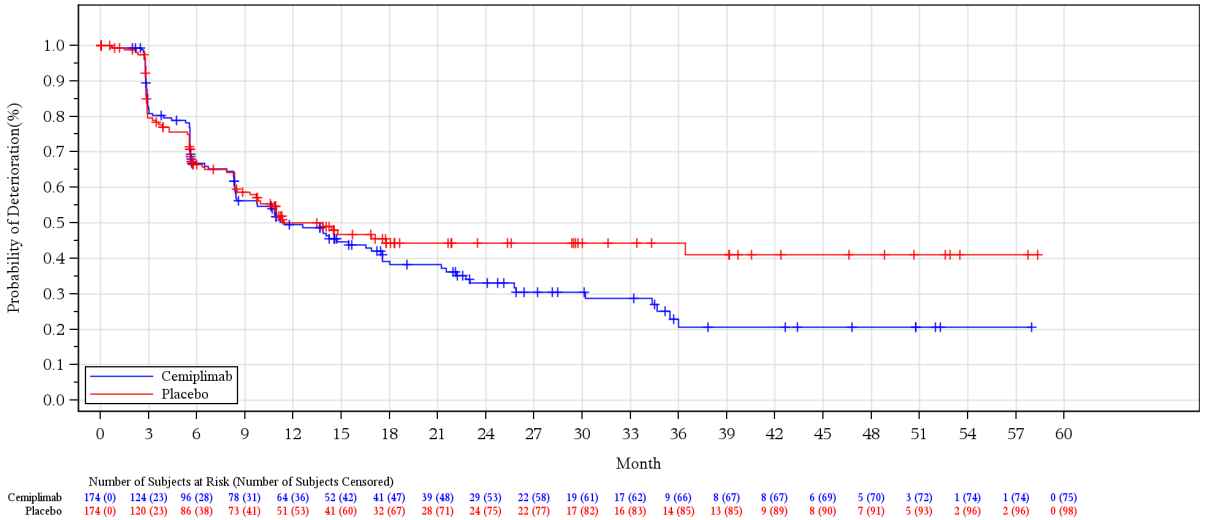
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	56 (9)	41 (10)	32 (12)	27 (13)	23 (15)	17 (17)	16 (17)	11 (18)	8 (19)	7 (20)	6 (21)	3 (22)	3 (22)	3 (22)	3 (22)	1 (24)	0 (25)	0 (25)	0 (25)
Placebo	72 (0)	44 (14)	33 (20)	28 (21)	21 (23)	16 (28)	11 (30)	10 (31)	9 (32)	8 (32)	5 (35)	5 (35)	5 (35)	5 (35)	4 (36)	4 (36)	4 (36)	3 (37)	1 (39)	1 (39)	0 (40)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



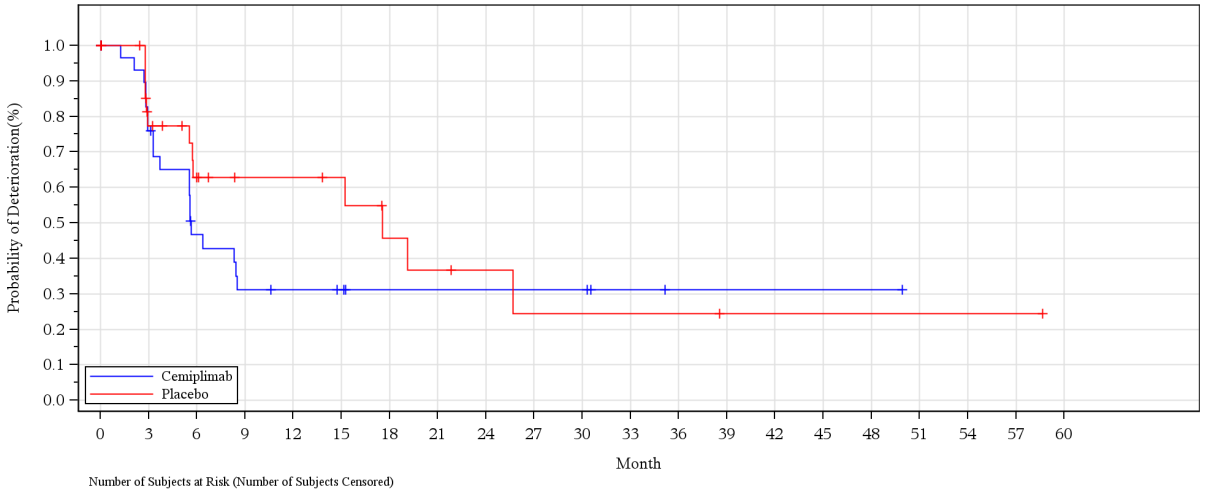
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	124 (23)	96 (28)	78 (31)	64 (36)	52 (42)	41 (47)	39 (48)	29 (53)	22 (58)	19 (61)	17 (62)	9 (66)	8 (67)	8 (67)	6 (69)	5 (70)	3 (72)	1 (74)	1 (74)	0 (75)
Placebo	174 (0)	120 (23)	86 (38)	73 (41)	51 (53)	41 (60)	32 (67)	28 (71)	24 (75)	22 (77)	17 (82)	16 (83)	14 (85)	13 (85)	9 (89)	8 (90)	7 (91)	5 (93)	2 (96)	2 (96)	0 (98)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



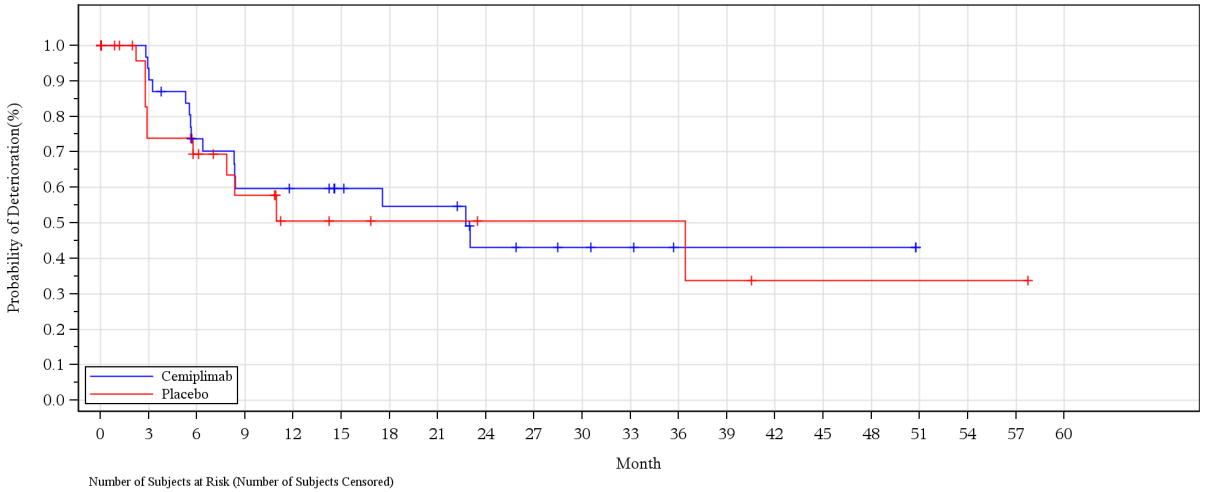
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	22 (6)	12 (8)	8 (8)	7 (9)	6 (10)	4 (12)	4 (12)	4 (12)	4 (12)	4 (12)	2 (14)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	32 (0)	19 (7)	13 (10)	9 (14)	9 (14)	8 (15)	5 (16)	4 (16)	3 (17)	2 (17)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (6)	21 (8)	17 (8)	16 (9)	13 (12)	11 (13)	11 (13)	7 (15)	6 (16)	5 (17)	4 (18)	2 (20)	2 (20)	2 (20)	2 (20)	2 (20)	0 (22)	0 (22)	0 (22)	0 (22)
Placebo	31 (0)	17 (8)	14 (10)	10 (12)	6 (15)	5 (16)	4 (17)	4 (17)	3 (18)	3 (18)	3 (18)	3 (18)	3 (18)	2 (18)	1 (19)	1 (19)	1 (19)	1 (19)	1 (19)	1 (19)	0 (20)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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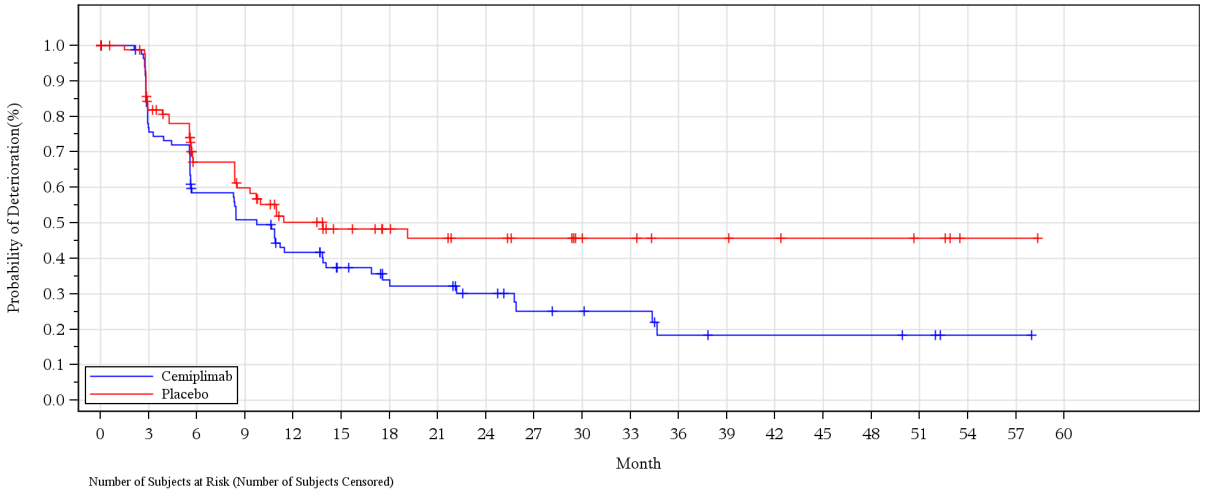
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	63 (8)	46 (10)	40 (10)	31 (12)	24 (16)	19 (19)	18 (19)	14 (22)	10 (24)	9 (25)	8 (26)	5 (27)	4 (28)	4 (28)	4 (28)	4 (28)	3 (29)	1 (31)	1 (31)	0 (32)
Placebo	90 (0)	66 (9)	46 (18)	40 (19)	29 (24)	23 (29)	19 (33)	17 (34)	15 (36)	13 (38)	9 (42)	9 (42)	7 (44)	7 (44)	6 (45)	5 (46)	5 (46)	4 (47)	1 (50)	1 (50)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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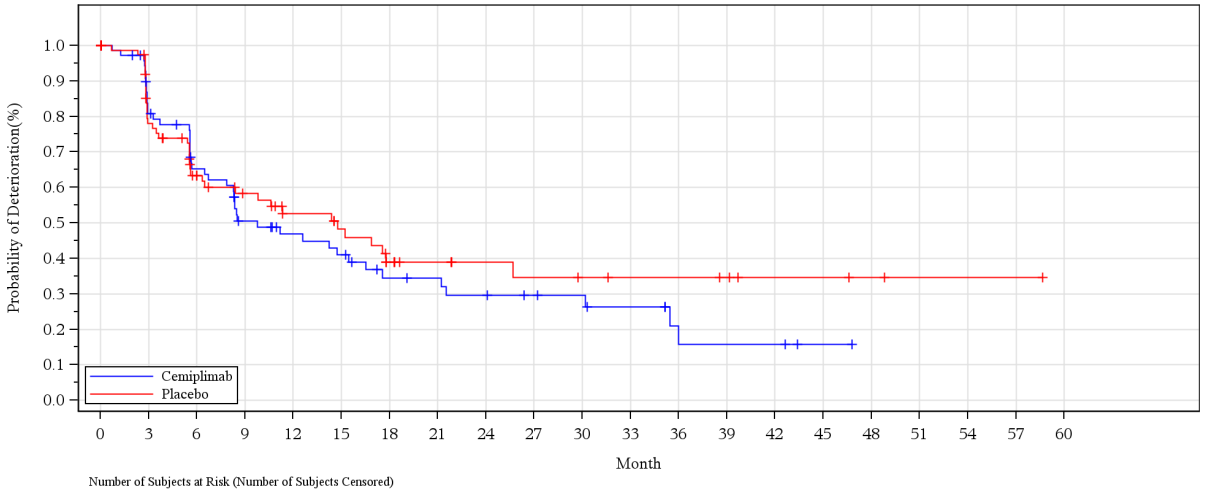
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



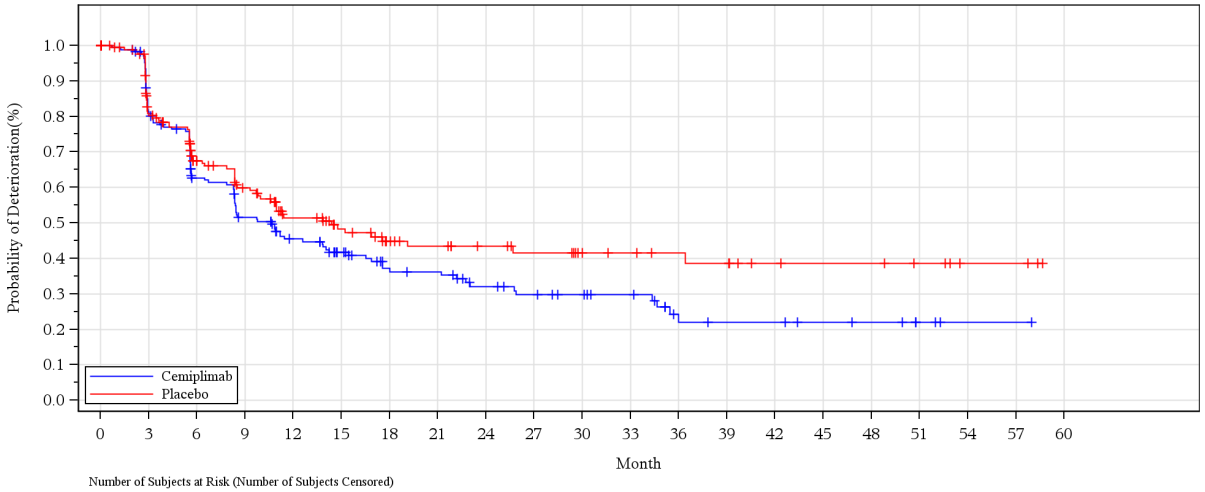
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	54 (15)	41 (18)	29 (21)	24 (24)	21 (24)	15 (27)	14 (28)	12 (28)	10 (30)	9 (31)	7 (32)	3 (34)	3 (34)	3 (34)	1 (36)	0 (37)	0 (37)	0 (37)	0 (37)	0 (37)
Placebo	85 (0)	56 (13)	39 (20)	32 (24)	25 (28)	21 (30)	14 (33)	11 (36)	9 (38)	8 (38)	7 (39)	6 (40)	6 (40)	5 (41)	3 (43)	3 (43)	2 (44)	1 (45)	1 (45)	1 (45)	0 (46)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



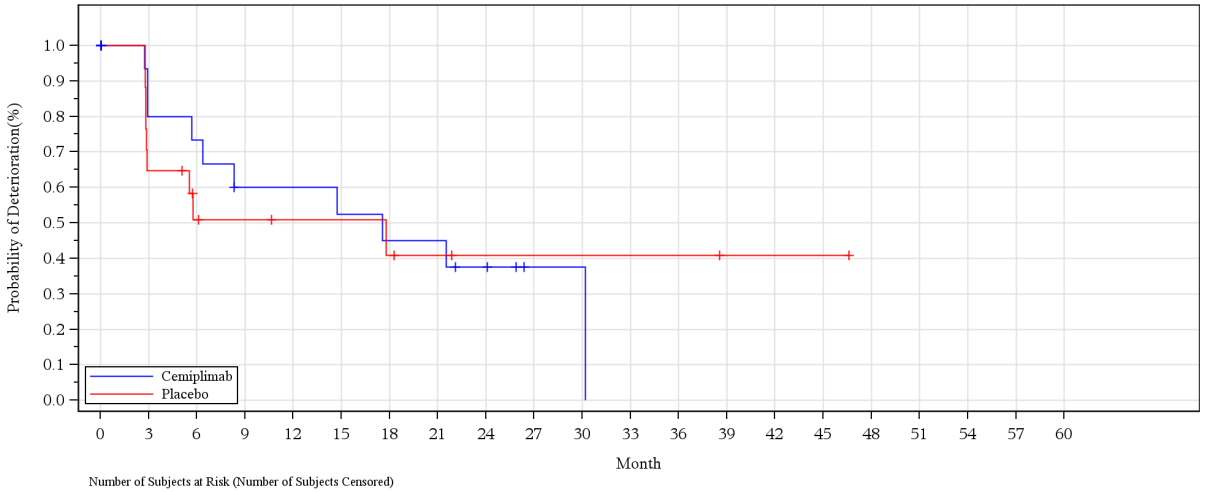
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	134 (24)	97 (31)	78 (33)	63 (39)	51 (46)	39 (53)	37 (54)	29 (58)	25 (60)	22 (63)	19 (66)	10 (71)	9 (72)	9 (72)	7 (74)	6 (75)	3 (78)	1 (80)	1 (80)	0 (81)
Placebo	189 (0)	128 (30)	92 (46)	76 (52)	55 (63)	44 (71)	33 (79)	29 (82)	25 (86)	22 (88)	17 (93)	16 (94)	14 (96)	13 (96)	9 (100)	8 (101)	8 (101)	6 (103)	3 (106)	3 (106)	0 (109)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	12 (5)	11 (5)	8 (6)	8 (6)	7 (6)	6 (6)	6 (6)	4 (7)	1 (10)	1 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)
Placebo	17 (0)	11 (0)	7 (2)	6 (3)	5 (4)	5 (4)	4 (4)	3 (5)	2 (6)	2 (6)	2 (6)	2 (6)	2 (6)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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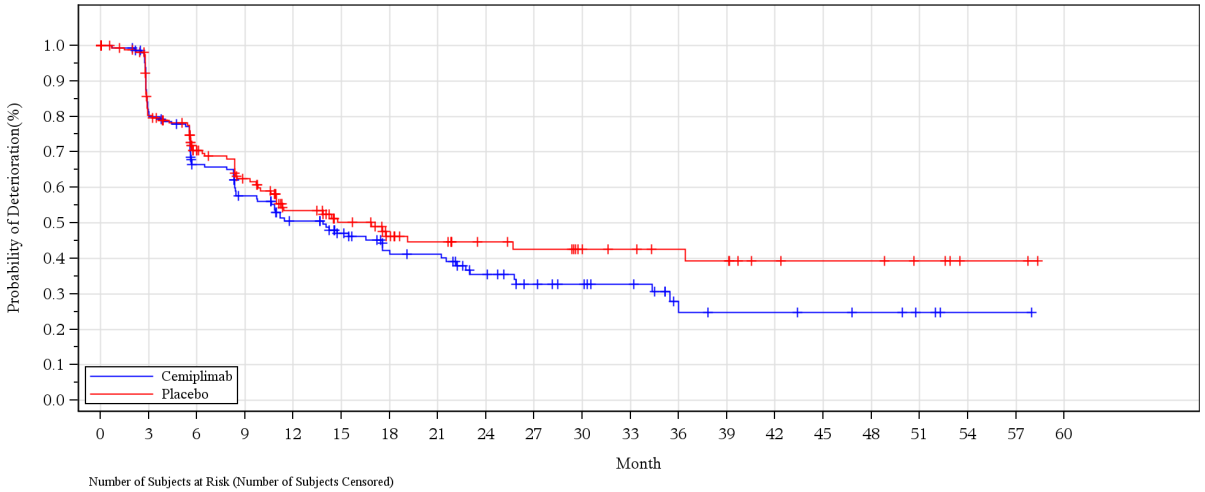
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



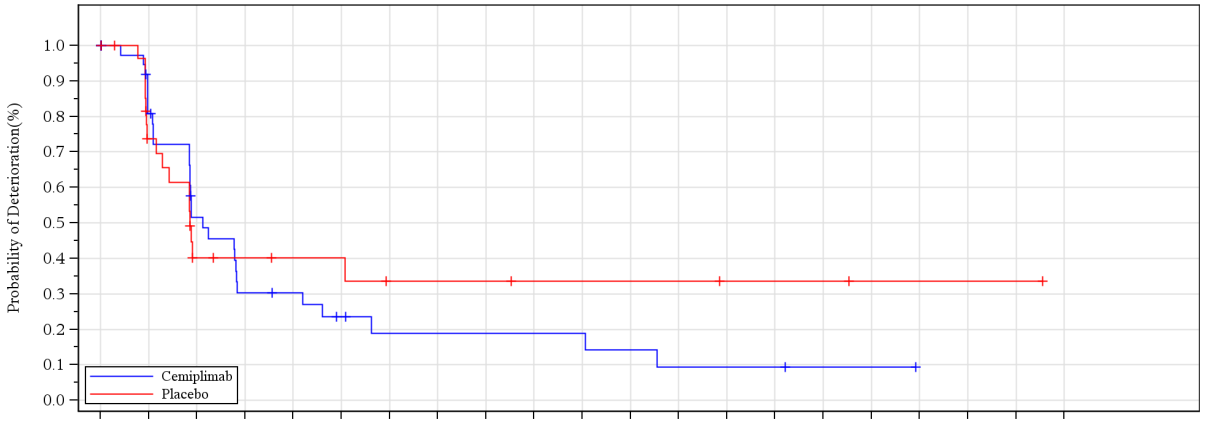
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	117 (22)	91 (27)	76 (30)	62 (35)	52 (41)	41 (47)	39 (48)	29 (53)	22 (58)	19 (61)	16 (64)	8 (69)	7 (70)	7 (70)	6 (71)	5 (72)	3 (74)	1 (76)	1 (76)	0 (77)
Placebo	177 (0)	121 (26)	91 (42)	75 (48)	54 (59)	43 (67)	33 (74)	28 (78)	23 (83)	21 (84)	16 (89)	15 (90)	13 (92)	12 (92)	8 (96)	7 (97)	7 (97)	5 (99)	2 (102)	2 (102)	0 (104)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



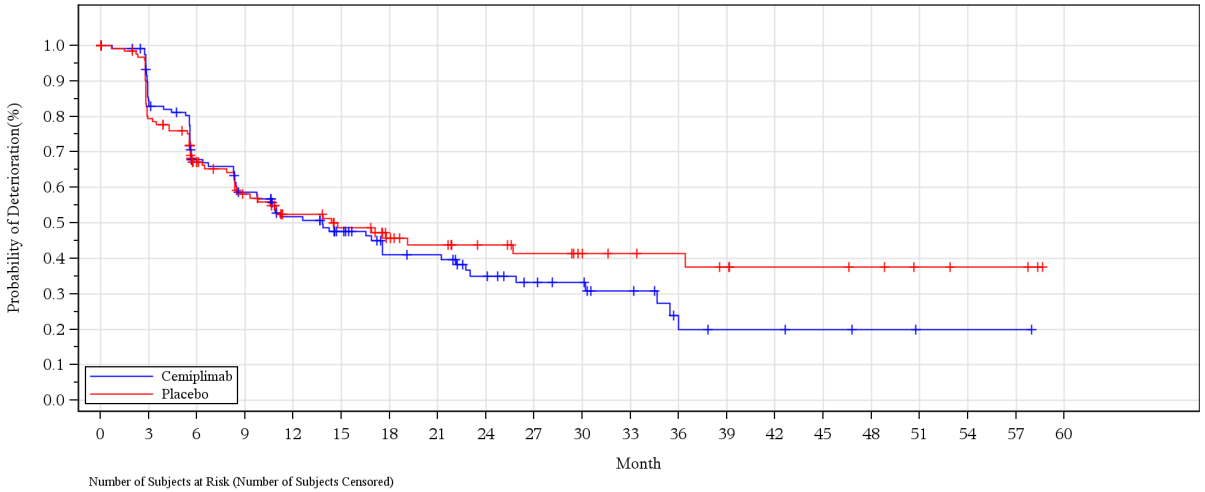
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (7)	17 (9)	10 (9)	9 (10)	6 (11)	4 (12)	4 (12)	4 (12)	4 (12)	4 (12)	3 (12)	2 (12)	2 (12)	2 (12)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)	0 (14)
Placebo	29 (0)	18 (4)	8 (6)	7 (7)	6 (8)	6 (8)	4 (9)	4 (9)	4 (9)	3 (10)	3 (10)	3 (10)	3 (10)	2 (11)	2 (11)	2 (11)	1 (12)	1 (12)	1 (12)	1 (12)	0 (13)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	98 (17)	74 (22)	62 (24)	51 (28)	42 (33)	31 (39)	30 (40)	22 (44)	17 (48)	15 (50)	11 (53)	5 (56)	4 (57)	4 (57)	3 (58)	2 (59)	1 (60)	1 (60)	1 (60)	0 (61)
Placebo	131 (0)	96 (10)	69 (23)	55 (28)	42 (36)	36 (39)	28 (45)	24 (48)	20 (52)	17 (54)	13 (58)	12 (59)	11 (60)	9 (61)	7 (63)	7 (63)	6 (64)	4 (66)	3 (67)	3 (67)	0 (70)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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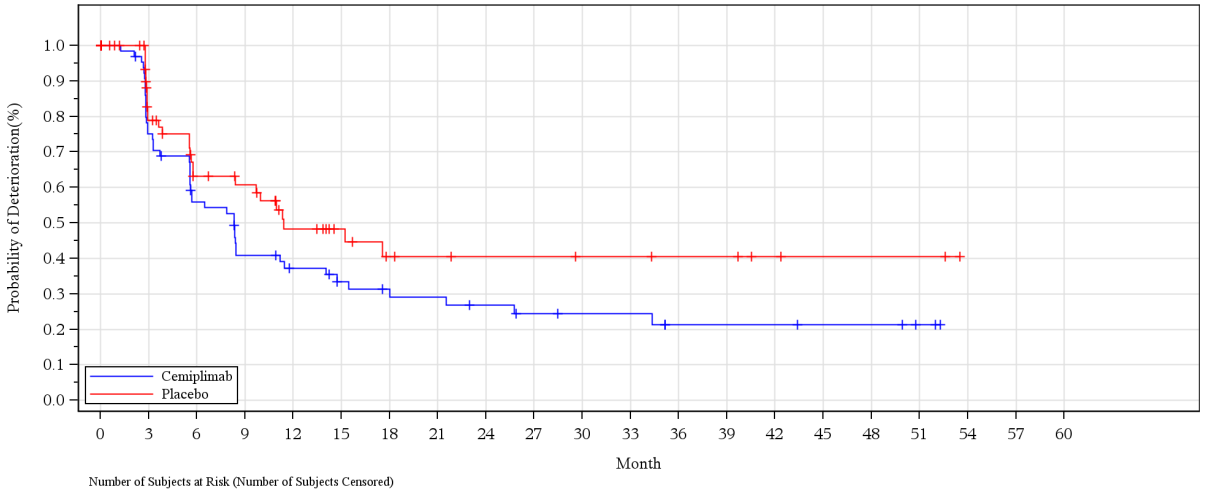
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



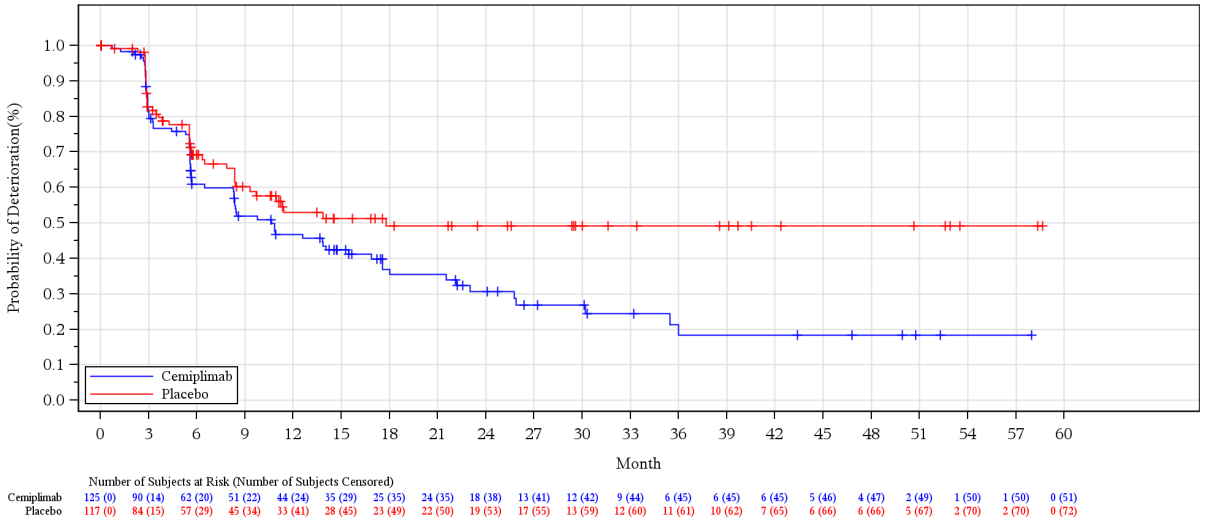
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	48 (12)	34 (14)	24 (15)	20 (17)	16 (19)	14 (20)	13 (20)	11 (21)	9 (22)	8 (23)	8 (23)	5 (25)	5 (25)	5 (25)	4 (26)	4 (26)	2 (28)	0 (30)	0 (30)	0 (30)
Placebo	75 (0)	43 (20)	30 (25)	27 (27)	18 (31)	13 (36)	9 (38)	8 (39)	7 (40)	7 (40)	6 (41)	6 (41)	5 (42)	5 (42)	3 (44)	2 (45)	2 (45)	2 (45)	0 (47)	0 (47)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	90 (14)	62 (20)	51 (22)	44 (24)	35 (29)	25 (35)	24 (35)	18 (38)	13 (41)	12 (42)	9 (44)	6 (45)	6 (45)	6 (45)	5 (46)	4 (47)	2 (49)	1 (50)	1 (50)	0 (51)
Placebo	117 (0)	84 (15)	57 (29)	45 (34)	33 (41)	28 (45)	23 (49)	22 (50)	19 (53)	17 (55)	13 (59)	12 (60)	11 (61)	10 (62)	7 (65)	6 (66)	6 (66)	5 (67)	2 (70)	2 (70)	0 (72)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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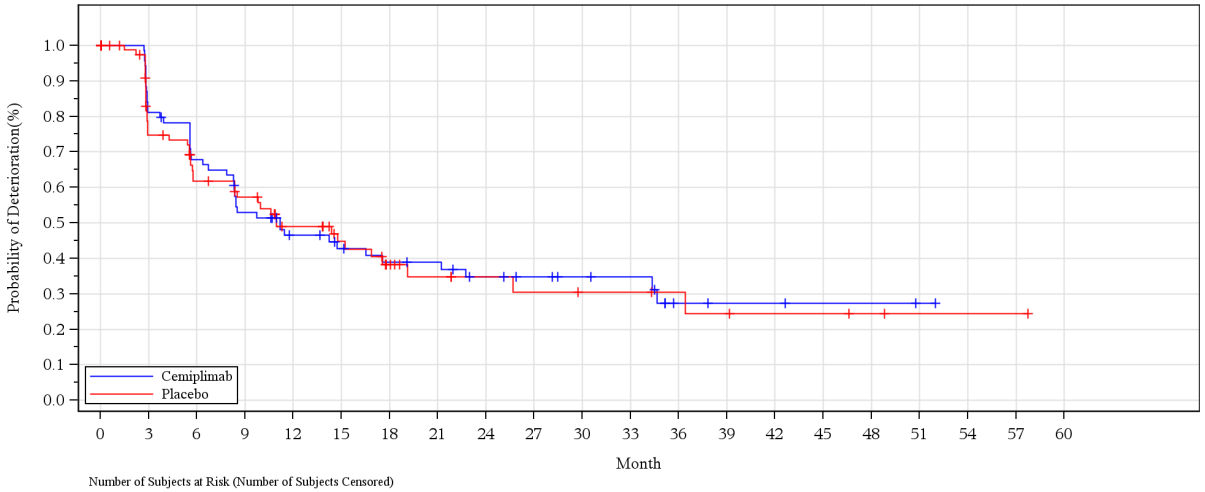
Figure 14.2.8.1.3 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Role Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



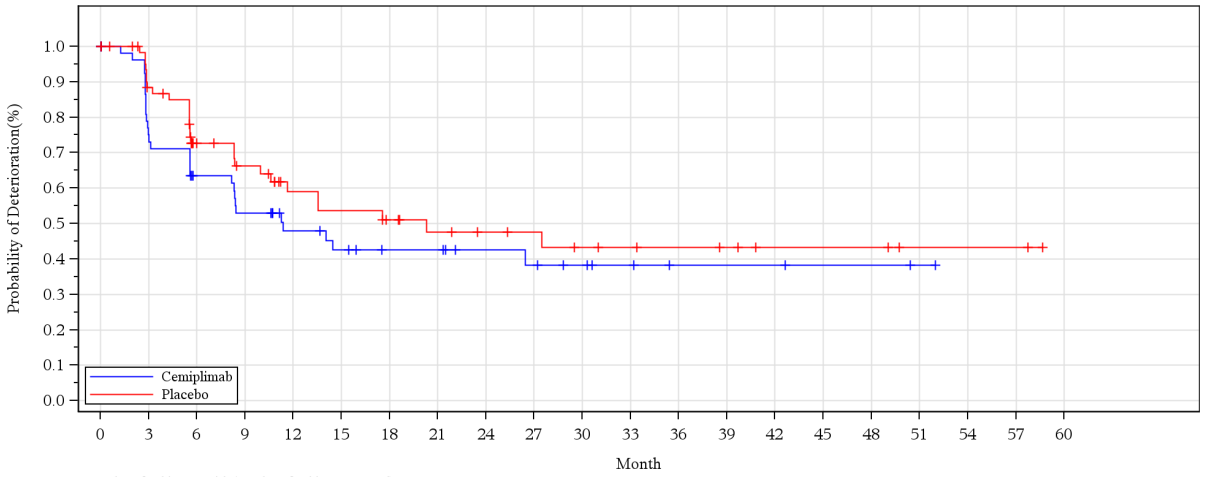
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	56 (15)	46 (16)	35 (17)	27 (21)	23 (23)	20 (24)	19 (25)	15 (27)	13 (29)	11 (31)	10 (32)	4 (36)	3 (37)	3 (37)	2 (38)	2 (38)	1 (39)	0 (40)	0 (40)	0 (40)
Placebo	89 (0)	55 (15)	42 (19)	37 (21)	27 (26)	21 (30)	14 (34)	10 (37)	8 (39)	7 (39)	6 (40)	6 (40)	5 (41)	4 (41)	3 (42)	3 (42)	2 (43)	1 (44)	1 (44)	1 (44)	0 (45)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



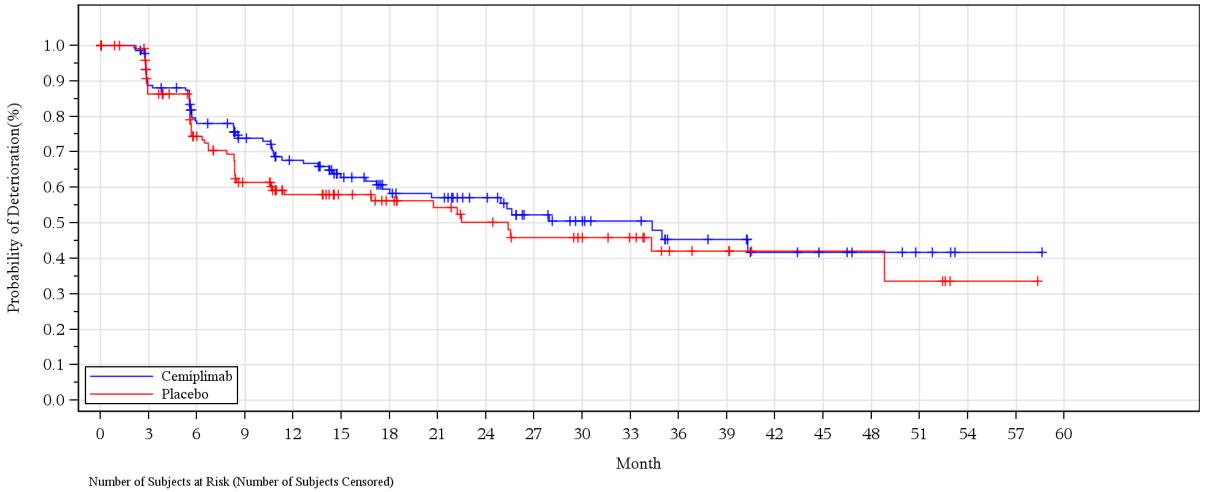
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	39 (4)	30 (7)	25 (7)	19 (11)	16 (12)	13 (15)	13 (15)	10 (18)	9 (18)	7 (20)	5 (22)	3 (24)	3 (24)	3 (24)	2 (25)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	52 (6)	36 (13)	30 (16)	22 (21)	20 (21)	17 (23)	14 (25)	12 (27)	11 (28)	9 (29)	8 (30)	7 (31)	6 (32)	4 (34)	4 (34)	4 (34)	2 (36)	2 (36)	2 (36)	0 (38)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



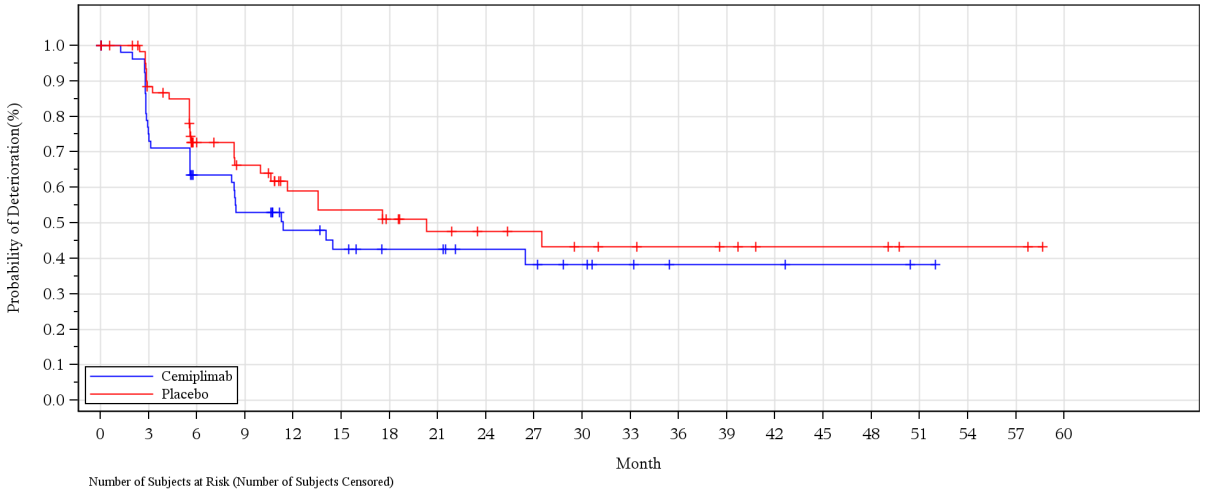
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	118 (20)	99 (25)	86 (33)	74 (38)	60 (47)	50 (54)	46 (56)	39 (63)	29 (70)	23 (75)	21 (77)	15 (81)	14 (82)	10 (85)	8 (87)	6 (89)	4 (91)	1 (94)	1 (94)	0 (95)
Placebo	141 (0)	100 (25)	76 (36)	58 (41)	46 (50)	38 (58)	32 (63)	28 (66)	24 (68)	20 (70)	17 (73)	15 (75)	9 (80)	8 (81)	5 (84)	5 (84)	5 (84)	4 (84)	1 (87)	1 (87)	0 (88)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	39 (4)	30 (7)	25 (7)	19 (11)	16 (12)	13 (15)	13 (15)	10 (18)	9 (18)	7 (20)	5 (22)	3 (24)	3 (24)	3 (24)	2 (25)	2 (25)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	52 (6)	36 (13)	30 (16)	22 (21)	20 (21)	17 (23)	14 (25)	12 (27)	11 (28)	9 (29)	8 (30)	7 (31)	6 (32)	4 (34)	4 (34)	4 (34)	2 (36)	2 (36)	2 (36)	0 (38)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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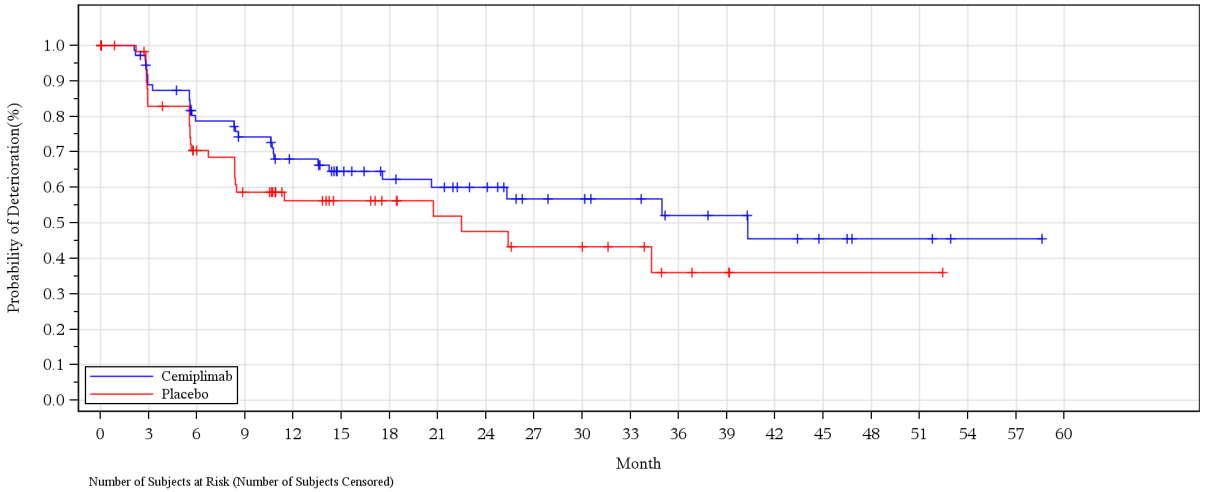
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	63 (9)	53 (12)	48 (14)	41 (17)	33 (23)	28 (27)	26 (28)	22 (32)	16 (37)	15 (38)	13 (40)	10 (42)	9 (43)	7 (44)	5 (46)	3 (48)	3 (48)	1 (50)	1 (50)	0 (51)
Placebo	69 (0)	48 (11)	36 (16)	29 (17)	22 (23)	18 (27)	15 (30)	12 (32)	11 (32)	9 (33)	8 (34)	7 (35)	4 (37)	3 (38)	1 (40)	1 (40)	1 (40)	1 (40)	0 (41)	0 (41)	0 (41)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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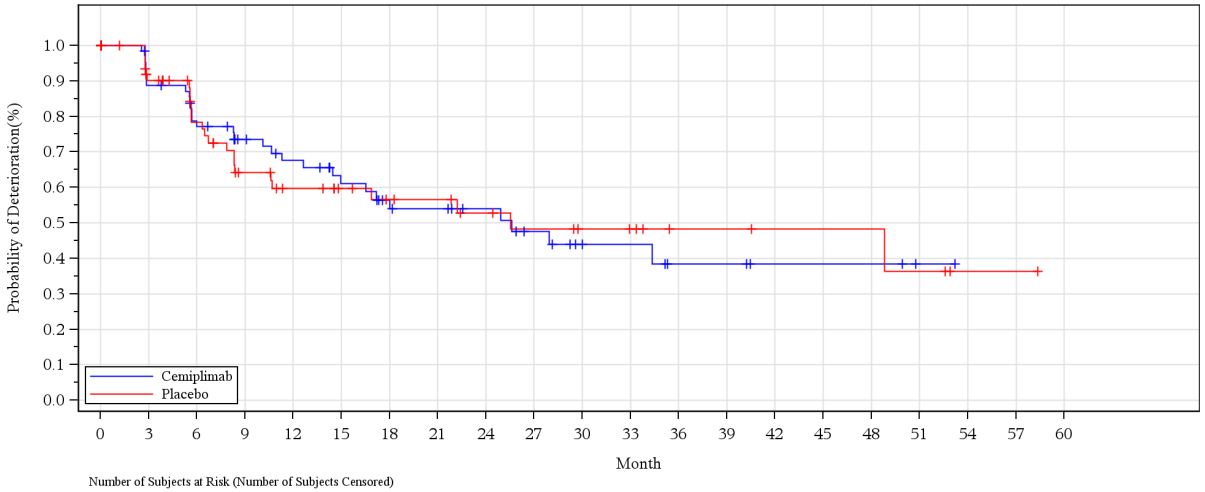
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	55 (11)	46 (13)	38 (19)	33 (21)	27 (24)	22 (27)	20 (28)	17 (31)	13 (33)	8 (37)	8 (37)	5 (39)	5 (39)	3 (41)	3 (41)	3 (41)	1 (43)	0 (44)	0 (44)	0 (44)
Placebo	72 (0)	52 (14)	40 (20)	29 (24)	24 (27)	20 (31)	17 (33)	16 (34)	13 (36)	11 (37)	9 (39)	8 (40)	5 (43)	5 (43)	4 (44)	4 (44)	4 (44)	3 (44)	1 (46)	1 (46)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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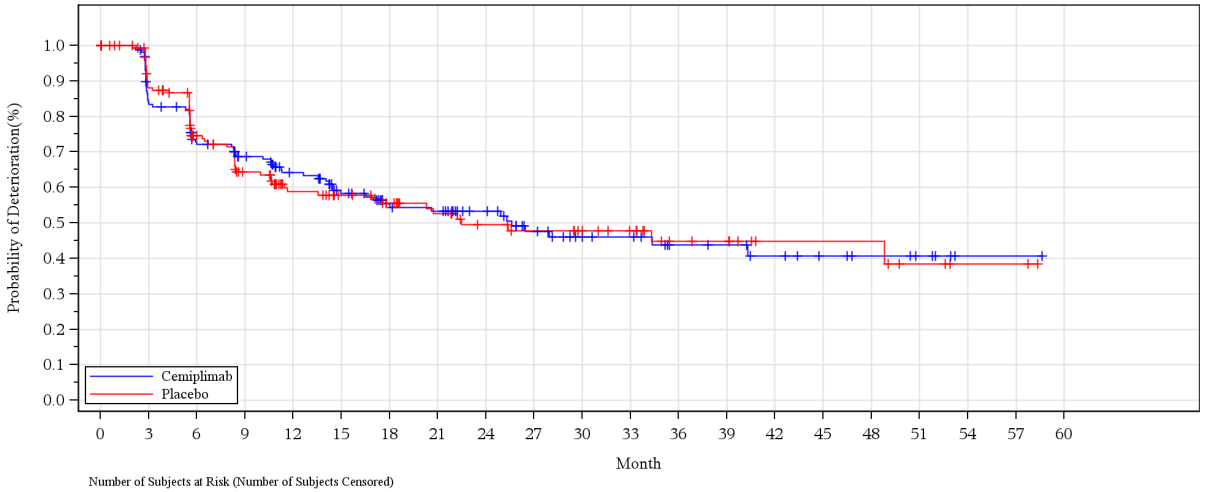
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



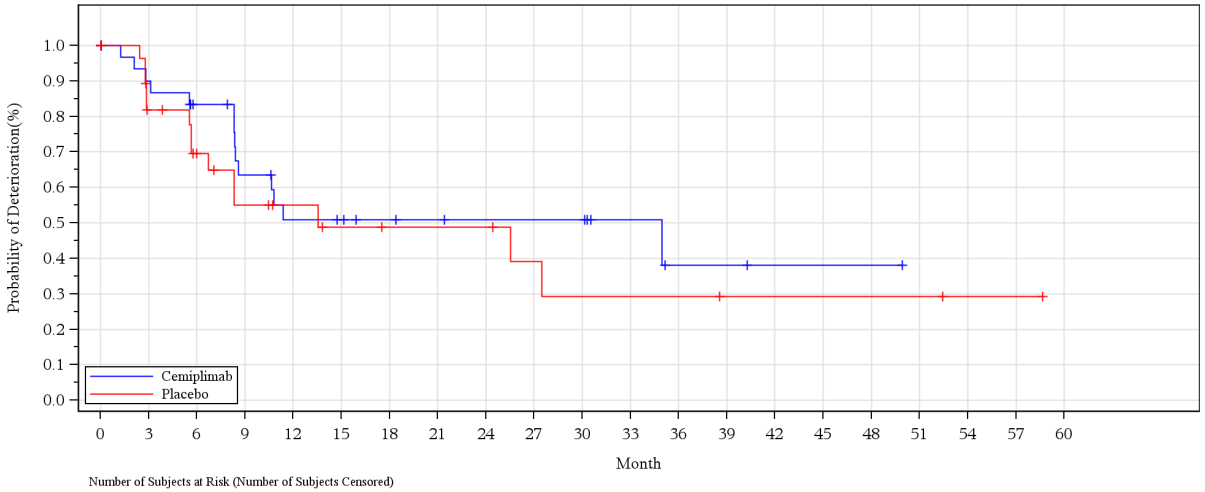
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	130 (19)	107 (24)	95 (31)	81 (39)	65 (48)	54 (56)	51 (57)	42 (66)	31 (73)	23 (80)	22 (81)	16 (86)	15 (87)	12 (89)	9 (92)	7 (94)	5 (96)	1 (100)	1 (100)	0 (101)
Placebo	174 (0)	131 (25)	96 (41)	77 (47)	59 (59)	51 (66)	43 (72)	36 (77)	30 (81)	27 (83)	23 (87)	20 (90)	13 (96)	12 (97)	7 (102)	7 (102)	7 (102)	4 (104)	2 (106)	2 (106)	0 (108)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	27 (5)	22 (8)	16 (9)	12 (10)	11 (11)	9 (13)	8 (14)	7 (15)	7 (15)	7 (15)	4 (18)	2 (19)	2 (19)	1 (20)	1 (20)	1 (20)	0 (21)	0 (21)	0 (21)	0 (21)
Placebo	32 (0)	21 (6)	16 (8)	11 (10)	9 (12)	7 (13)	6 (14)	6 (14)	6 (14)	4 (15)	3 (15)	3 (15)	3 (15)	2 (16)	2 (16)	2 (16)	2 (16)	2 (16)	1 (17)	1 (17)	0 (18)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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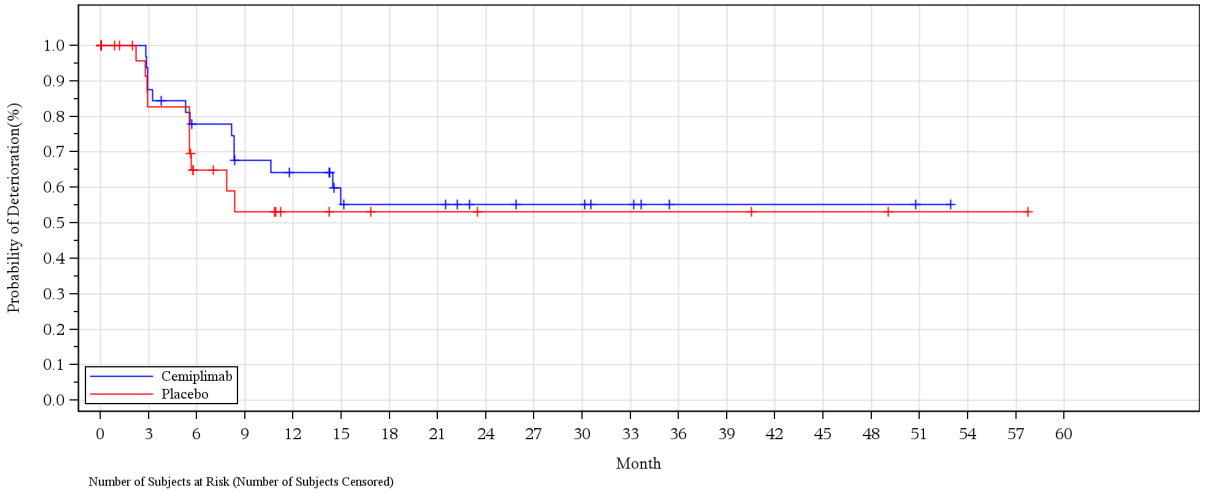
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	28 (5)	23 (7)	19 (8)	17 (9)	12 (12)	11 (13)	11 (13)	8 (16)	7 (17)	7 (17)	5 (19)	2 (22)	2 (22)	2 (22)	2 (22)	2 (22)	1 (23)	0 (24)	0 (24)	0 (24)
Placebo	31 (0)	19 (8)	12 (11)	9 (12)	6 (15)	5 (16)	4 (17)	4 (17)	3 (18)	3 (18)	3 (18)	3 (18)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	1 (20)	1 (20)	1 (20)	0 (21)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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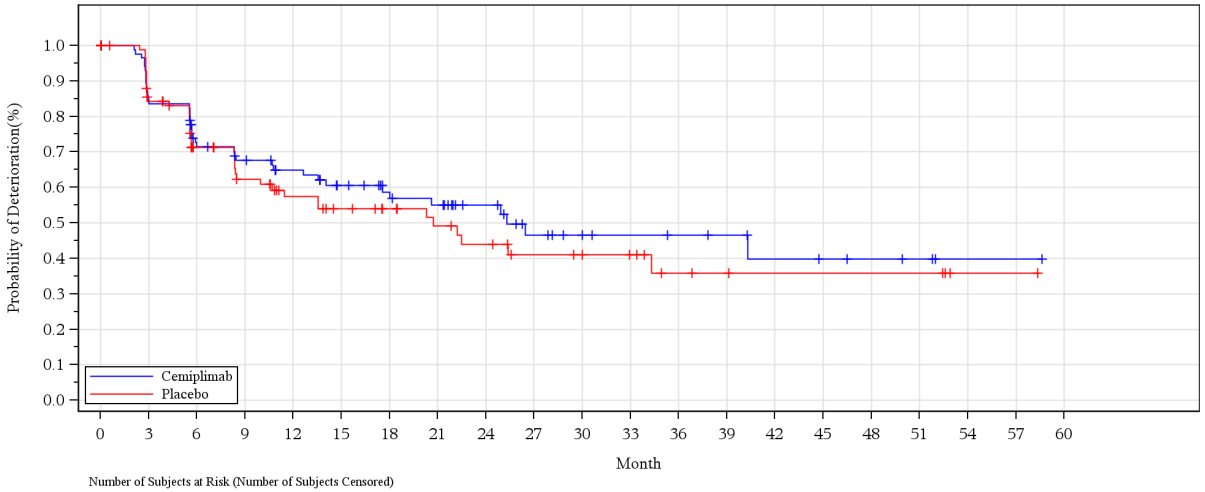
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



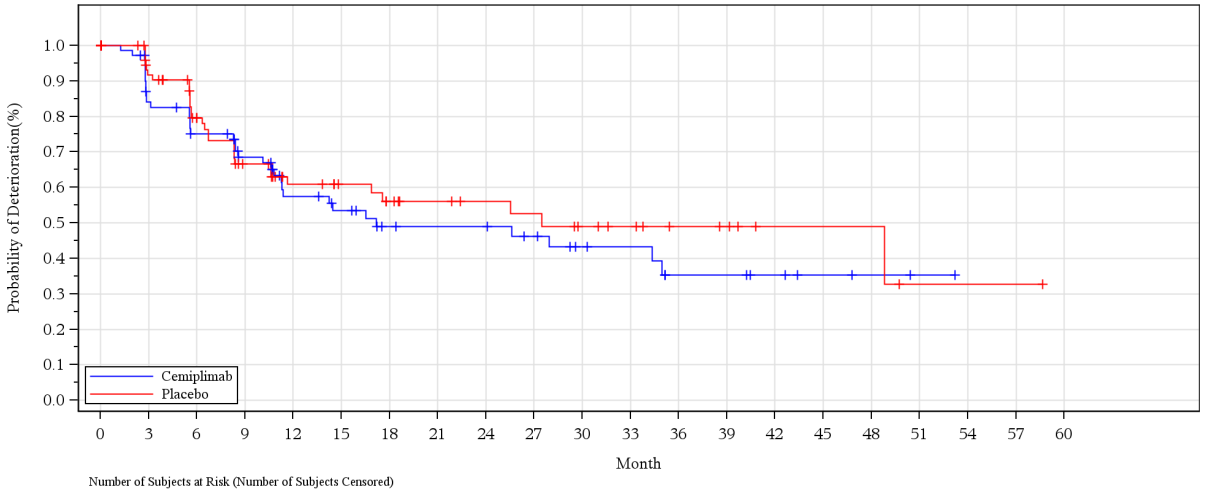
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	72 (5)	57 (9)	52 (11)	46 (15)	38 (20)	32 (25)	29 (26)	22 (33)	15 (37)	11 (41)	10 (42)	9 (43)	8 (44)	6 (45)	5 (46)	4 (47)	3 (48)	1 (50)	1 (50)	0 (51)
Placebo	90 (0)	68 (9)	50 (17)	41 (20)	33 (25)	28 (28)	24 (32)	20 (34)	17 (35)	13 (38)	11 (40)	10 (41)	6 (44)	5 (45)	4 (46)	4 (46)	4 (46)	4 (46)	1 (49)	1 (49)	0 (50)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	57 (14)	49 (16)	40 (21)	30 (25)	26 (27)	20 (31)	19 (32)	19 (32)	16 (34)	12 (37)	11 (38)	7 (40)	7 (40)	5 (42)	3 (44)	2 (45)	1 (46)	0 (47)	0 (47)	0 (47)
Placebo	85 (0)	65 (14)	50 (21)	38 (25)	29 (31)	25 (35)	21 (37)	18 (40)	16 (42)	15 (42)	12 (44)	10 (46)	7 (49)	6 (50)	3 (53)	3 (53)	3 (53)	1 (54)	1 (54)	1 (54)	0 (55)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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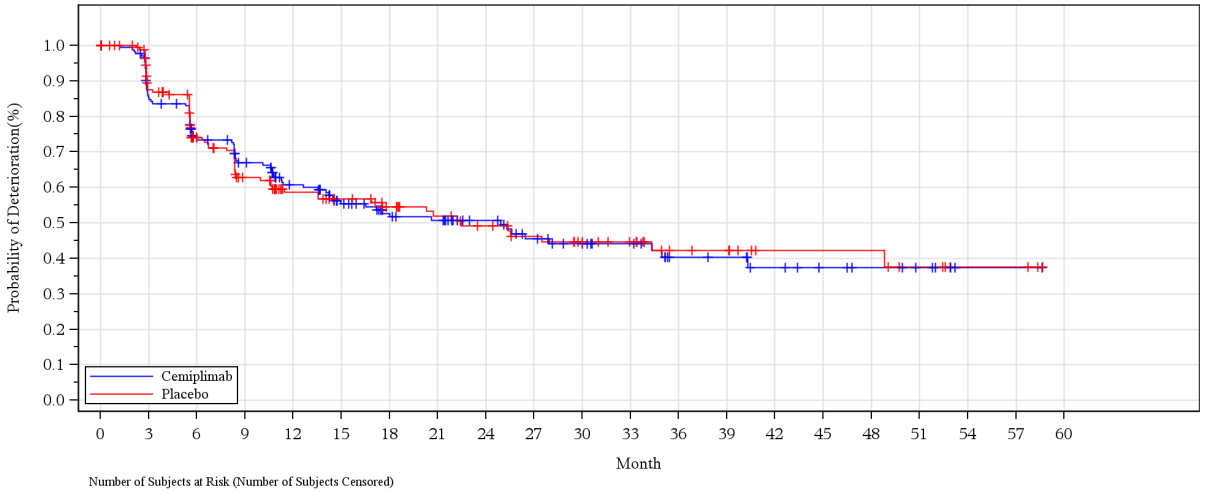
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	145 (19)	117 (27)	102 (32)	84 (41)	68 (50)	55 (60)	51 (62)	42 (71)	34 (75)	28 (80)	25 (83)	17 (89)	16 (90)	12 (93)	9 (96)	7 (98)	5 (100)	1 (104)	1 (104)	0 (105)
Placebo	189 (0)	138 (31)	102 (47)	79 (55)	62 (67)	54 (73)	46 (79)	40 (83)	35 (86)	30 (89)	25 (93)	22 (96)	15 (102)	14 (103)	9 (108)	9 (108)	9 (108)	6 (110)	3 (113)	3 (113)	0 (116)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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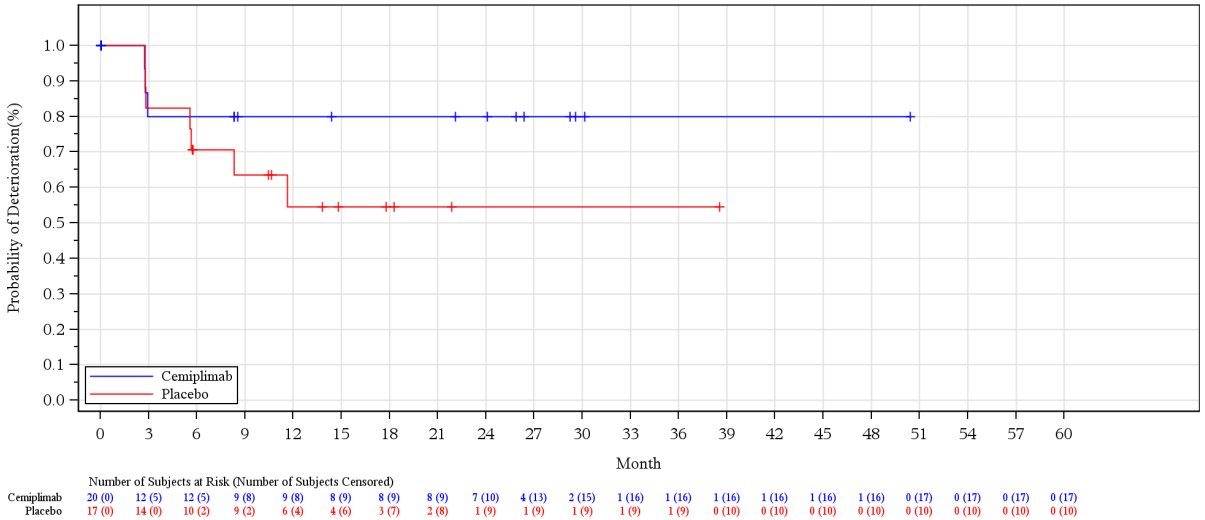
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	12 (5)	12 (5)	9 (8)	9 (8)	8 (9)	8 (9)	8 (9)	7 (10)	4 (13)	2 (15)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	1 (16)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	17 (0)	14 (0)	10 (2)	9 (2)	6 (4)	4 (6)	3 (7)	2 (8)	1 (9)	1 (9)	1 (9)	1 (9)	1 (9)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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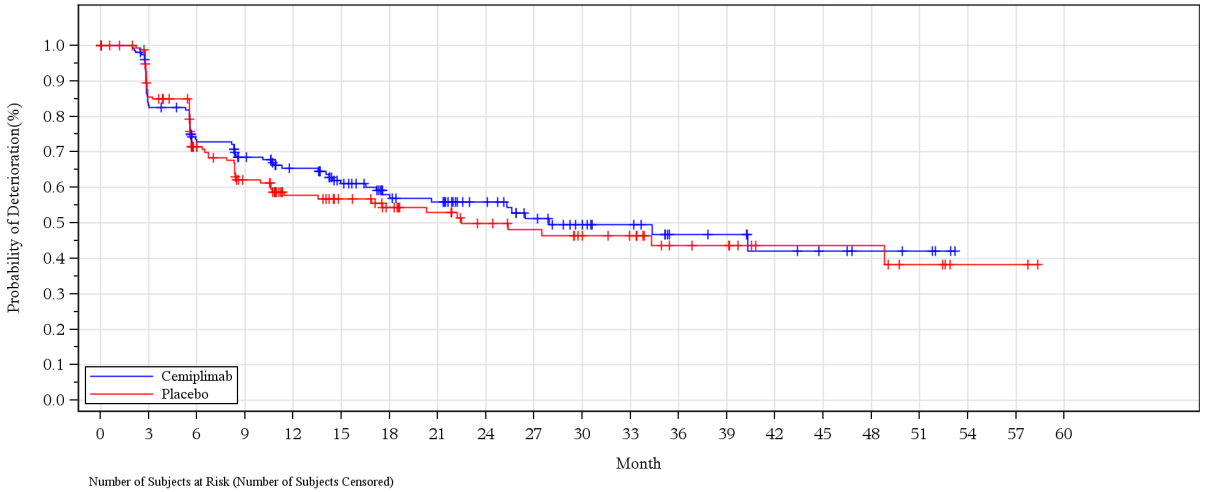
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	123 (18)	103 (23)	92 (28)	81 (35)	67 (44)	54 (54)	50 (56)	40 (66)	31 (72)	23 (79)	20 (82)	13 (88)	12 (89)	9 (91)	7 (93)	5 (95)	4 (96)	0 (100)	0 (100)	0 (100)
Placebo	177 (0)	129 (26)	93 (42)	75 (48)	58 (60)	50 (67)	42 (73)	37 (77)	31 (81)	28 (83)	23 (87)	21 (89)	14 (95)	13 (96)	8 (101)	8 (101)	8 (101)	5 (103)	2 (106)	2 (106)	0 (108)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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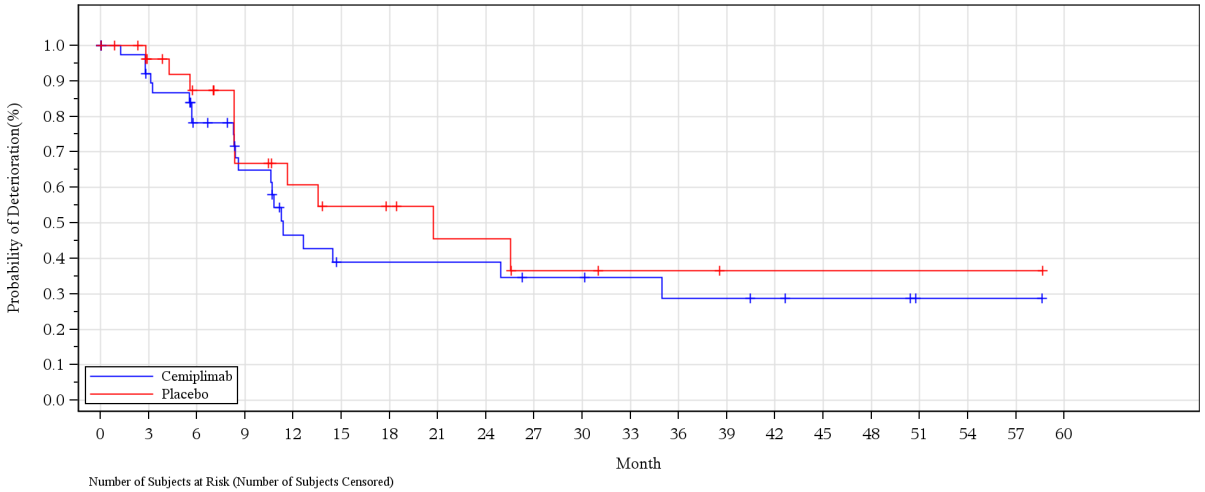
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	34 (6)	26 (9)	19 (12)	12 (14)	9 (15)	9 (15)	9 (15)	9 (15)	7 (16)	7 (16)	6 (17)	5 (17)	5 (17)	4 (18)	3 (19)	3 (19)	1 (21)	1 (21)	1 (21)	0 (22)
Placebo	29 (0)	23 (5)	19 (7)	13 (9)	10 (11)	8 (12)	7 (13)	5 (14)	5 (14)	3 (15)	3 (15)	2 (16)	2 (16)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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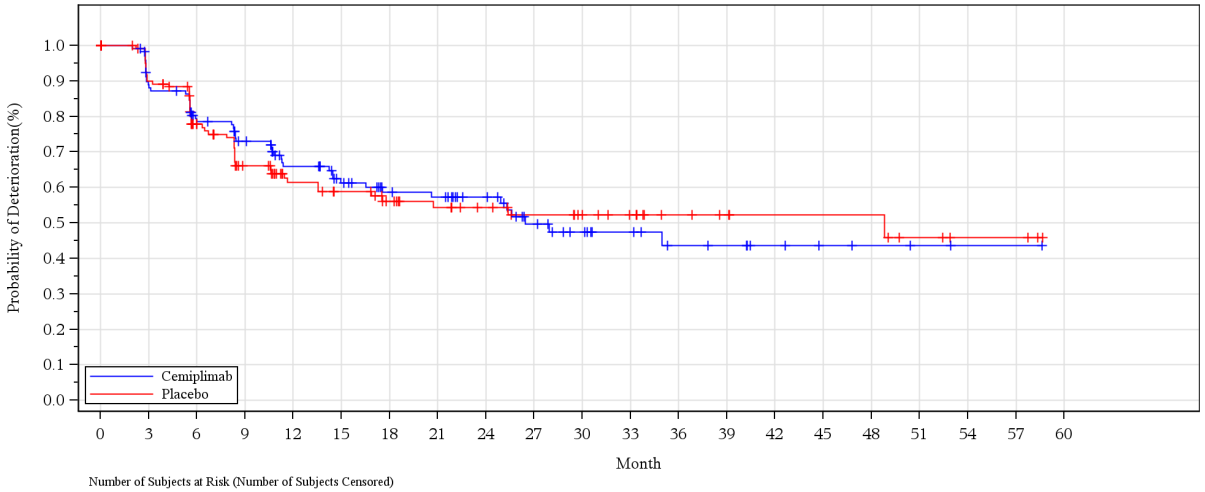
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	104 (16)	87 (21)	77 (25)	63 (32)	52 (39)	43 (46)	41 (47)	34 (54)	24 (60)	18 (65)	14 (69)	10 (72)	9 (73)	6 (76)	4 (78)	3 (79)	2 (80)	1 (81)	1 (81)	0 (82)
Placebo	131 (0)	108 (11)	83 (22)	63 (30)	49 (40)	44 (43)	37 (48)	32 (52)	28 (56)	24 (59)	20 (63)	17 (66)	12 (71)	10 (73)	8 (75)	8 (75)	8 (75)	5 (77)	3 (79)	3 (79)	0 (82)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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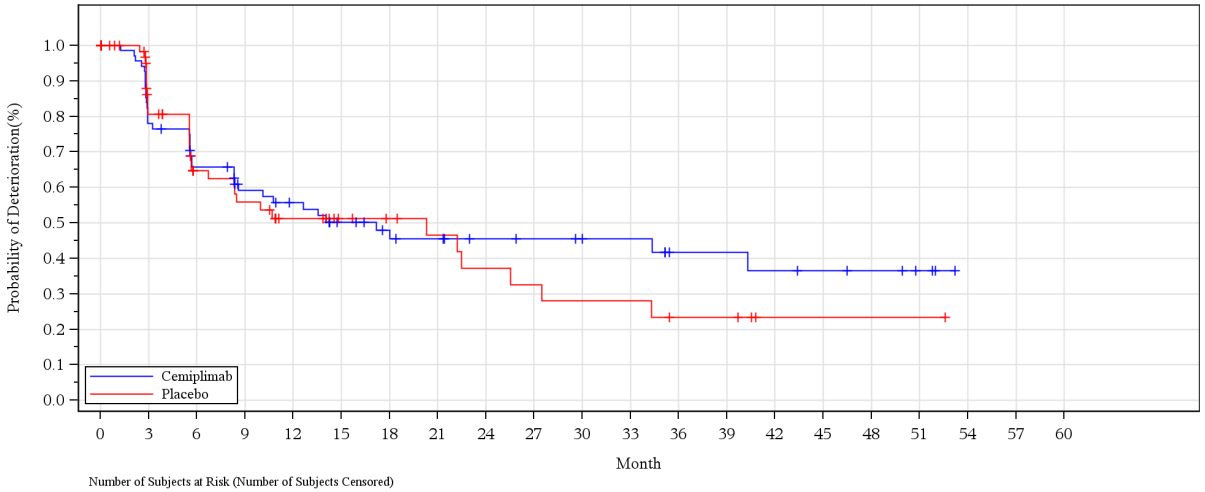
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	53 (8)	42 (11)	34 (15)	30 (17)	24 (20)	20 (23)	18 (24)	15 (27)	14 (28)	12 (30)	12 (30)	8 (33)	8 (33)	7 (33)	6 (34)	5 (35)	3 (37)	0 (40)	0 (40)	0 (40)
Placebo	75 (0)	44 (20)	29 (27)	25 (27)	19 (31)	14 (36)	12 (38)	10 (39)	8 (39)	7 (39)	6 (39)	6 (39)	4 (40)	4 (40)	1 (43)	1 (43)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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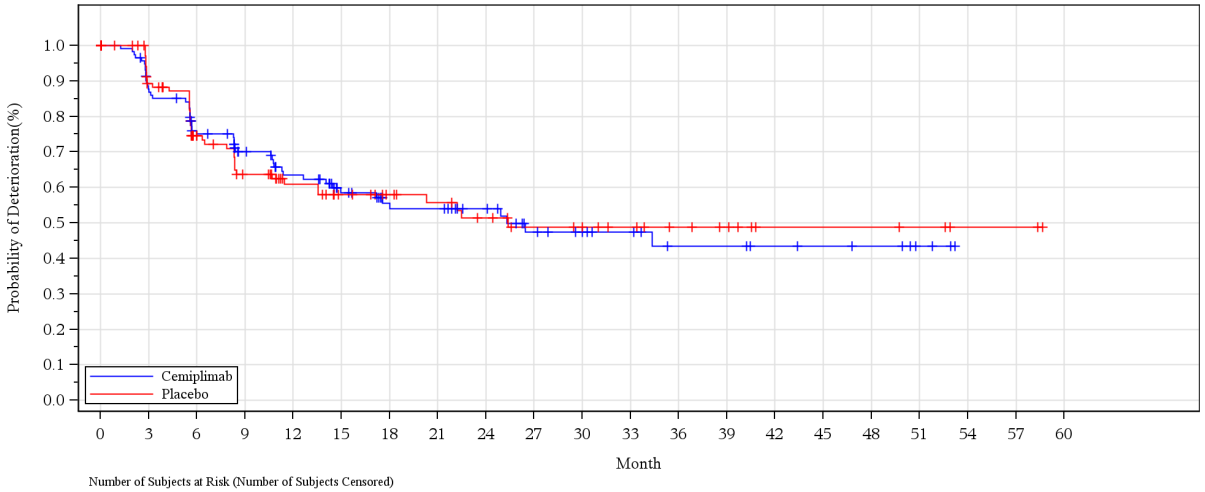
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	99 (12)	79 (18)	66 (26)	56 (30)	44 (38)	35 (45)	34 (45)	28 (51)	20 (56)	16 (60)	14 (62)	10 (65)	10 (65)	8 (67)	7 (68)	6 (69)	3 (72)	0 (75)	0 (75)	0 (75)
Placebo	117 (0)	89 (17)	64 (28)	51 (32)	41 (40)	34 (45)	29 (50)	26 (52)	22 (54)	18 (57)	16 (59)	14 (61)	11 (64)	9 (66)	5 (70)	5 (70)	5 (70)	4 (71)	2 (73)	2 (73)	0 (75)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
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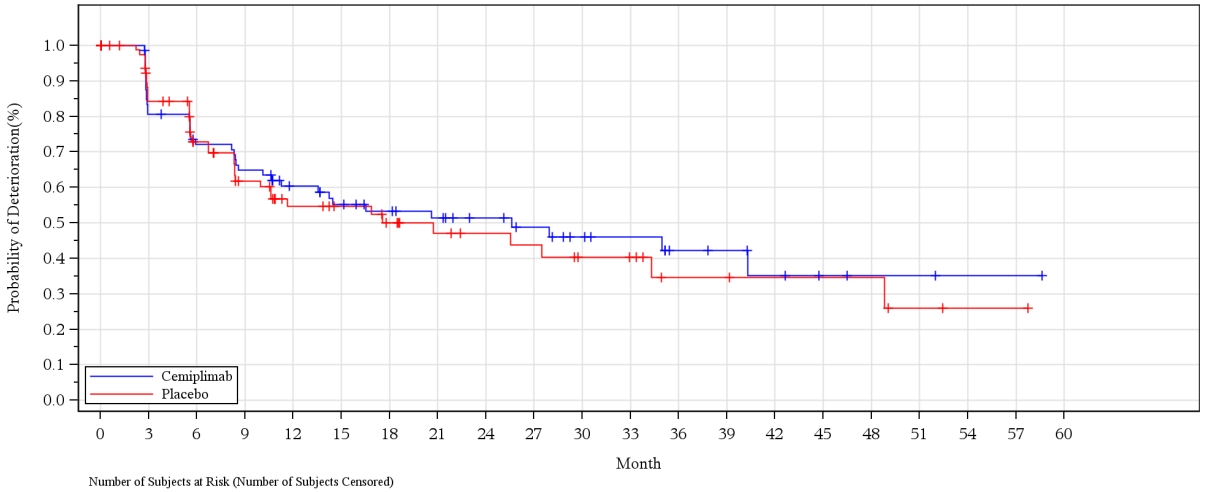
Figure 14.2.8.1.4 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Emotional Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



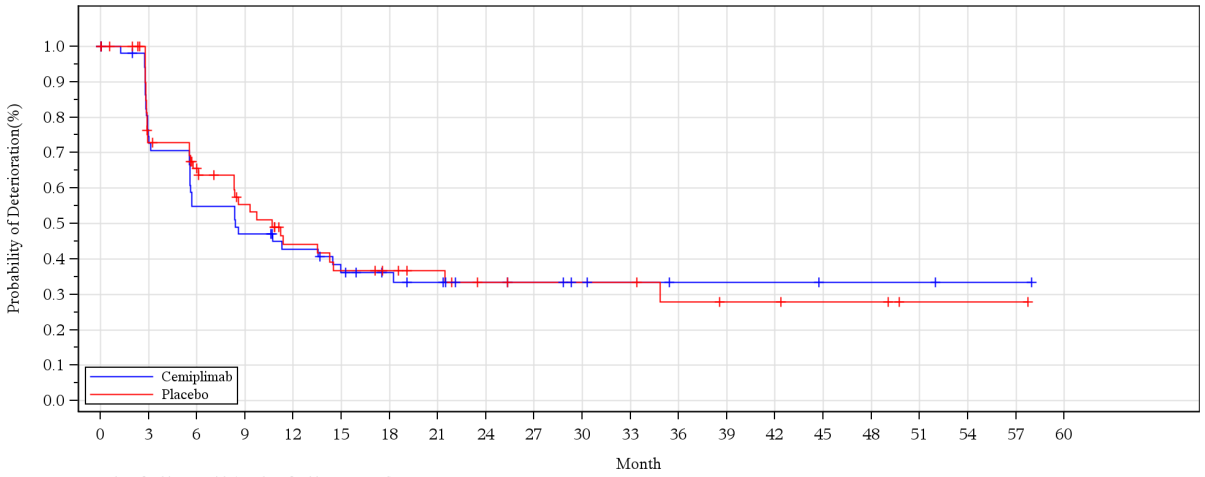
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	58 (12)	50 (14)	45 (14)	37 (19)	32 (21)	28 (24)	25 (26)	21 (30)	18 (32)	14 (35)	12 (37)	8 (40)	7 (41)	5 (42)	3 (44)	2 (45)	2 (45)	1 (46)	1 (46)	0 (47)
Placebo	89 (0)	63 (14)	48 (21)	37 (25)	27 (31)	24 (34)	20 (36)	16 (39)	14 (41)	13 (41)	10 (43)	9 (44)	5 (47)	5 (47)	4 (48)	4 (48)	4 (48)	2 (49)	1 (50)	1 (50)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



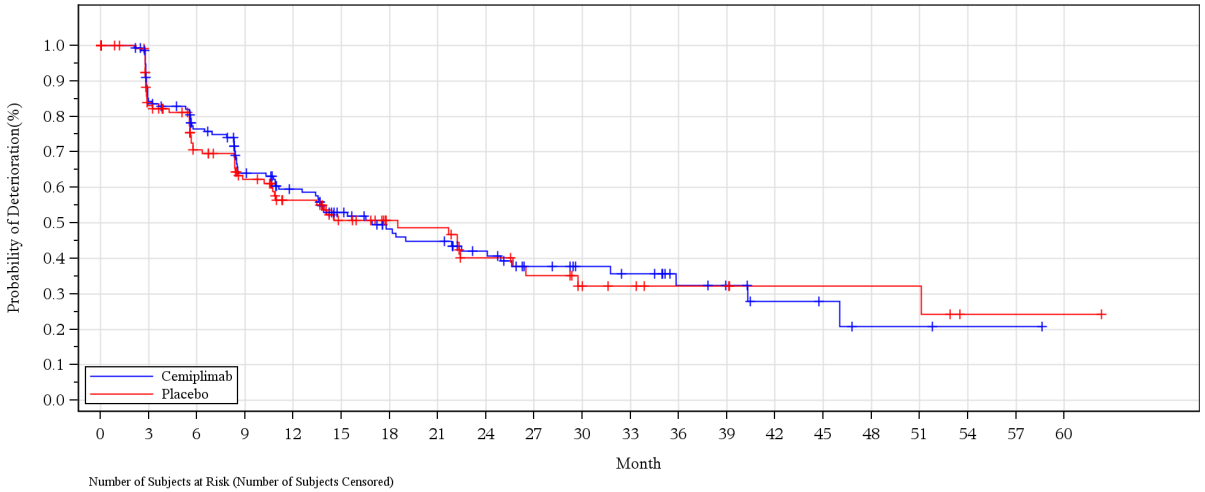
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (5)	28 (5)	24 (5)	20 (7)	16 (8)	13 (11)	11 (12)	8 (15)	7 (16)	5 (18)	4 (19)	3 (20)	3 (20)	3 (20)	2 (21)	2 (21)	2 (21)	1 (22)	1 (22)	0 (23)
Placebo	65 (0)	42 (7)	35 (10)	26 (14)	18 (17)	15 (17)	13 (19)	11 (21)	8 (23)	7 (24)	7 (24)	7 (24)	5 (25)	4 (26)	4 (26)	3 (27)	3 (27)	1 (29)	1 (29)	1 (29)	0 (30)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



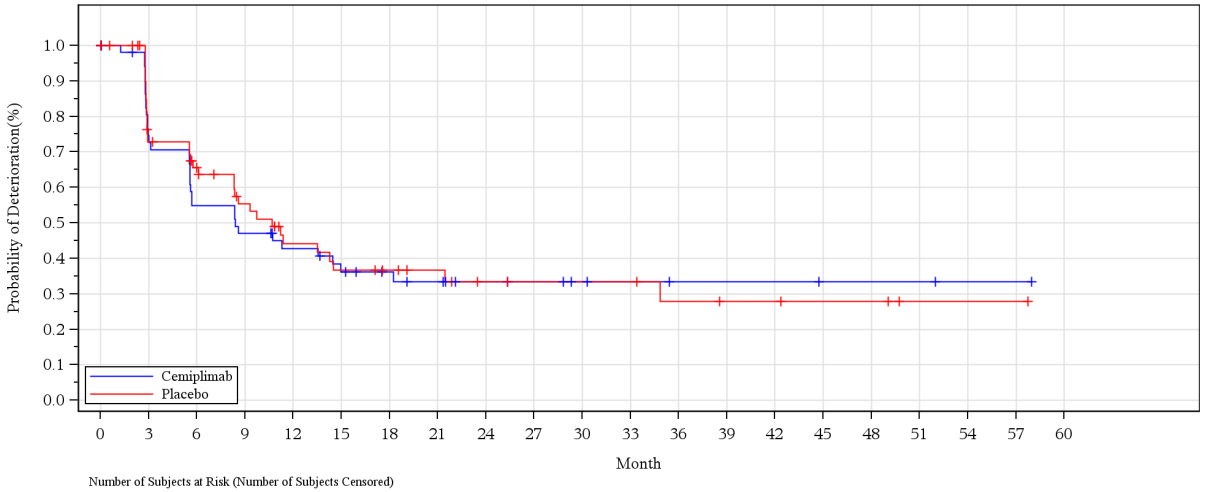
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	112 (20)	96 (26)	75 (32)	64 (38)	50 (45)	40 (51)	37 (51)	30 (56)	22 (61)	18 (65)	16 (66)	10 (71)	8 (73)	5 (75)	4 (76)	2 (77)	2 (77)	1 (78)	1 (78)	0 (79)
Placebo	141 (0)	95 (26)	71 (37)	57 (43)	43 (52)	33 (58)	25 (66)	24 (66)	17 (69)	14 (70)	9 (74)	8 (75)	6 (77)	6 (77)	4 (79)	4 (79)	4 (79)	4 (79)	1 (81)	1 (81)	1 (81)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



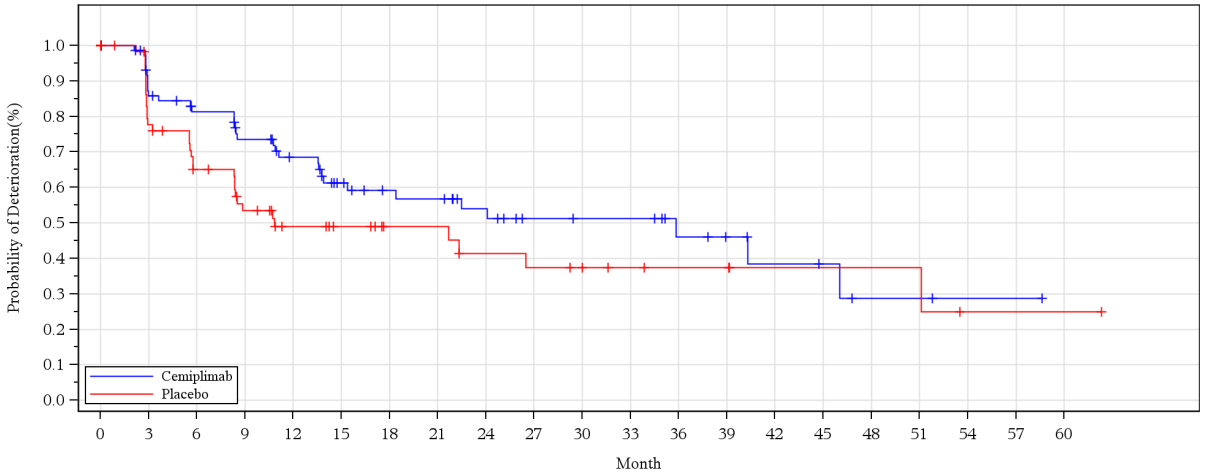
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (5)	28 (5)	24 (5)	20 (7)	16 (8)	13 (11)	11 (12)	8 (15)	7 (16)	5 (18)	4 (19)	3 (20)	3 (20)	3 (20)	2 (21)	2 (21)	2 (21)	1 (22)	1 (22)	0 (23)
Placebo	65 (0)	42 (7)	35 (10)	26 (14)	18 (17)	15 (17)	13 (19)	11 (21)	8 (23)	7 (24)	7 (24)	7 (24)	5 (25)	4 (26)	4 (26)	3 (27)	3 (27)	1 (29)	1 (29)	1 (29)	0 (30)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



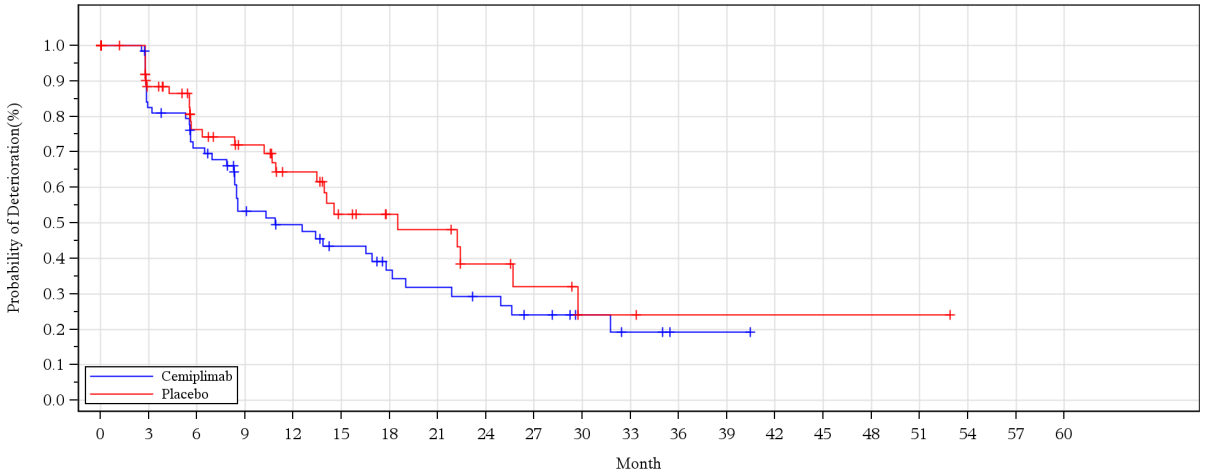
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	60 (10)	53 (14)	46 (16)	39 (20)	30 (25)	25 (29)	24 (29)	19 (33)	14 (37)	13 (38)	13 (38)	9 (41)	7 (43)	5 (44)	4 (45)	2 (46)	2 (46)	1 (47)	1 (47)	0 (48)
Placebo	69 (0)	45 (11)	35 (14)	27 (16)	20 (21)	17 (24)	13 (28)	13 (28)	10 (29)	9 (29)	7 (31)	6 (32)	5 (33)	5 (33)	3 (35)	3 (35)	3 (35)	3 (35)	1 (36)	1 (36)	1 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



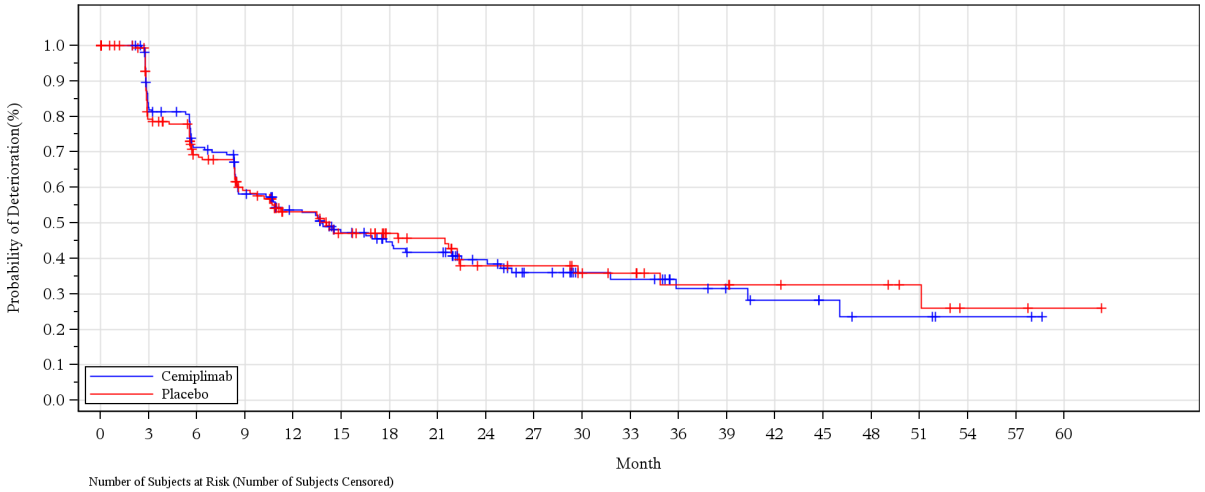
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	52 (10)	43 (12)	29 (16)	25 (18)	20 (20)	15 (22)	13 (22)	11 (23)	8 (24)	5 (27)	3 (28)	1 (30)	1 (30)	0 (31)	0 (31)	0 (31)	0 (31)	0 (31)	0 (31)
Placebo	72 (0)	50 (15)	36 (23)	30 (27)	23 (31)	16 (34)	12 (38)	11 (38)	7 (40)	5 (41)	2 (43)	2 (43)	1 (44)	1 (44)	1 (44)	1 (44)	1 (44)	1 (44)	0 (45)	0 (45)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



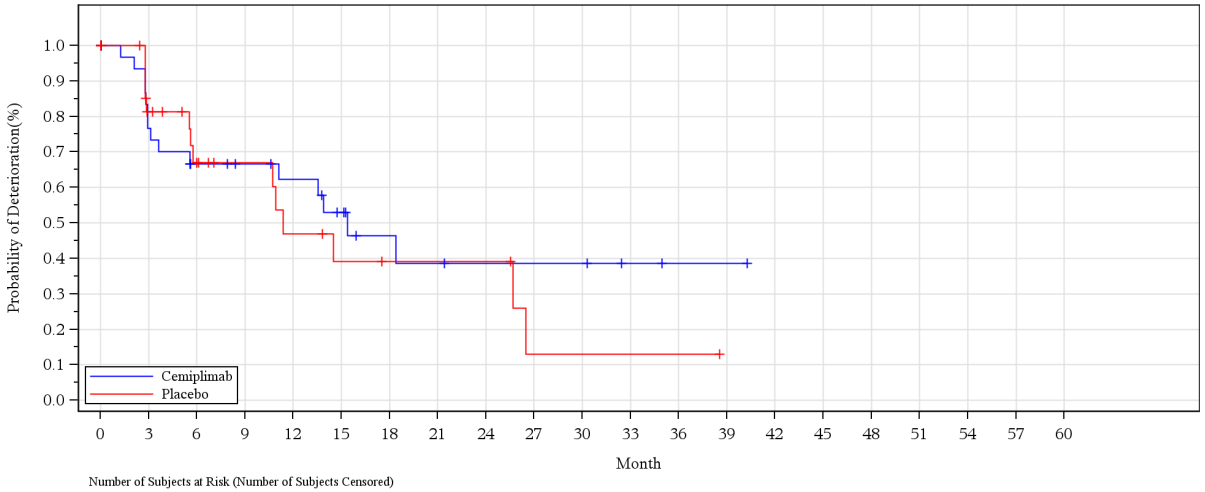
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	127 (20)	106 (24)	83 (28)	70 (35)	56 (41)	47 (47)	43 (48)	34 (55)	25 (61)	19 (67)	18 (67)	12 (72)	10 (74)	8 (75)	6 (77)	4 (78)	4 (78)	2 (80)	2 (80)	0 (82)
Placebo	174 (0)	117 (26)	92 (37)	73 (43)	54 (55)	43 (60)	34 (69)	31 (71)	21 (76)	20 (77)	15 (81)	14 (82)	10 (85)	10 (85)	8 (87)	7 (88)	7 (88)	5 (90)	2 (92)	2 (92)	1 (93)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



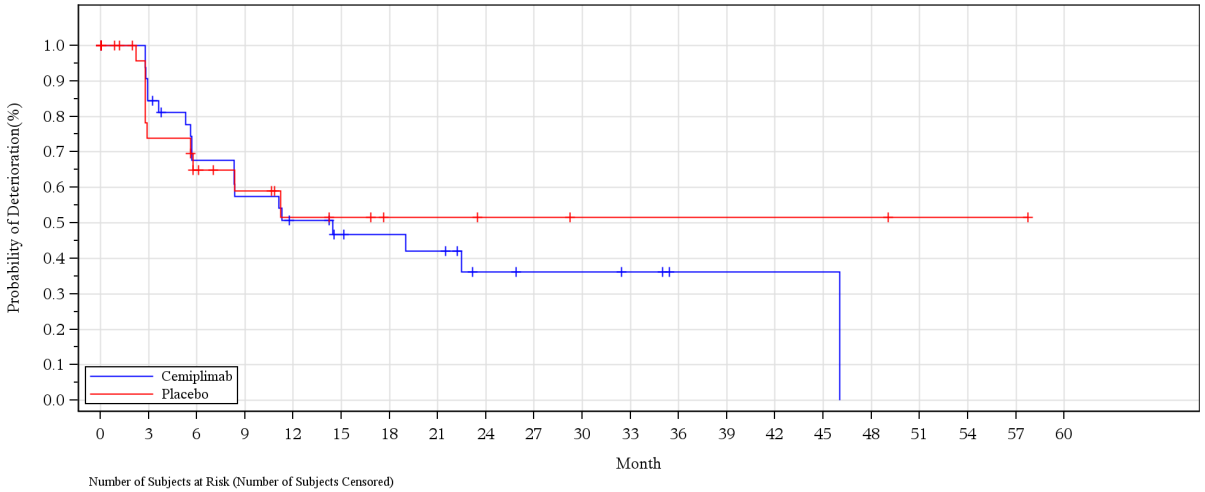
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	23 (5)	18 (7)	16 (9)	14 (10)	10 (12)	6 (15)	5 (15)	4 (16)	4 (16)	4 (16)	2 (18)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	32 (0)	20 (7)	14 (10)	10 (14)	7 (14)	5 (15)	4 (16)	4 (16)	4 (16)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



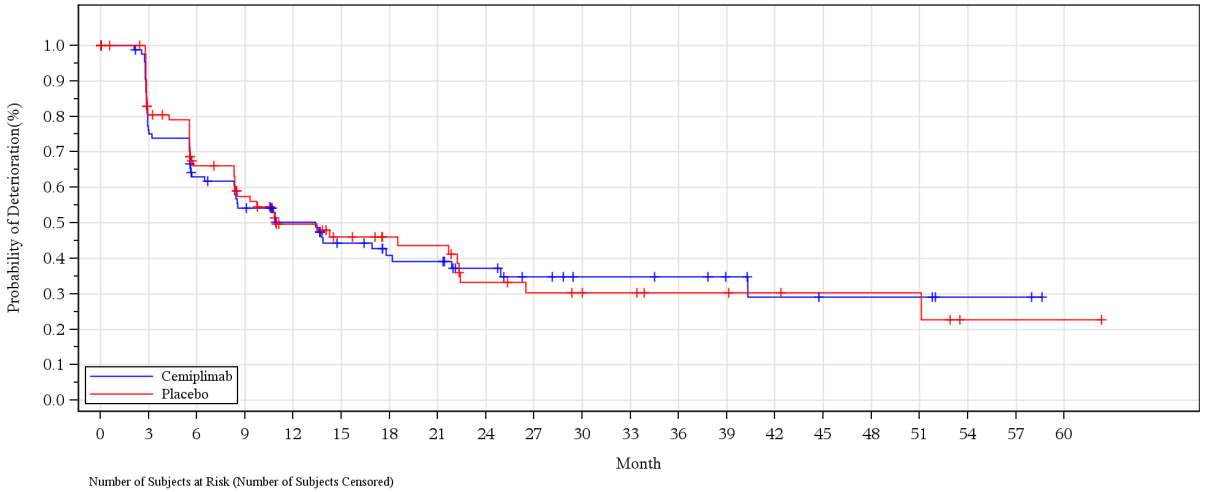
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	27 (5)	20 (7)	17 (7)	14 (8)	11 (10)	10 (11)	9 (11)	5 (14)	4 (15)	4 (15)	3 (16)	1 (18)	1 (18)	1 (18)	1 (18)	0 (18)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	31 (0)	17 (8)	13 (10)	10 (12)	7 (14)	6 (15)	4 (17)	4 (17)	3 (18)	3 (18)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	2 (19)	1 (20)	1 (20)	1 (20)	0 (21)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



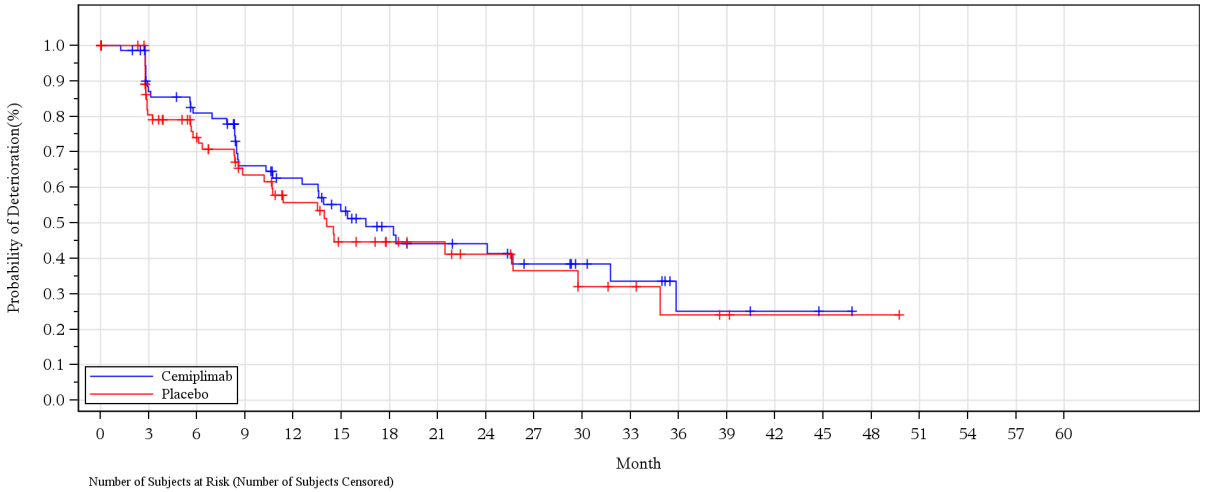
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	64 (6)	51 (8)	43 (9)	36 (13)	28 (17)	23 (20)	22 (20)	17 (24)	13 (27)	10 (30)	10 (30)	9 (31)	7 (33)	5 (34)	4 (35)	4 (35)	4 (35)	2 (37)	2 (37)	0 (39)
Placebo	90 (0)	64 (10)	48 (15)	39 (18)	28 (24)	23 (27)	19 (31)	18 (31)	12 (33)	10 (34)	8 (36)	8 (36)	6 (38)	6 (38)	5 (39)	4 (40)	4 (40)	4 (40)	1 (42)	1 (42)	1 (42)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	59 (14)	53 (16)	39 (21)	34 (24)	27 (26)	20 (31)	17 (32)	16 (33)	12 (35)	9 (38)	7 (39)	3 (42)	3 (42)	2 (43)	1 (44)	0 (45)	0 (45)	0 (45)	0 (45)	0 (45)
Placebo	85 (0)	56 (15)	45 (22)	34 (27)	26 (31)	19 (33)	15 (37)	13 (39)	10 (41)	8 (42)	6 (43)	5 (44)	3 (45)	2 (46)	1 (47)	1 (47)	1 (47)	0 (48)	0 (48)	0 (48)	0 (48)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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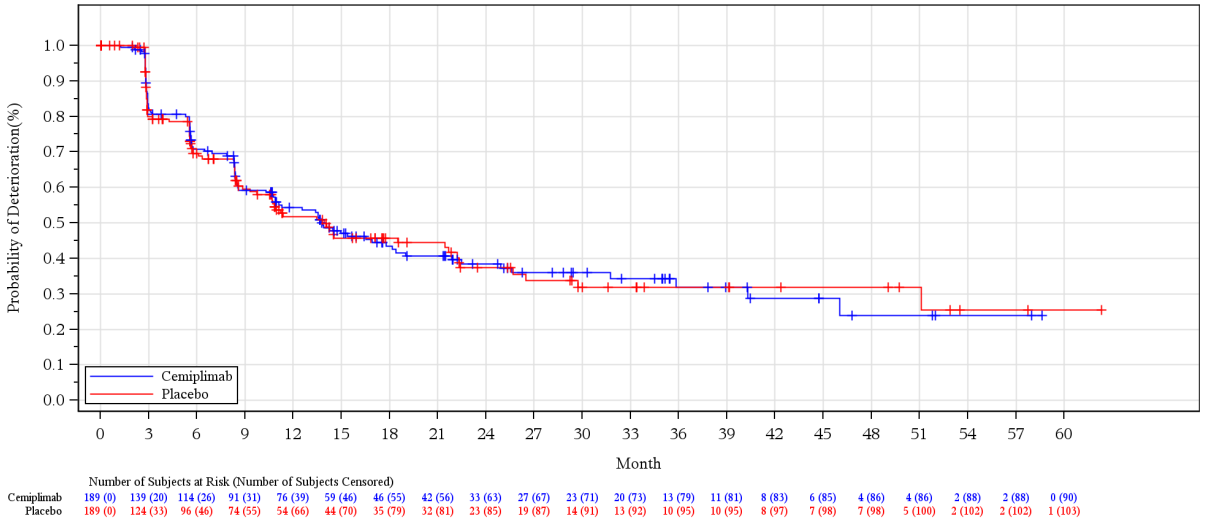
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	139 (20)	114 (26)	91 (31)	76 (39)	59 (46)	46 (55)	42 (56)	33 (63)	27 (67)	23 (71)	20 (73)	13 (79)	11 (81)	8 (83)	6 (85)	4 (86)	4 (86)	2 (88)	2 (88)	0 (90)
Placebo	189 (0)	124 (33)	96 (46)	74 (55)	54 (66)	44 (70)	35 (79)	32 (81)	23 (85)	19 (87)	14 (91)	13 (92)	10 (95)	10 (95)	8 (97)	7 (98)	7 (98)	5 (100)	2 (102)	2 (102)	1 (103)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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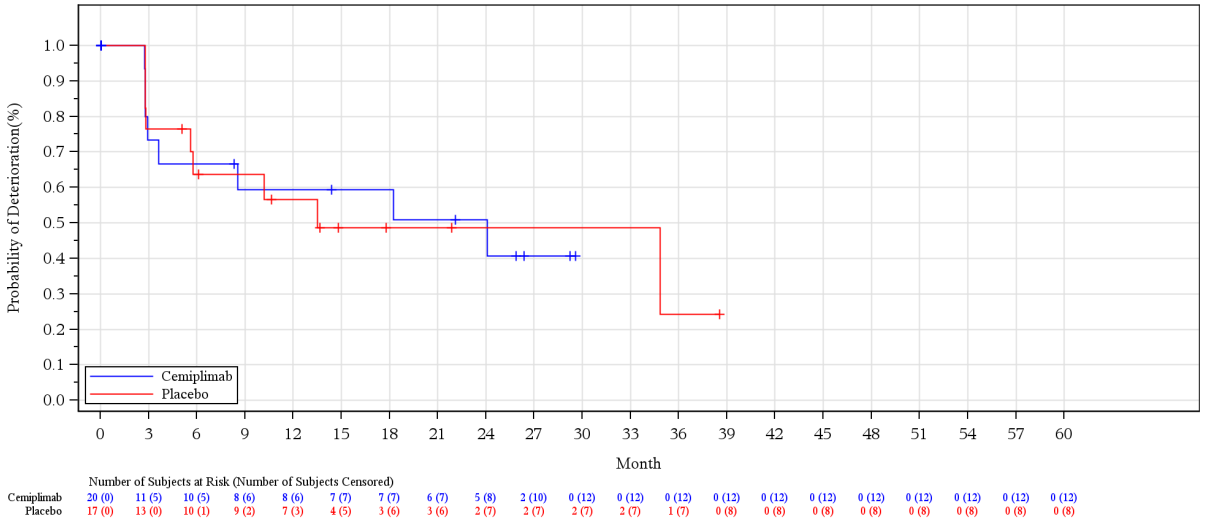
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



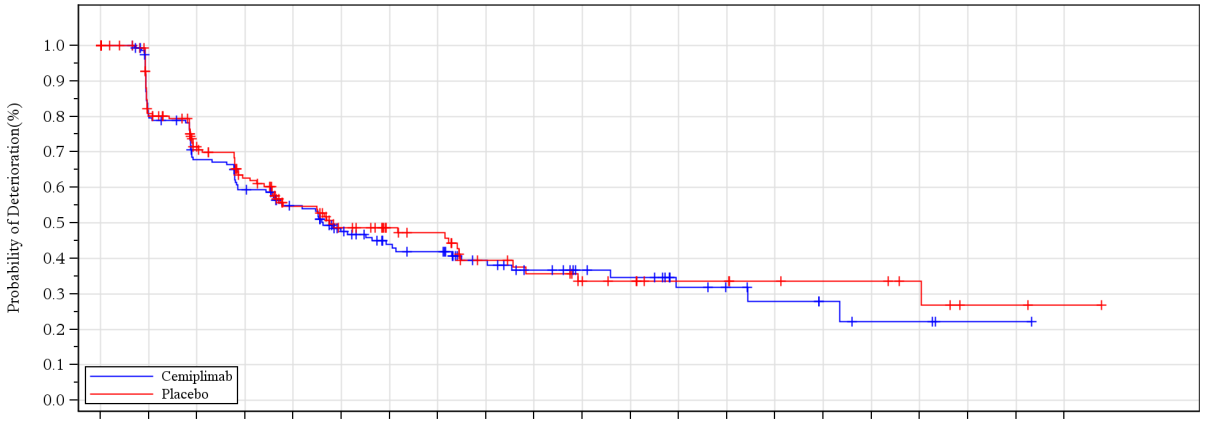
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (5)	10 (5)	8 (6)	8 (6)	7 (7)	7 (7)	6 (7)	5 (8)	2 (10)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)
Placebo	17 (0)	13 (0)	10 (1)	9 (2)	7 (3)	4 (5)	3 (6)	3 (6)	2 (7)	2 (7)	2 (7)	2 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	118 (19)	97 (22)	83 (24)	71 (30)	55 (37)	43 (45)	40 (46)	30 (54)	24 (58)	19 (63)	17 (64)	11 (69)	9 (71)	7 (72)	5 (74)	3 (75)	3 (75)	1 (77)	1 (77)	0 (78)
Placebo	177 (0)	120 (28)	95 (40)	76 (48)	56 (59)	44 (65)	35 (74)	32 (76)	22 (81)	19 (82)	14 (86)	13 (87)	10 (90)	10 (90)	8 (92)	7 (93)	7 (93)	5 (95)	2 (97)	2 (97)	1 (98)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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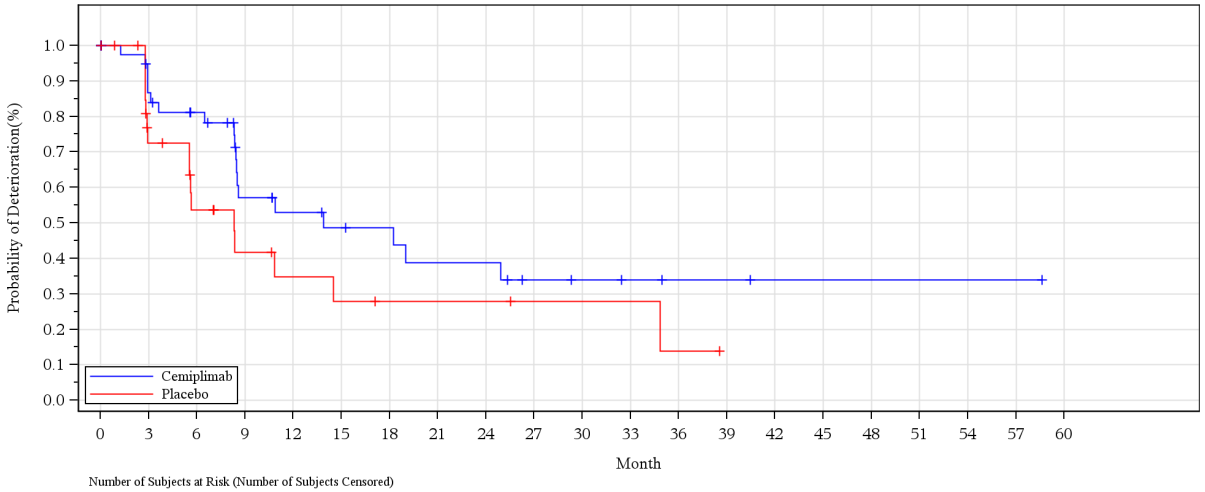
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



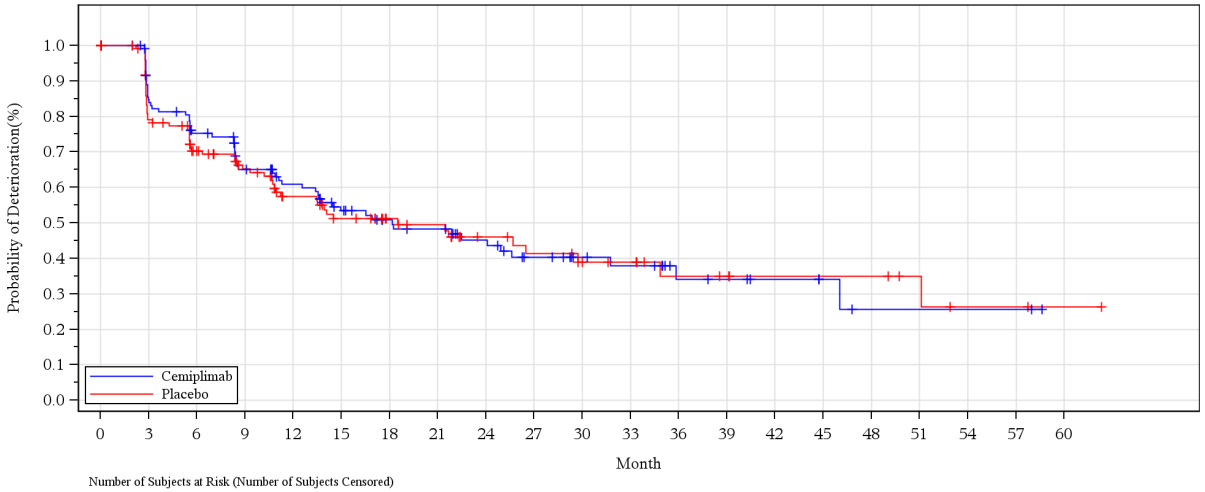
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	32 (6)	27 (9)	16 (13)	13 (15)	11 (16)	10 (17)	8 (17)	8 (17)	5 (19)	4 (20)	3 (21)	2 (22)	2 (22)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	0 (24)
Placebo	29 (0)	17 (5)	11 (7)	7 (9)	5 (10)	4 (10)	3 (11)	3 (11)	3 (11)	2 (12)	2 (12)	2 (12)	1 (12)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



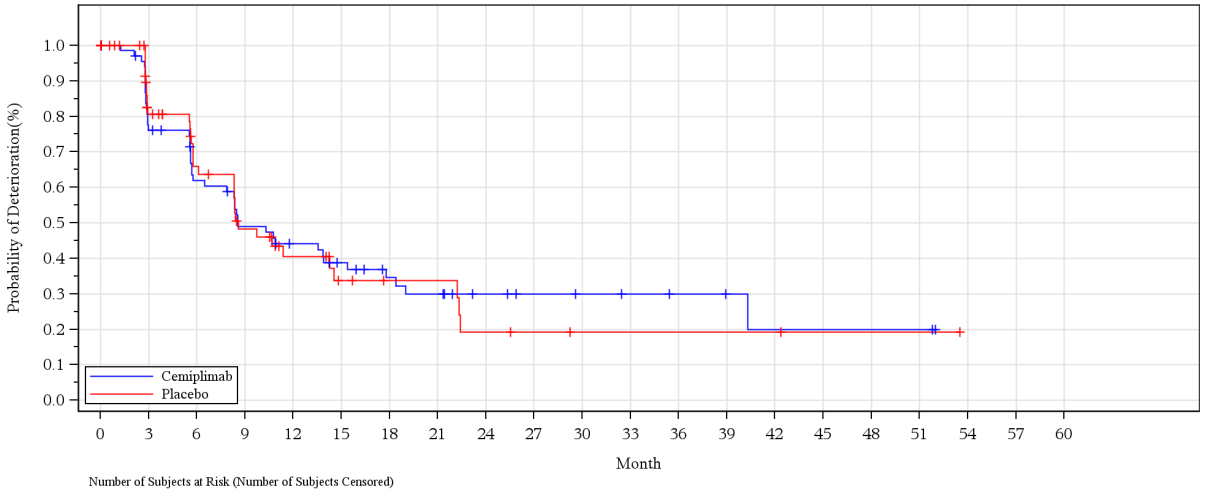
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	99 (16)	85 (19)	69 (24)	59 (30)	46 (36)	38 (42)	35 (43)	29 (47)	22 (51)	17 (56)	15 (57)	9 (62)	8 (63)	6 (65)	4 (67)	2 (68)	2 (68)	2 (68)	2 (68)	0 (70)
Placebo	131 (0)	94 (12)	75 (21)	62 (29)	47 (37)	39 (40)	31 (48)	28 (50)	21 (55)	18 (56)	14 (59)	13 (60)	9 (63)	8 (64)	6 (66)	6 (66)	6 (66)	4 (68)	2 (69)	2 (69)	1 (70)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	51 (9)	39 (12)	30 (13)	25 (15)	20 (17)	15 (20)	13 (20)	9 (24)	7 (26)	6 (27)	5 (28)	4 (29)	3 (30)	2 (30)	2 (30)	2 (30)	2 (30)	0 (32)	0 (32)	0 (32)
Placebo	75 (0)	43 (21)	31 (26)	21 (28)	14 (32)	9 (35)	7 (37)	7 (37)	4 (37)	3 (38)	2 (39)	2 (39)	2 (39)	2 (39)	2 (39)	1 (40)	1 (40)	1 (40)	0 (41)	0 (41)	0 (41)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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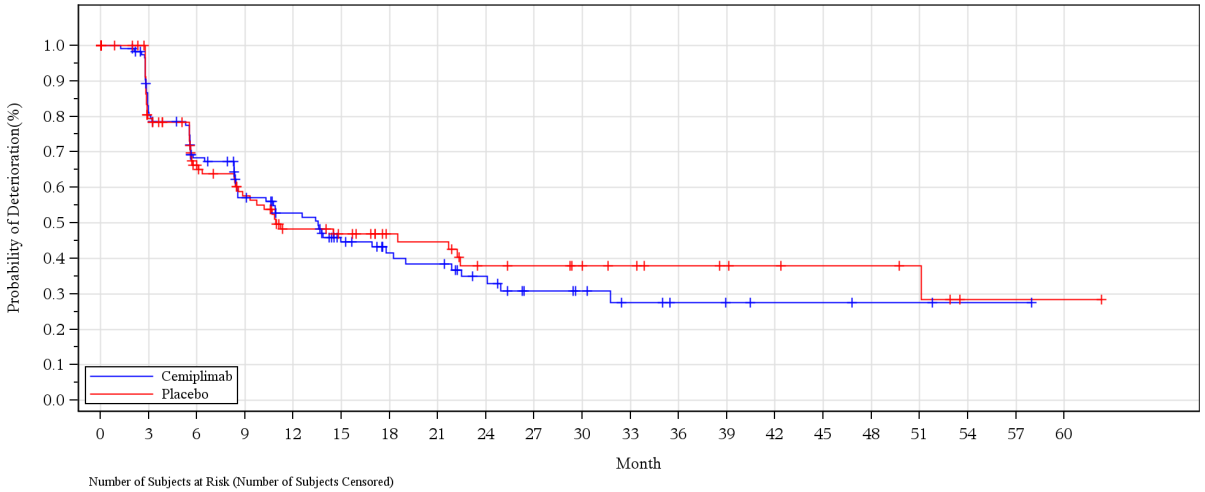
Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



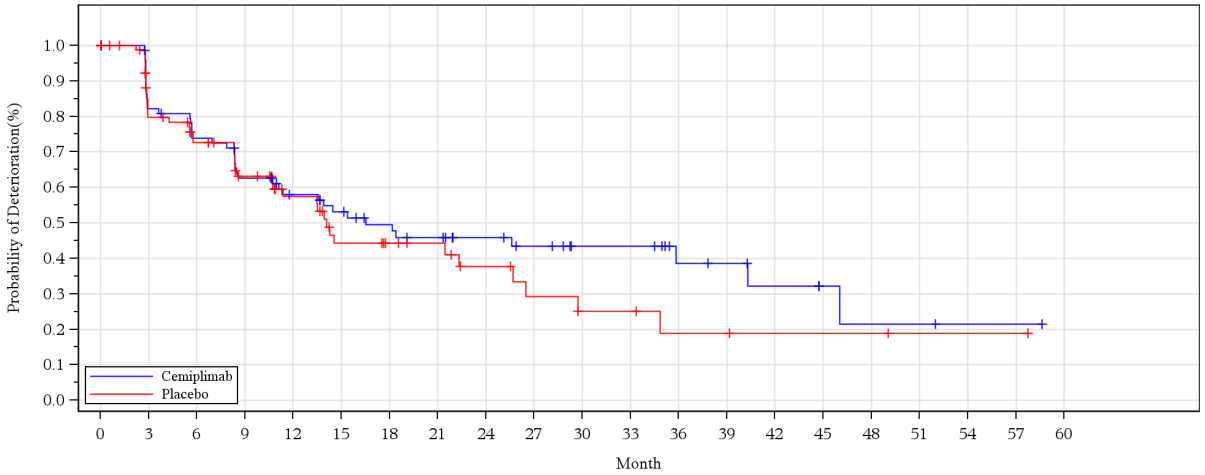
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	90 (14)	71 (19)	55 (24)	47 (28)	34 (34)	26 (40)	24 (40)	18 (44)	12 (48)	10 (50)	7 (52)	5 (54)	4 (55)	3 (56)	3 (56)	2 (57)	2 (57)	1 (58)	1 (58)	0 (59)
Placebo	117 (0)	79 (17)	57 (27)	45 (32)	33 (37)	29 (40)	22 (47)	21 (47)	15 (50)	14 (51)	11 (54)	10 (55)	8 (57)	7 (58)	6 (59)	5 (60)	5 (60)	4 (61)	1 (63)	1 (63)	1 (63)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.5 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Cognitive Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



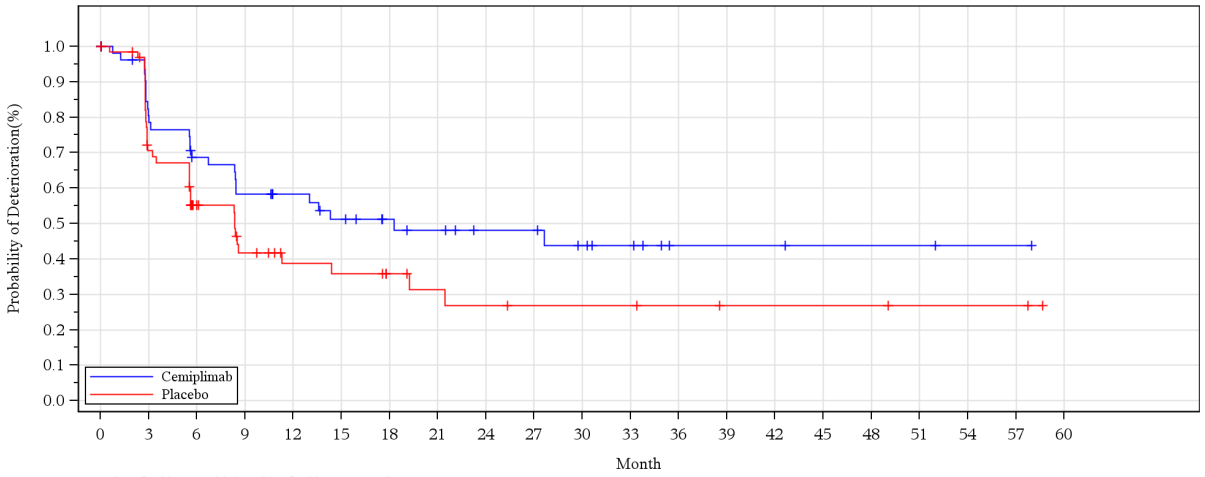
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	60 (11)	53 (12)	44 (13)	37 (17)	32 (19)	27 (22)	24 (23)	20 (27)	17 (29)	13 (33)	13 (33)	8 (37)	7 (38)	5 (39)	3 (41)	2 (41)	2 (41)	1 (42)	1 (42)	0 (43)
Placebo	89 (0)	58 (16)	49 (20)	38 (25)	28 (32)	19 (35)	16 (38)	14 (40)	10 (42)	7 (43)	5 (44)	5 (44)	3 (45)	3 (45)	2 (46)	2 (46)	2 (46)	1 (47)	1 (47)	1 (47)	0 (48)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



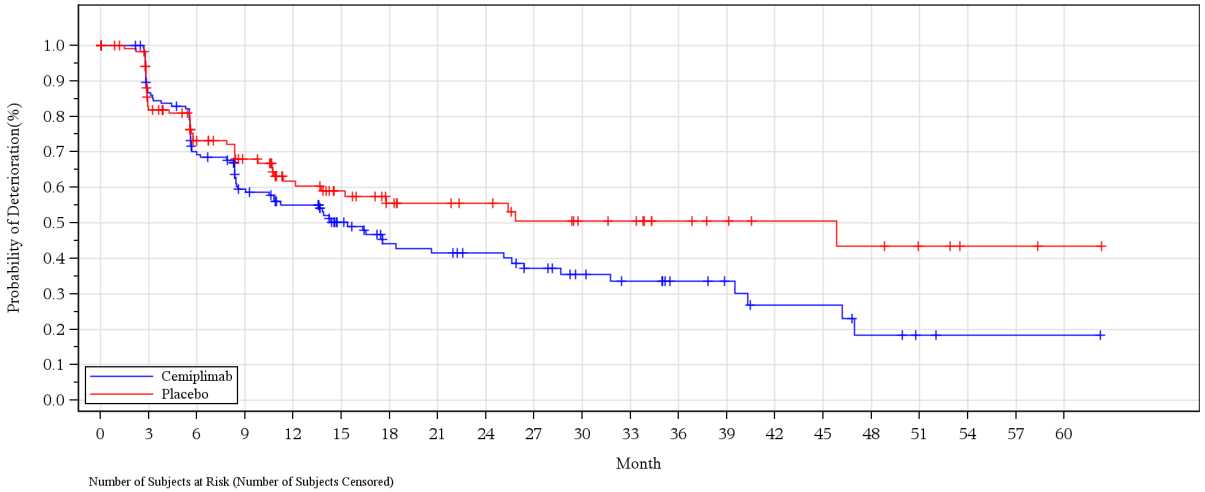
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (5)	33 (7)	28 (7)	25 (10)	21 (11)	17 (15)	15 (16)	12 (19)	12 (19)	9 (21)	7 (23)	3 (27)	3 (27)	3 (27)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)
Placebo	65 (0)	42 (5)	27 (11)	18 (14)	13 (18)	12 (18)	9 (21)	7 (22)	6 (22)	5 (23)	5 (23)	5 (23)	4 (24)	3 (25)	3 (25)	3 (25)	3 (25)	2 (26)	2 (26)	2 (26)	0 (28)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



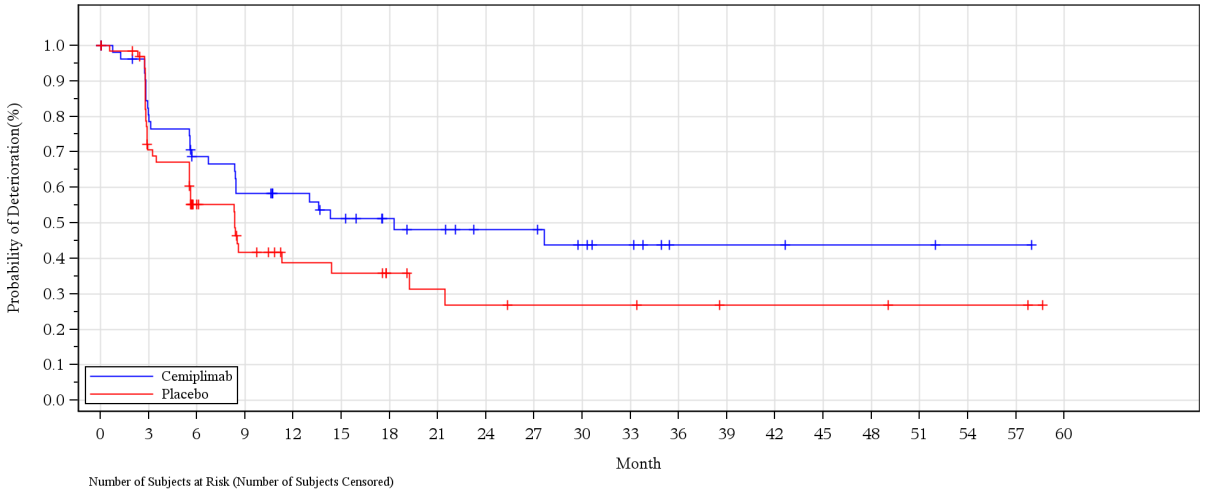
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	116 (19)	90 (22)	70 (30)	61 (34)	45 (45)	34 (51)	32 (51)	29 (54)	24 (56)	19 (60)	16 (62)	12 (66)	10 (68)	7 (69)	7 (69)	4 (70)	2 (72)	1 (73)	1 (73)	1 (73)
Placebo	141 (0)	93 (27)	72 (39)	61 (45)	45 (56)	37 (62)	29 (68)	26 (71)	24 (73)	20 (75)	17 (78)	16 (79)	11 (84)	9 (86)	7 (88)	7 (88)	6 (88)	4 (90)	2 (92)	2 (92)	1 (93)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



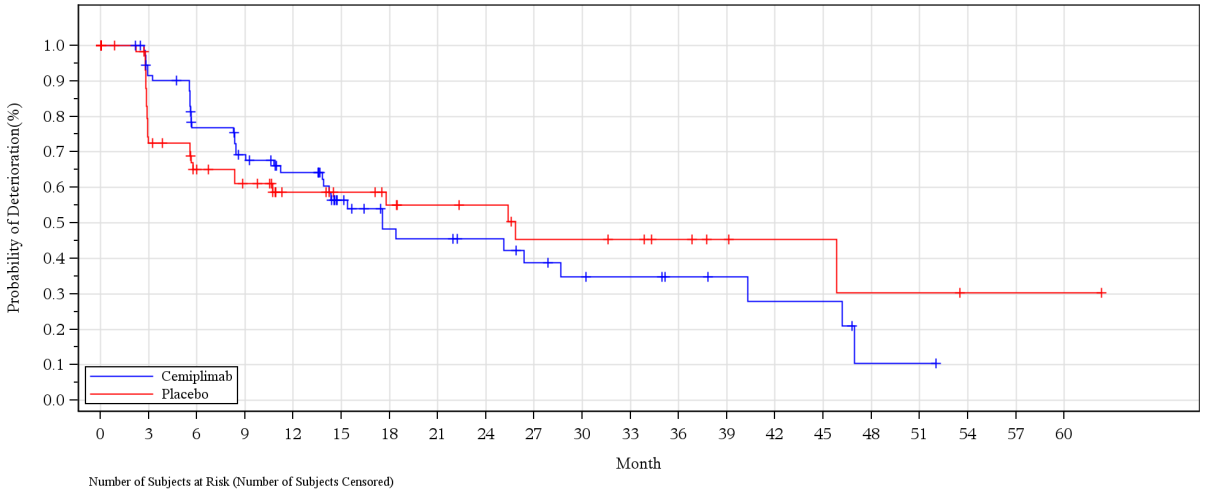
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	41 (5)	33 (7)	28 (7)	25 (10)	21 (11)	17 (15)	15 (16)	12 (19)	12 (19)	9 (21)	7 (23)	3 (27)	3 (27)	3 (27)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)
Placebo	65 (0)	42 (5)	27 (11)	18 (14)	13 (18)	12 (18)	9 (21)	7 (22)	6 (22)	5 (23)	5 (23)	5 (23)	4 (24)	3 (25)	3 (25)	3 (25)	3 (25)	2 (26)	2 (26)	2 (26)	0 (28)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	64 (10)	51 (13)	44 (15)	37 (19)	24 (28)	17 (32)	16 (32)	14 (34)	11 (35)	9 (36)	8 (37)	6 (39)	5 (40)	4 (40)	4 (40)	1 (41)	1 (41)	0 (42)	0 (42)	0 (42)
Placebo	69 (0)	42 (11)	33 (16)	29 (18)	21 (25)	18 (28)	15 (30)	13 (32)	12 (33)	9 (34)	9 (34)	8 (35)	6 (37)	4 (39)	3 (40)	3 (40)	2 (40)	2 (40)	1 (41)	1 (41)	1 (41)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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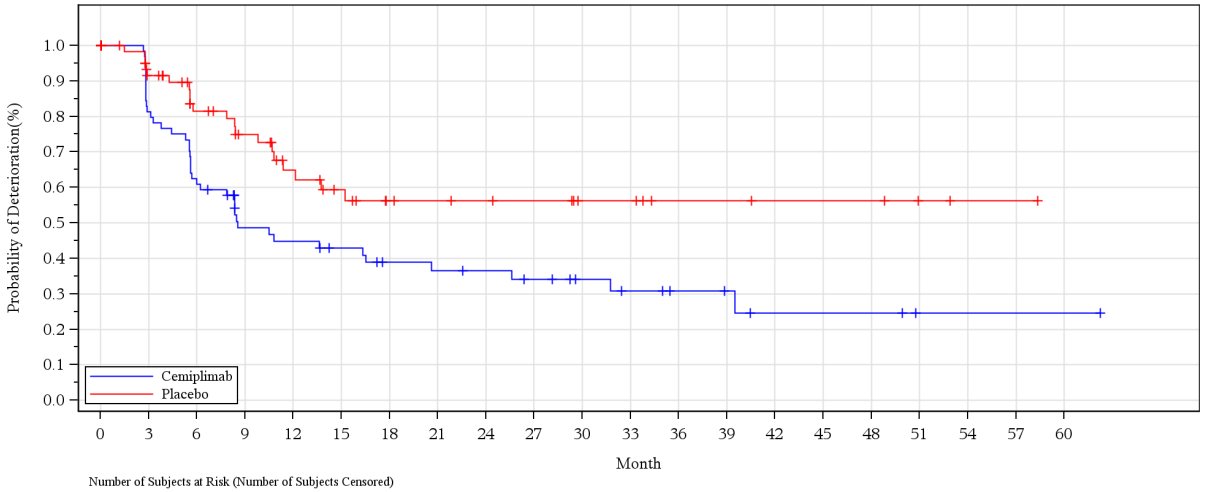
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



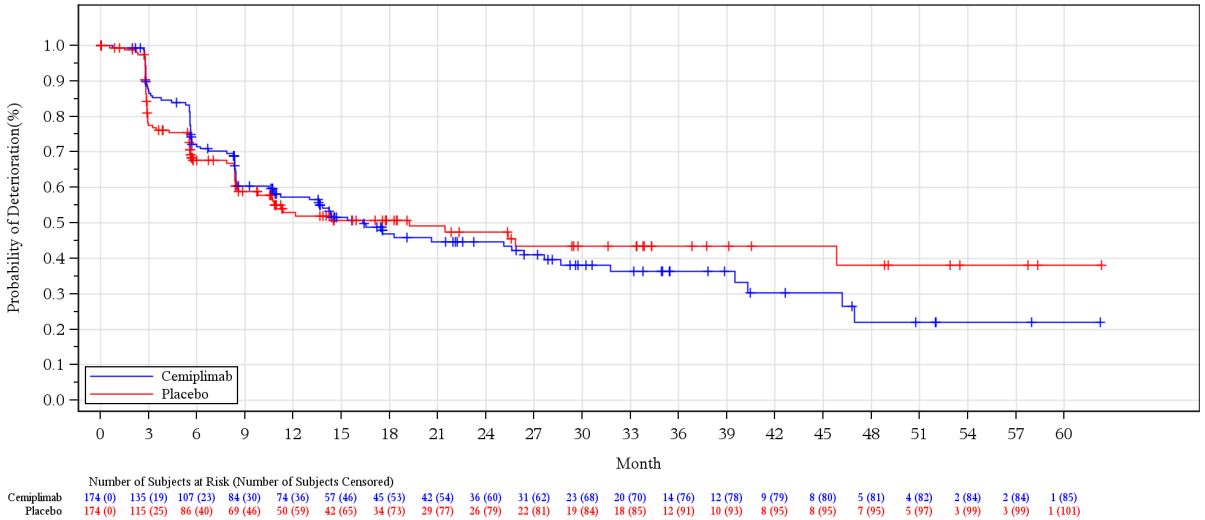
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	52 (9)	39 (9)	26 (15)	24 (15)	21 (17)	17 (19)	16 (19)	15 (20)	13 (21)	10 (24)	8 (25)	6 (27)	5 (28)	3 (29)	3 (29)	3 (29)	1 (31)	1 (31)	1 (31)	1 (31)
Placebo	72 (0)	51 (16)	39 (23)	32 (27)	24 (31)	19 (34)	14 (38)	13 (39)	12 (40)	11 (41)	8 (44)	8 (44)	5 (47)	5 (47)	4 (48)	4 (48)	4 (48)	2 (50)	1 (51)	1 (51)	0 (52)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Male



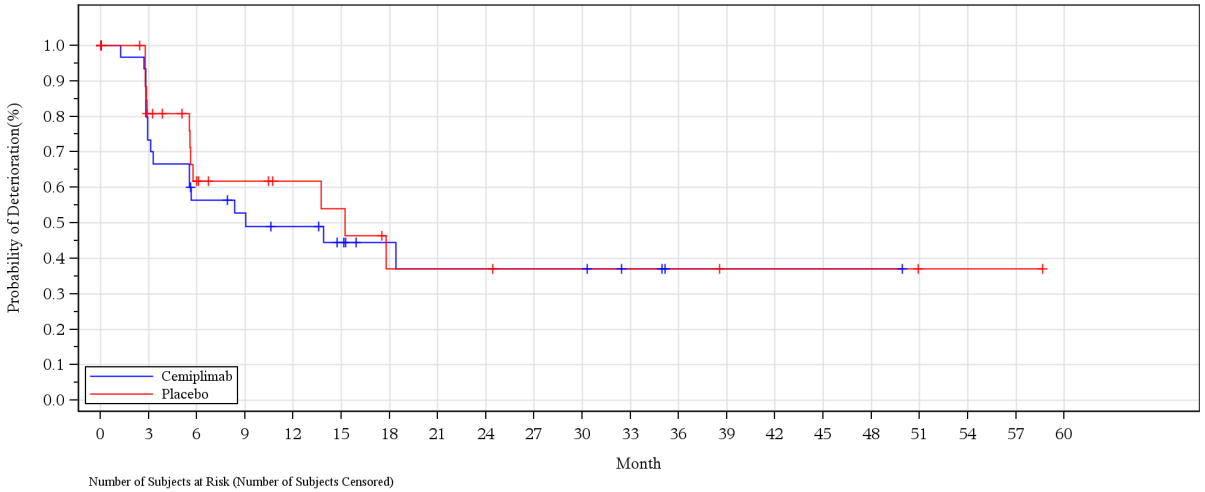
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	135 (19)	107 (23)	84 (30)	74 (36)	57 (46)	45 (53)	42 (54)	36 (60)	31 (62)	23 (68)	20 (70)	14 (76)	12 (78)	9 (79)	8 (80)	5 (81)	4 (82)	2 (84)	2 (84)	1 (85)
Placebo	174 (0)	115 (25)	86 (40)	69 (46)	50 (59)	42 (65)	34 (73)	29 (77)	26 (79)	22 (81)	19 (84)	18 (85)	12 (91)	10 (93)	8 (95)	8 (95)	7 (95)	5 (97)	3 (99)	3 (99)	1 (101)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	22 (5)	16 (6)	14 (7)	12 (8)	9 (10)	6 (13)	5 (13)	5 (13)	5 (13)	5 (13)	3 (15)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	32 (0)	20 (7)	13 (10)	10 (13)	8 (15)	7 (15)	4 (16)	4 (16)	4 (16)	3 (17)	3 (17)	3 (17)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	1 (19)	1 (19)	0 (20)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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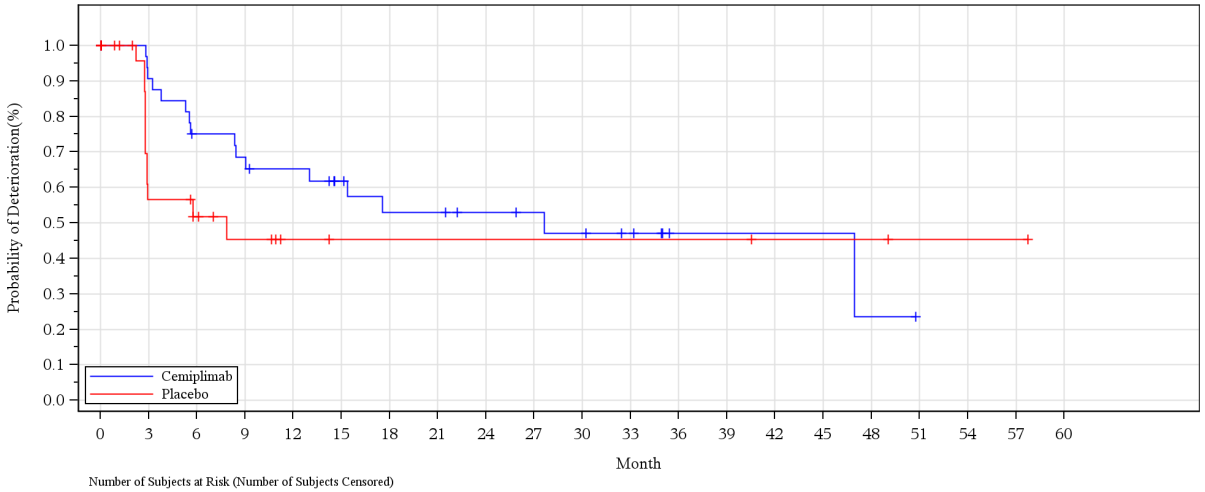
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (5)	23 (6)	21 (6)	19 (7)	15 (10)	12 (11)	12 (11)	10 (13)	9 (14)	8 (14)	6 (16)	2 (20)	2 (20)	2 (20)	2 (20)	1 (20)	0 (21)	0 (21)	0 (21)	0 (21)
Placebo	31 (0)	13 (8)	10 (10)	7 (12)	4 (15)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	3 (16)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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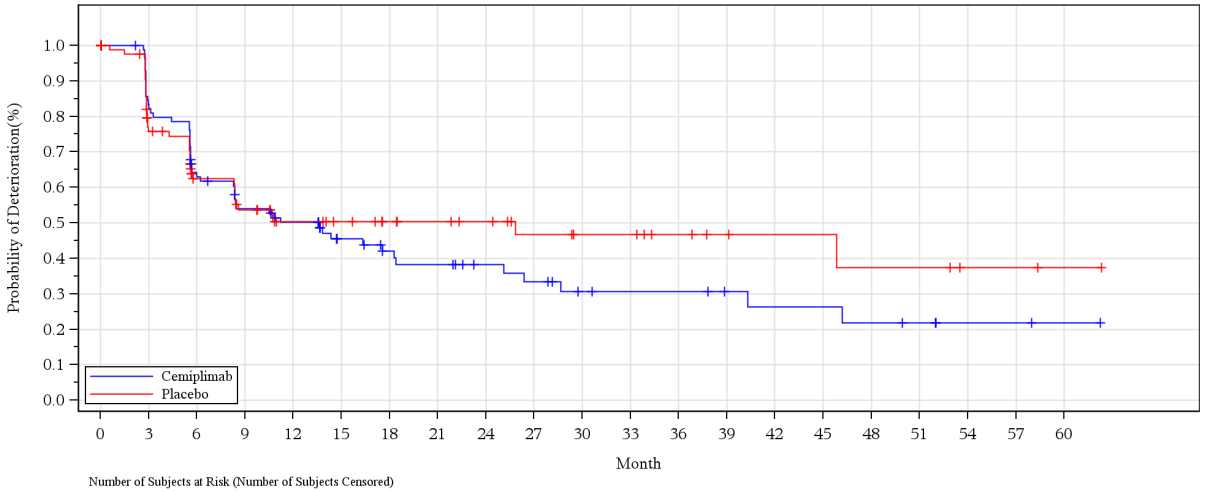
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	70 (6)	51 (8)	42 (10)	37 (12)	27 (19)	22 (22)	20 (22)	16 (26)	14 (26)	10 (29)	9 (30)	9 (30)	7 (32)	6 (32)	6 (32)	5 (32)	4 (33)	2 (35)	2 (35)	1 (36)
Placebo	90 (0)	60 (10)	43 (17)	36 (18)	28 (24)	25 (27)	21 (31)	19 (33)	17 (35)	13 (38)	11 (40)	11 (40)	8 (43)	6 (45)	5 (46)	5 (46)	4 (46)	4 (46)	2 (48)	2 (48)	1 (49)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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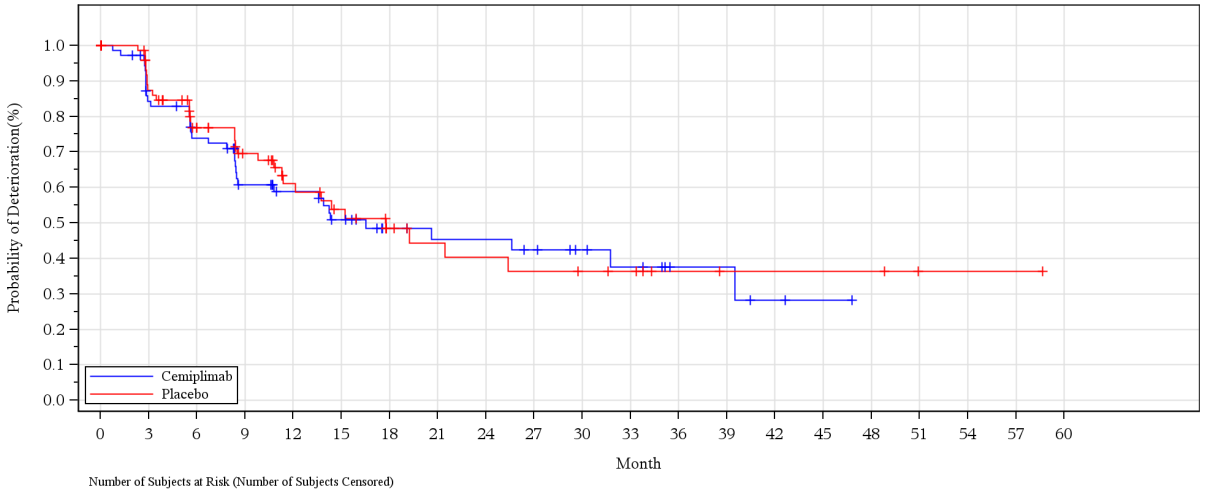
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	58 (13)	49 (15)	35 (21)	30 (25)	24 (27)	17 (33)	15 (34)	15 (34)	13 (35)	10 (38)	8 (39)	4 (43)	4 (43)	2 (44)	1 (45)	0 (46)	0 (46)	0 (46)	0 (46)	0 (46)
Placebo	85 (0)	62 (14)	46 (23)	36 (29)	26 (35)	21 (37)	14 (42)	11 (44)	10 (44)	9 (44)	8 (45)	7 (46)	4 (49)	3 (50)	3 (50)	3 (50)	3 (50)	1 (52)	1 (52)	1 (52)	0 (53)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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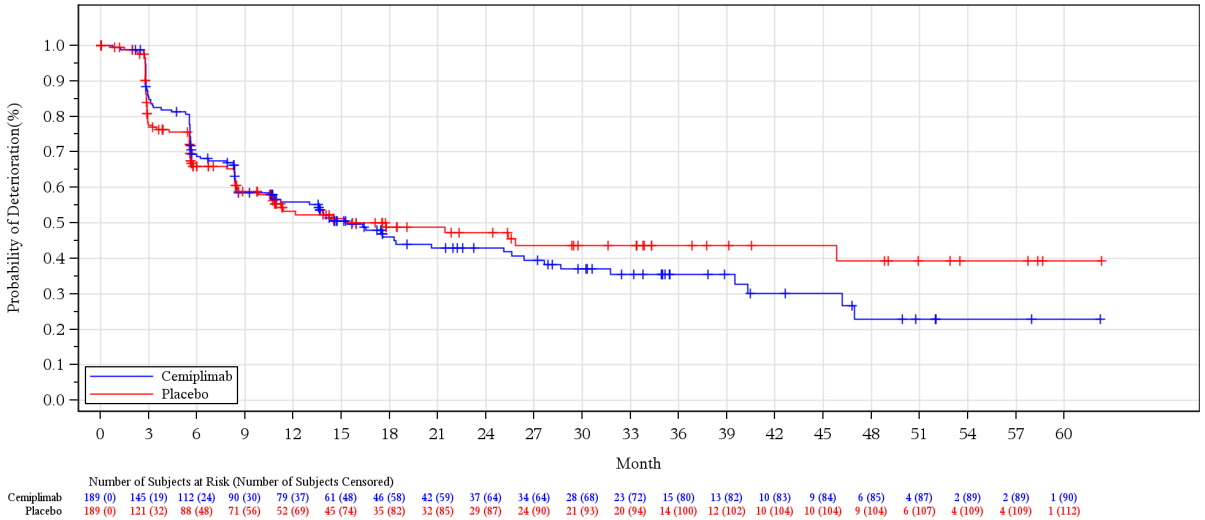
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	145 (19)	112 (24)	90 (30)	79 (37)	61 (48)	46 (58)	42 (59)	37 (64)	34 (64)	28 (68)	23 (72)	15 (80)	13 (82)	10 (83)	9 (84)	6 (85)	4 (87)	2 (89)	2 (89)	1 (90)
Placebo	189 (0)	121 (32)	88 (48)	71 (56)	52 (69)	45 (74)	35 (82)	32 (85)	29 (87)	24 (90)	21 (93)	20 (94)	14 (100)	12 (102)	10 (104)	10 (104)	9 (104)	6 (107)	4 (109)	4 (109)	1 (112)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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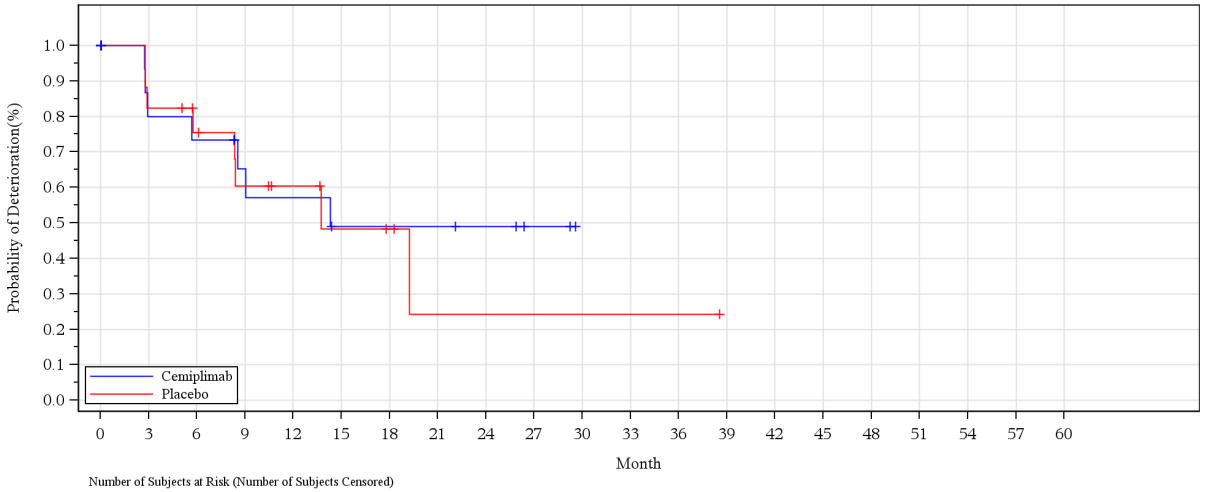
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	12 (5)	11 (5)	8 (7)	7 (7)	5 (8)	5 (8)	5 (8)	4 (9)	2 (11)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)
Placebo	17 (0)	14 (0)	11 (2)	8 (3)	6 (5)	4 (6)	3 (7)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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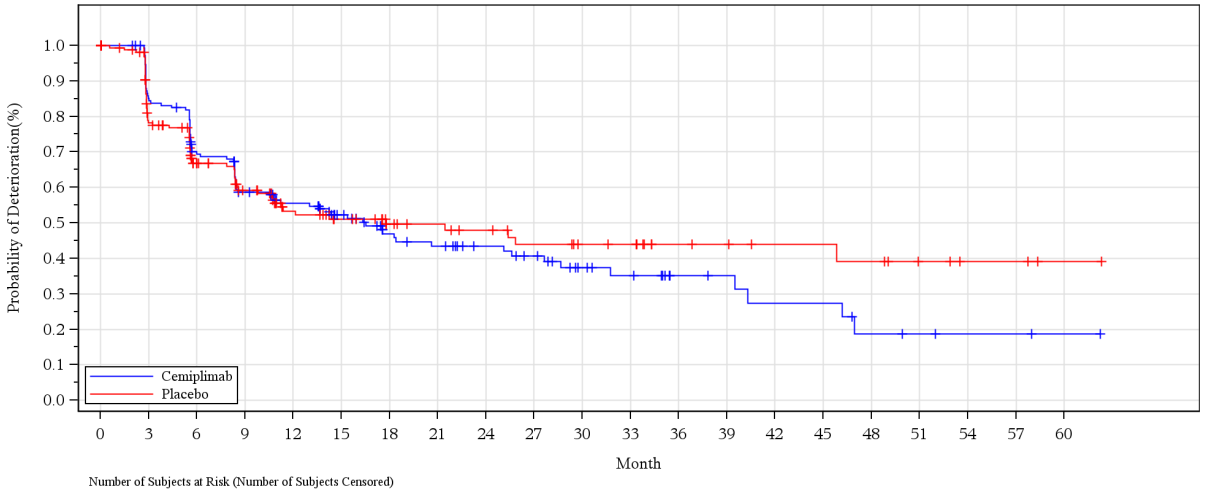
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	126 (18)	99 (22)	80 (26)	70 (32)	55 (43)	41 (52)	37 (53)	31 (59)	27 (61)	19 (67)	16 (69)	10 (75)	9 (76)	7 (76)	7 (76)	4 (77)	3 (78)	2 (79)	2 (79)	1 (80)
Placebo	177 (0)	116 (28)	85 (43)	68 (51)	49 (64)	41 (70)	32 (78)	29 (81)	26 (83)	22 (85)	19 (88)	18 (89)	12 (95)	11 (96)	9 (98)	9 (98)	8 (98)	5 (101)	3 (103)	3 (103)	1 (105)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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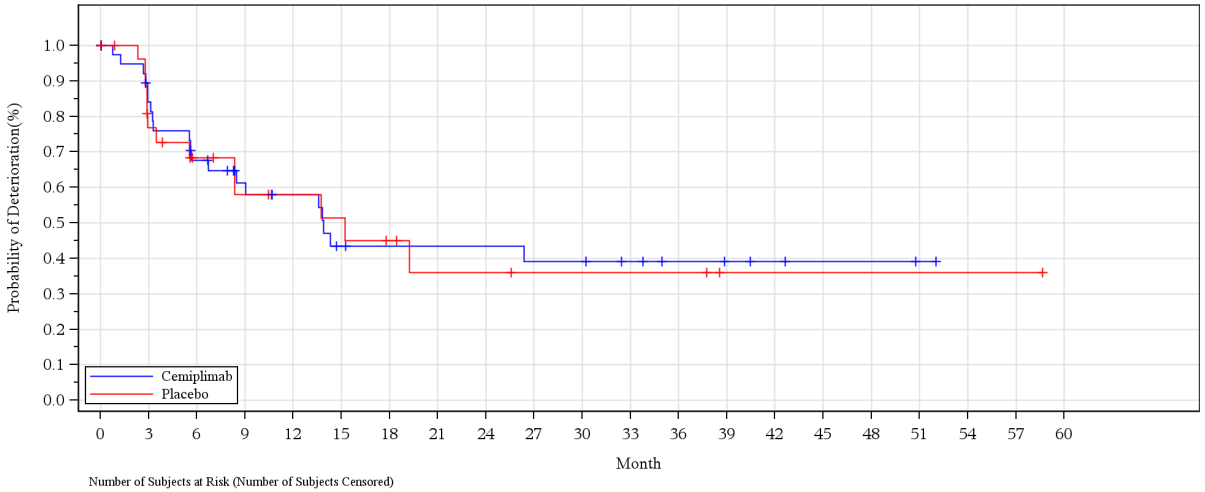
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	31 (6)	24 (7)	18 (11)	16 (12)	11 (13)	10 (14)	10 (14)	10 (14)	9 (14)	9 (14)	7 (16)	5 (18)	4 (19)	3 (20)	2 (21)	2 (21)	1 (22)	0 (23)	0 (23)	0 (23)
Placebo	29 (0)	19 (4)	14 (7)	11 (8)	9 (10)	8 (10)	6 (11)	4 (12)	4 (12)	3 (13)	3 (13)	3 (13)	3 (13)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	1 (15)	0 (16)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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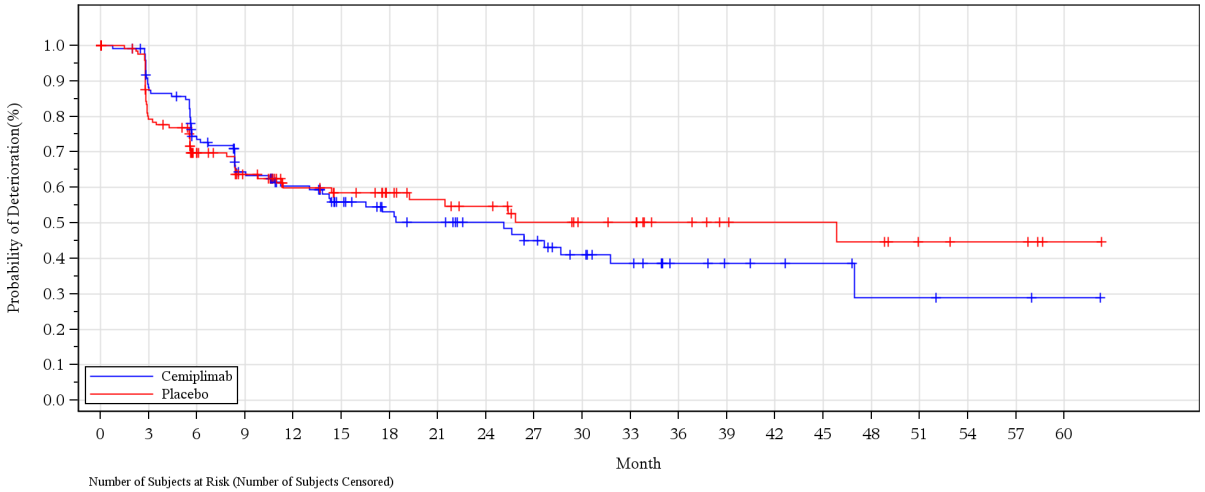
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	104 (15)	83 (19)	67 (25)	57 (31)	45 (39)	37 (45)	34 (46)	29 (51)	25 (52)	19 (56)	15 (59)	9 (65)	7 (67)	6 (68)	5 (69)	3 (70)	3 (70)	2 (71)	2 (71)	1 (72)
Placebo	131 (0)	95 (11)	72 (23)	58 (31)	45 (41)	41 (44)	34 (51)	30 (54)	27 (56)	22 (59)	19 (62)	18 (63)	13 (68)	10 (71)	9 (72)	9 (72)	8 (72)	5 (75)	4 (76)	4 (76)	1 (79)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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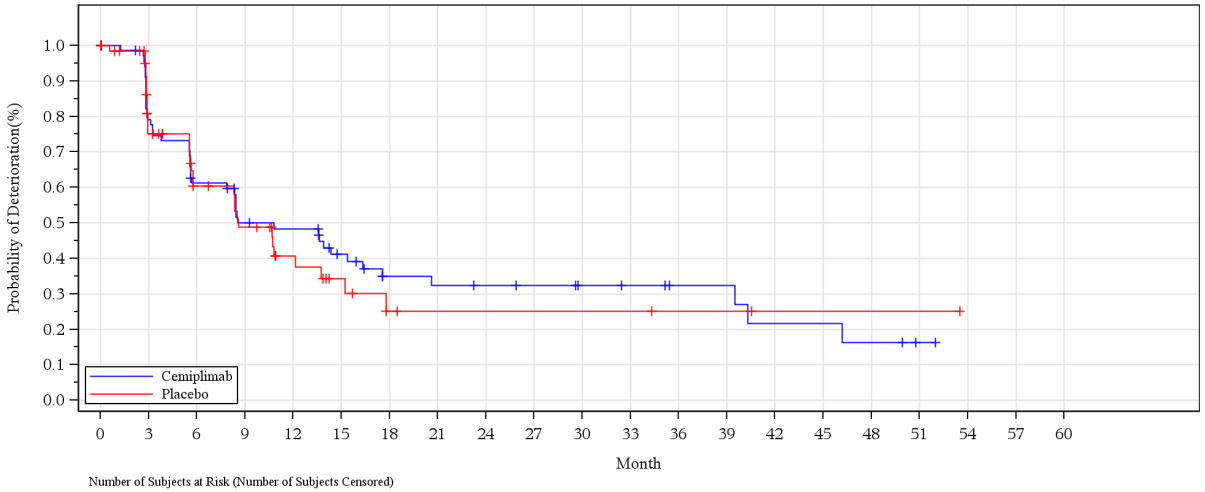
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	53 (9)	40 (10)	31 (12)	29 (13)	21 (17)	14 (21)	13 (21)	12 (22)	11 (23)	9 (25)	8 (26)	6 (28)	6 (28)	4 (28)	4 (28)	3 (28)	1 (30)	0 (31)	0 (31)	0 (31)
Placebo	75 (0)	40 (21)	27 (27)	21 (28)	13 (33)	8 (36)	4 (38)	3 (39)	3 (39)	3 (39)	3 (39)	3 (39)	2 (40)	2 (40)	1 (41)	1 (41)	1 (41)	1 (41)	0 (42)	0 (42)	0 (42)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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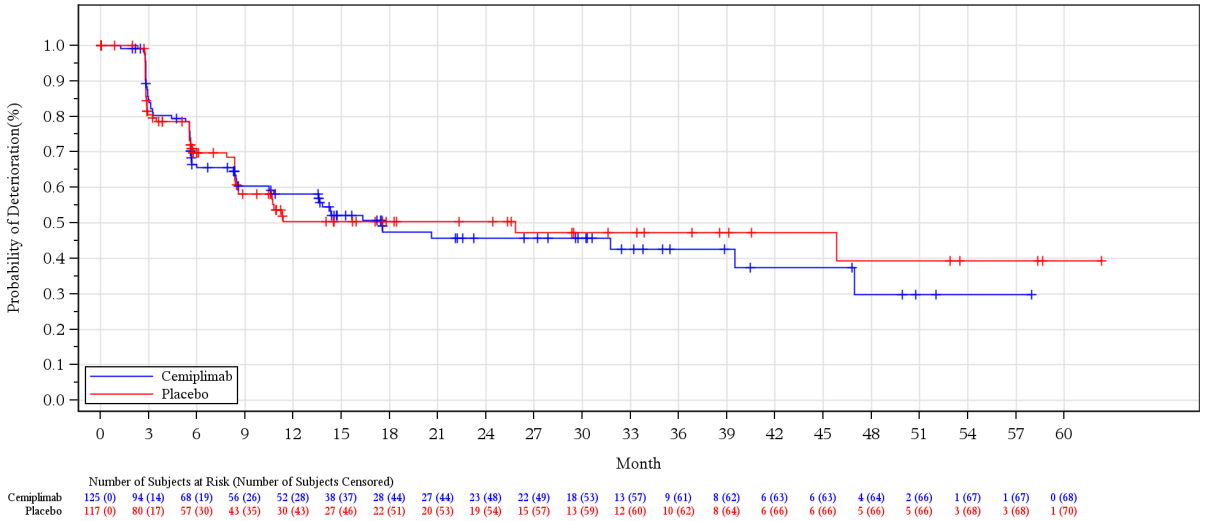
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	94 (14)	68 (19)	56 (26)	52 (28)	38 (37)	28 (44)	27 (44)	23 (48)	22 (49)	18 (53)	13 (57)	9 (61)	8 (62)	6 (63)	6 (63)	4 (64)	2 (66)	1 (67)	1 (67)	0 (68)
Placebo	117 (0)	80 (17)	57 (30)	43 (35)	30 (43)	27 (46)	22 (51)	20 (53)	19 (54)	15 (57)	13 (59)	12 (60)	10 (62)	8 (64)	6 (66)	6 (66)	5 (66)	5 (66)	3 (68)	3 (68)	1 (70)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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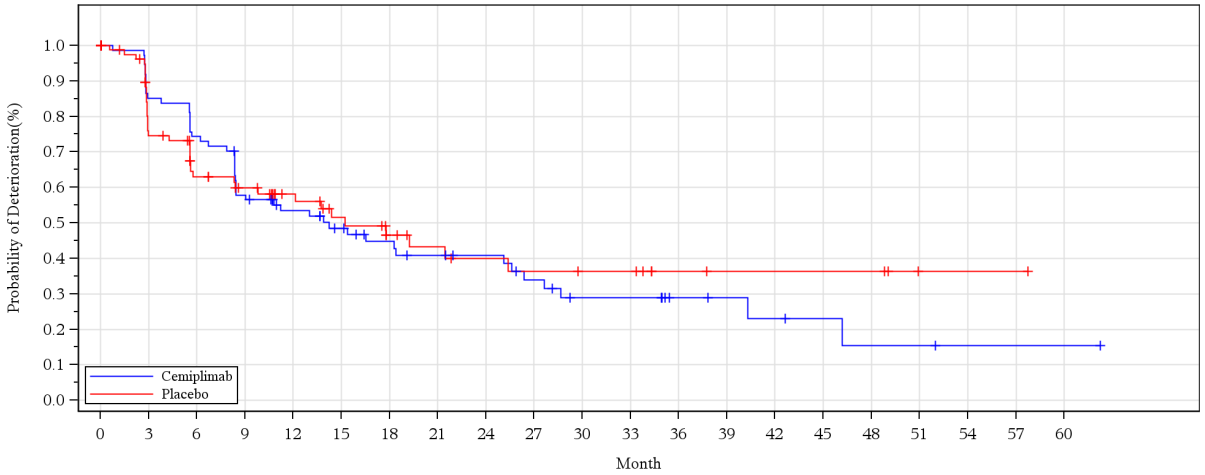
Figure 14.2.8.1.6 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Social Functioning Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



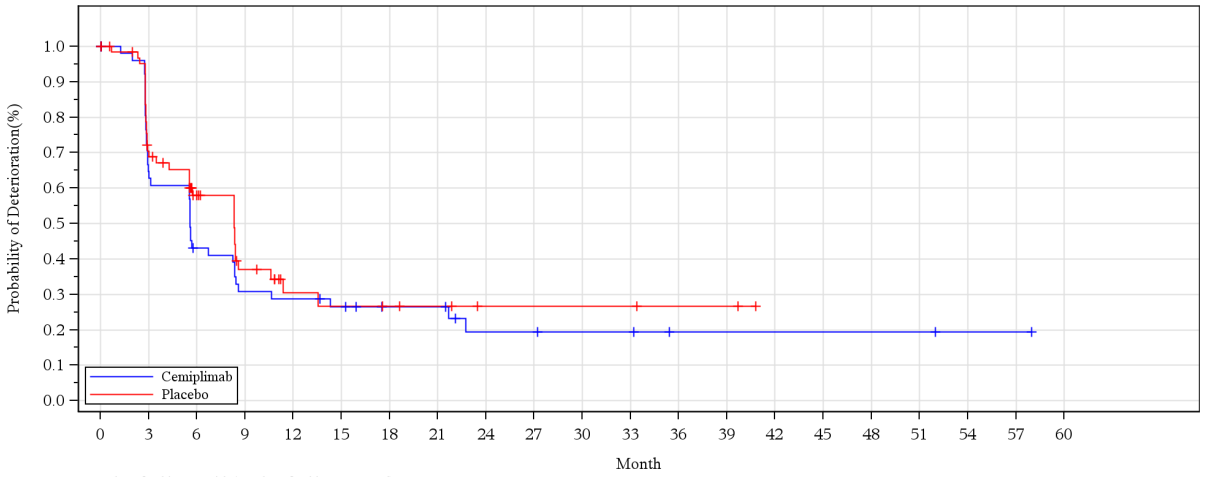
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	63 (10)	55 (10)	42 (11)	34 (16)	28 (19)	23 (22)	20 (23)	18 (25)	14 (26)	10 (28)	10 (28)	6 (32)	5 (33)	4 (33)	3 (34)	2 (34)	2 (34)	1 (35)	1 (35)	1 (35)
Placebo	89 (0)	55 (15)	42 (20)	36 (24)	28 (31)	22 (34)	16 (38)	13 (40)	11 (41)	10 (41)	9 (42)	9 (42)	5 (46)	4 (47)	4 (47)	4 (47)	4 (47)	1 (50)	1 (50)	1 (50)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



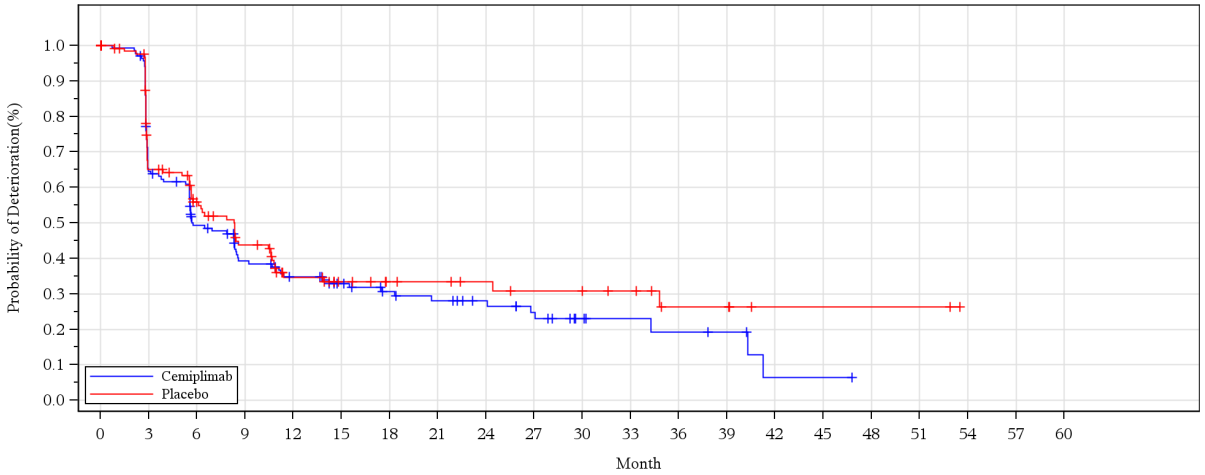
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	33 (5)	21 (6)	15 (6)	14 (6)	12 (7)	9 (10)	9 (10)	5 (12)	5 (12)	4 (13)	4 (13)	2 (15)	2 (15)	2 (15)	2 (15)	2 (15)	2 (15)	1 (16)	1 (16)	0 (17)
Placebo	65 (0)	42 (5)	28 (12)	15 (16)	8 (21)	7 (21)	6 (22)	5 (23)	3 (25)	3 (25)	3 (25)	3 (25)	2 (26)	2 (26)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



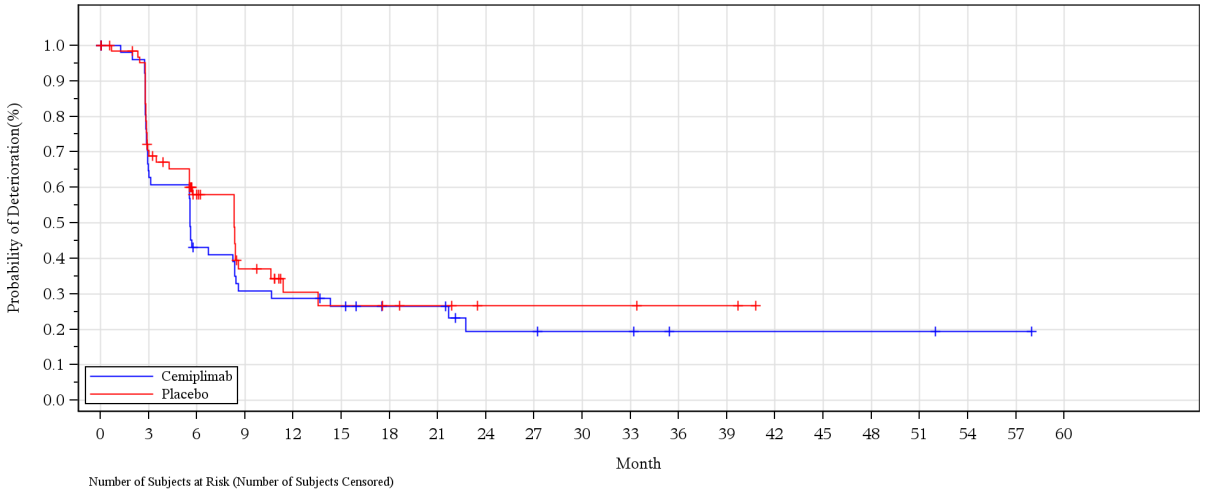
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	87 (18)	62 (23)	46 (27)	38 (30)	31 (35)	25 (39)	22 (40)	18 (44)	14 (46)	8 (51)	6 (53)	5 (53)	4 (54)	1 (55)	1 (55)	0 (56)	0 (56)	0 (56)	0 (56)	0 (56)
Placebo	141 (0)	75 (25)	57 (33)	42 (36)	27 (43)	20 (49)	16 (53)	15 (54)	13 (56)	11 (57)	10 (58)	9 (59)	5 (62)	5 (62)	2 (65)	2 (65)	2 (65)	2 (65)	0 (67)	0 (67)	0 (67)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



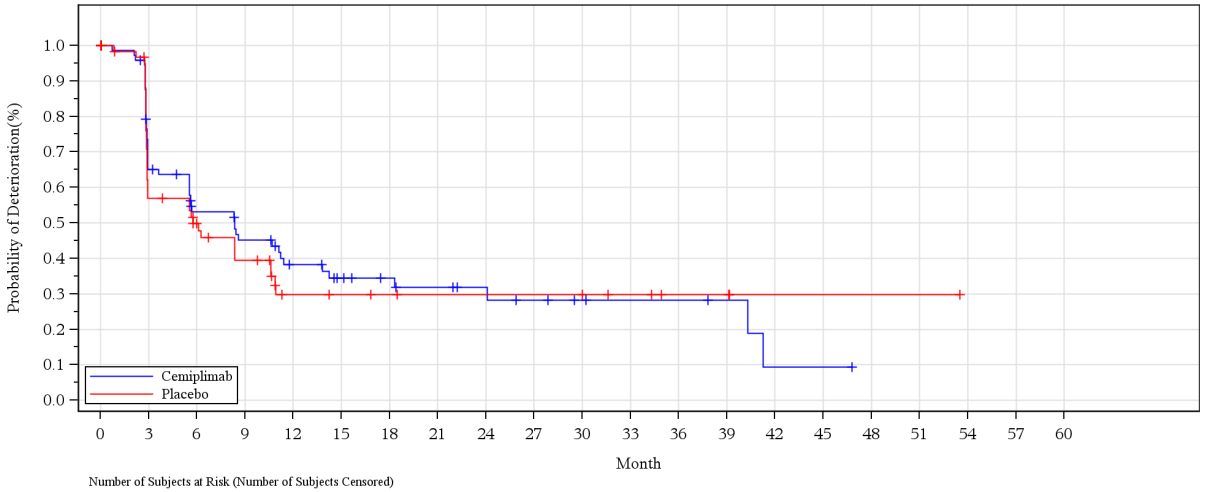
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	33 (5)	21 (6)	15 (6)	14 (6)	12 (7)	9 (10)	9 (10)	5 (12)	5 (12)	4 (13)	4 (13)	2 (15)	2 (15)	2 (15)	2 (15)	2 (15)	2 (15)	1 (16)	1 (16)	0 (17)
Placebo	65 (0)	42 (5)	28 (12)	15 (16)	8 (21)	7 (21)	6 (22)	5 (23)	3 (25)	3 (25)	3 (25)	3 (25)	2 (26)	2 (26)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)	0 (28)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



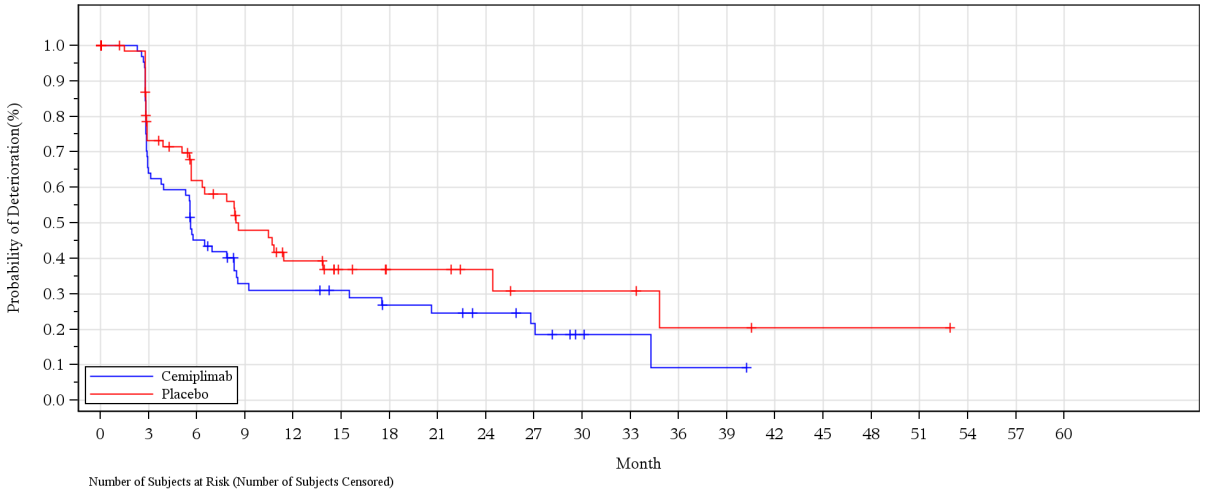
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	46 (9)	34 (13)	28 (14)	21 (17)	16 (20)	13 (23)	11 (24)	9 (26)	7 (27)	5 (29)	4 (30)	4 (30)	3 (31)	1 (31)	1 (31)	0 (32)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	69 (0)	33 (11)	25 (15)	19 (16)	10 (21)	9 (22)	8 (23)	7 (24)	7 (24)	7 (24)	6 (25)	5 (26)	3 (28)	3 (28)	1 (30)	1 (30)	1 (30)	1 (30)	0 (31)	0 (31)	0 (31)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



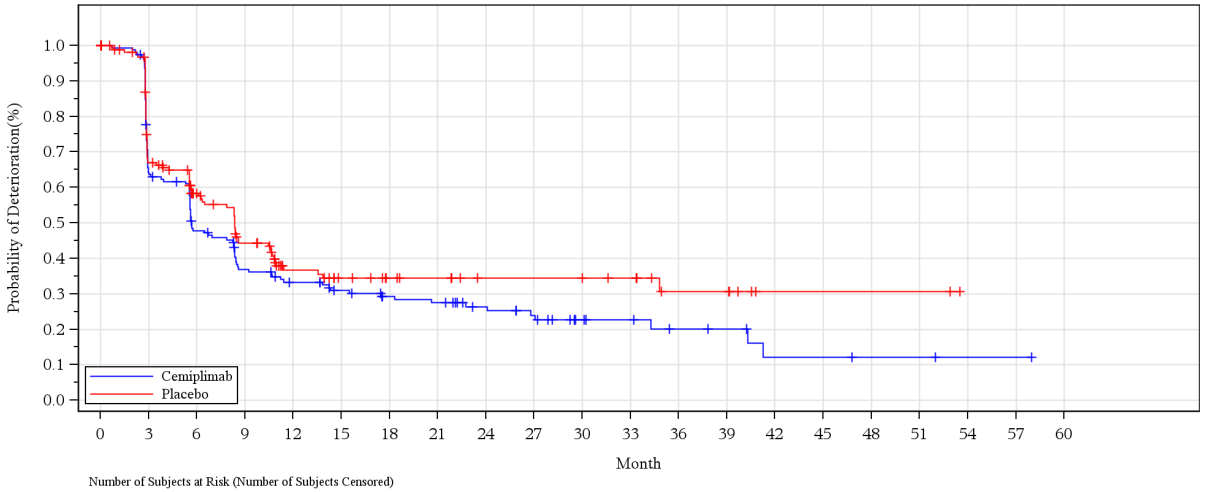
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	41 (9)	28 (10)	18 (13)	17 (13)	15 (15)	12 (16)	11 (16)	9 (18)	7 (19)	3 (22)	2 (23)	1 (23)	1 (23)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)	0 (24)
Placebo	72 (0)	42 (14)	32 (18)	23 (20)	17 (22)	11 (27)	8 (30)	8 (30)	6 (32)	4 (33)	4 (33)	4 (33)	2 (34)	2 (34)	1 (35)	1 (35)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Gender group: Male



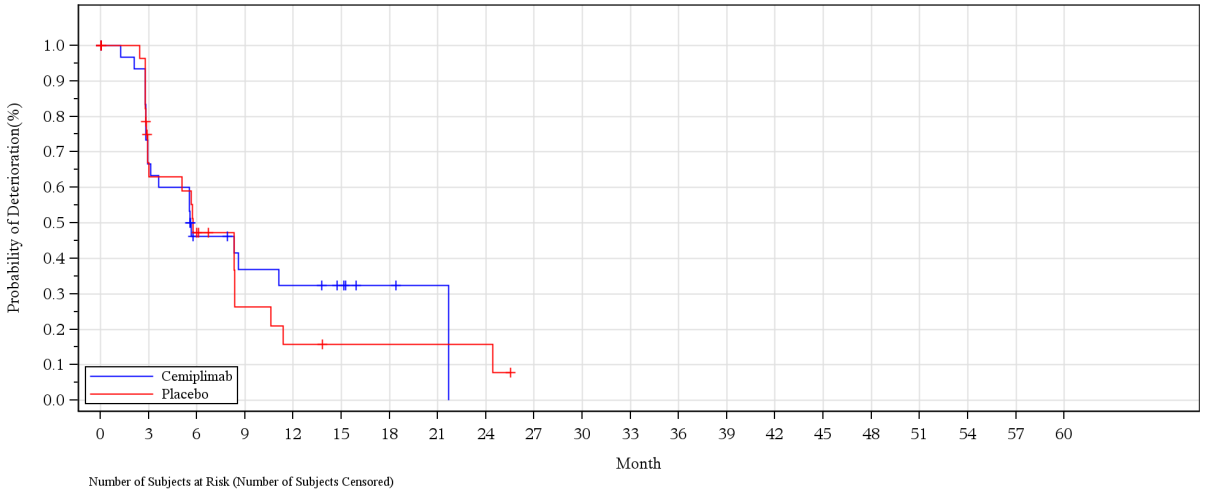
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	100 (18)	72 (21)	53 (24)	45 (27)	38 (31)	32 (35)	30 (35)	23 (41)	19 (43)	12 (49)	10 (51)	7 (53)	6 (54)	3 (55)	3 (55)	2 (56)	2 (56)	1 (57)	1 (57)	0 (58)
Placebo	174 (0)	100 (24)	73 (39)	52 (43)	32 (55)	25 (60)	20 (65)	18 (67)	14 (71)	14 (71)	13 (72)	12 (73)	7 (77)	7 (77)	2 (82)	2 (82)	2 (82)	2 (82)	0 (84)	0 (84)	0 (84)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Gender group: Female



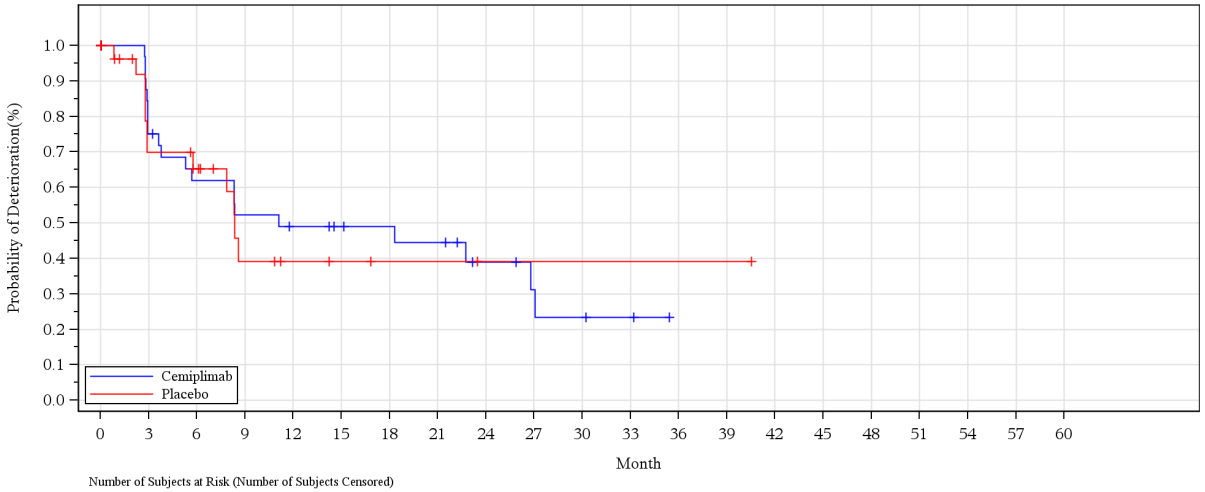
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	20 (5)	11 (8)	8 (9)	7 (9)	5 (11)	2 (14)	1 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)
Placebo	32 (0)	17 (6)	12 (6)	5 (9)	3 (9)	2 (10)	2 (10)	2 (10)	2 (10)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



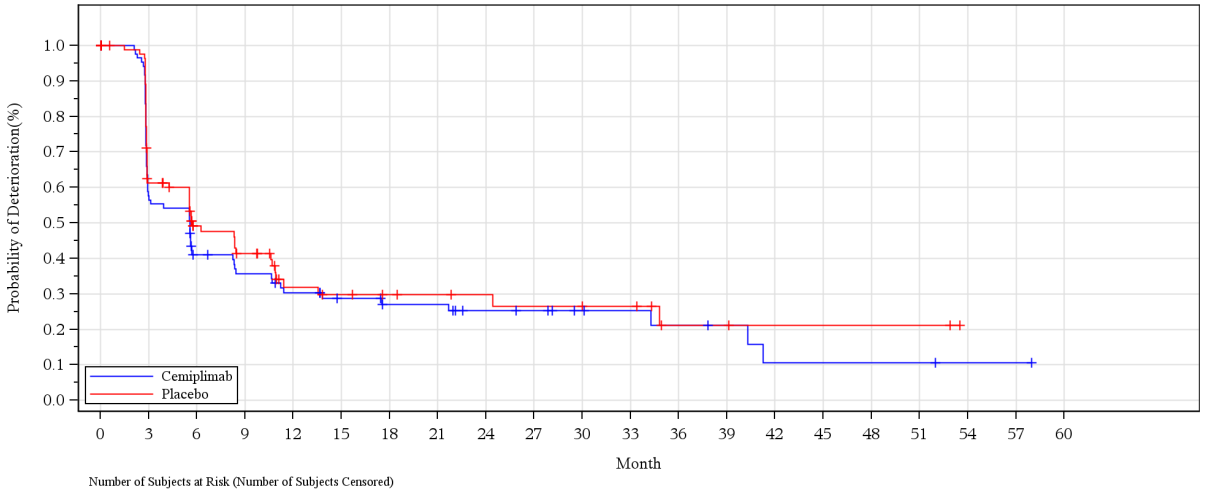
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	24 (5)	19 (6)	16 (6)	14 (7)	12 (9)	11 (10)	10 (10)	6 (13)	4 (14)	3 (14)	2 (15)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	31 (0)	16 (8)	13 (10)	6 (13)	4 (15)	3 (16)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)	0 (19)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



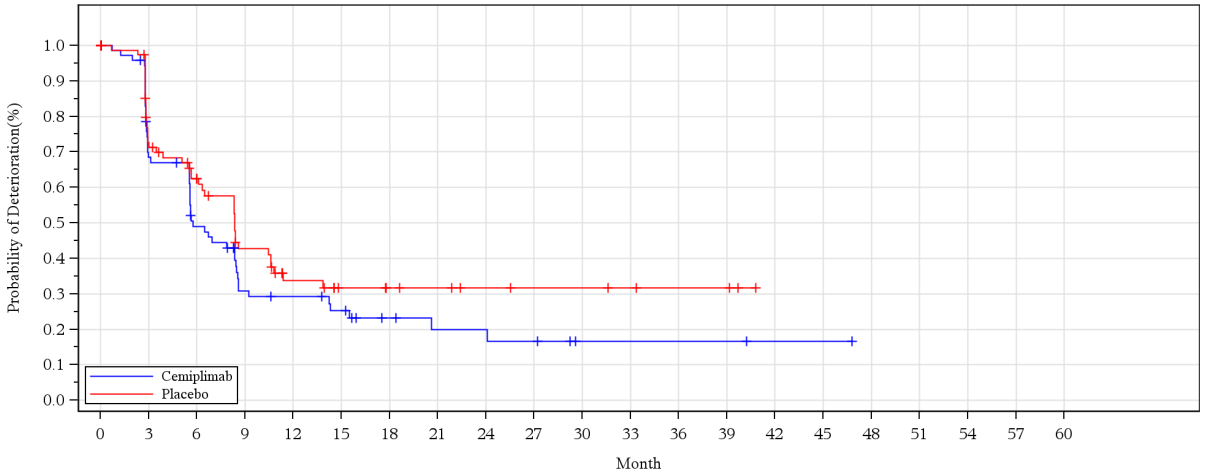
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	49 (5)	32 (8)	27 (9)	22 (10)	18 (13)	15 (15)	15 (15)	11 (18)	10 (19)	7 (22)	6 (23)	5 (23)	4 (24)	2 (24)	2 (24)	2 (24)	2 (24)	1 (25)	1 (25)	0 (26)
Placebo	90 (0)	49 (9)	32 (17)	26 (18)	15 (24)	13 (25)	11 (27)	10 (28)	9 (29)	8 (29)	7 (30)	7 (30)	3 (33)	3 (33)	2 (34)	2 (34)	2 (34)	2 (34)	0 (36)	0 (36)	0 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	47 (13)	32 (15)	18 (18)	16 (19)	13 (20)	8 (24)	6 (25)	6 (25)	5 (25)	2 (28)	2 (28)	2 (28)	2 (28)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)	0 (30)
Placebo	85 (0)	52 (13)	40 (18)	25 (21)	16 (25)	11 (29)	9 (31)	8 (32)	6 (34)	5 (35)	5 (35)	4 (36)	3 (37)	3 (37)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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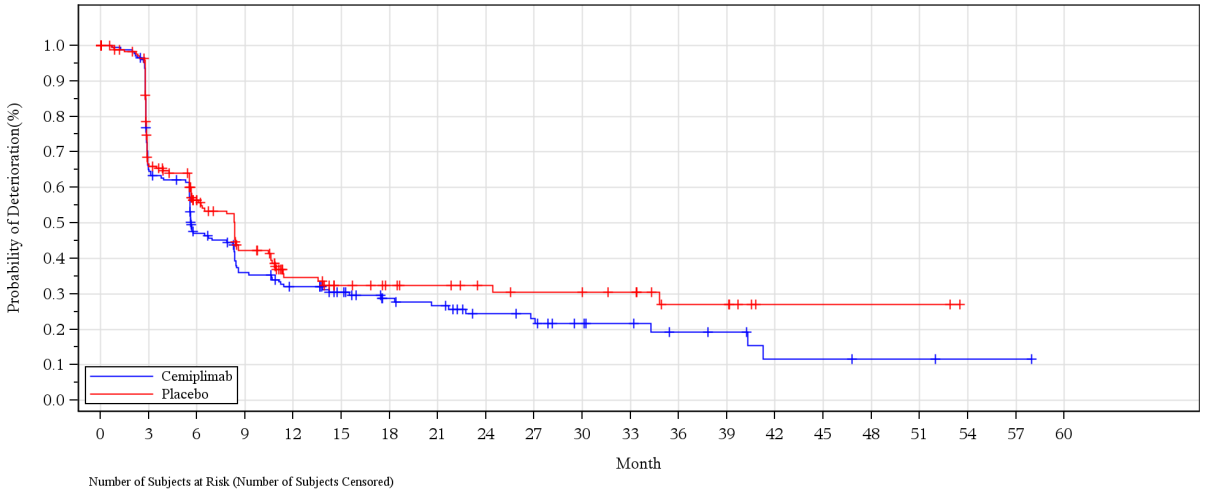
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	111 (18)	75 (24)	55 (27)	46 (30)	38 (36)	29 (43)	26 (44)	19 (49)	17 (50)	12 (54)	10 (56)	7 (58)	6 (59)	3 (60)	3 (60)	2 (61)	2 (61)	1 (62)	1 (62)	0 (63)
Placebo	189 (0)	105 (30)	75 (45)	51 (51)	32 (62)	25 (67)	21 (71)	19 (73)	16 (76)	14 (77)	13 (78)	12 (79)	7 (83)	7 (83)	2 (88)	2 (88)	2 (88)	2 (88)	0 (90)	0 (90)	0 (90)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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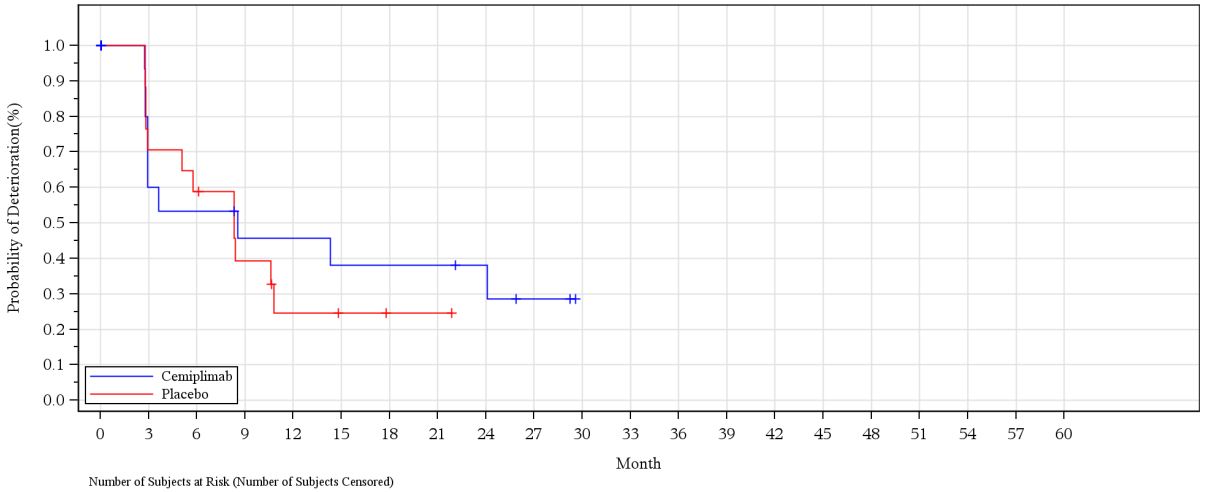
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Race: Non-white



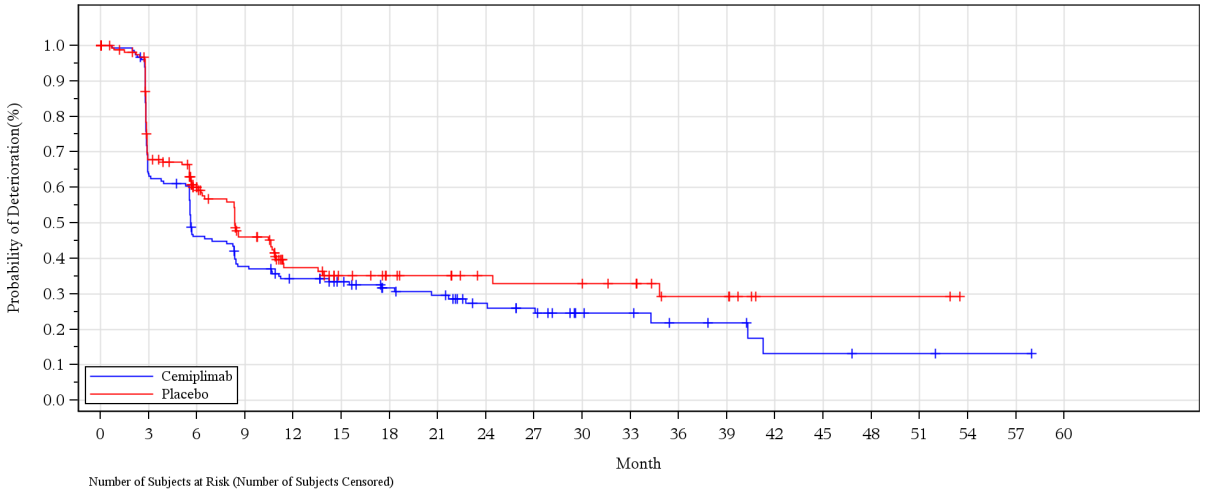
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (5)	8 (5)	6 (6)	6 (6)	5 (6)	5 (6)	5 (6)	4 (7)	2 (8)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)
Placebo	17 (0)	12 (0)	10 (0)	6 (1)	3 (2)	2 (3)	1 (4)	1 (4)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



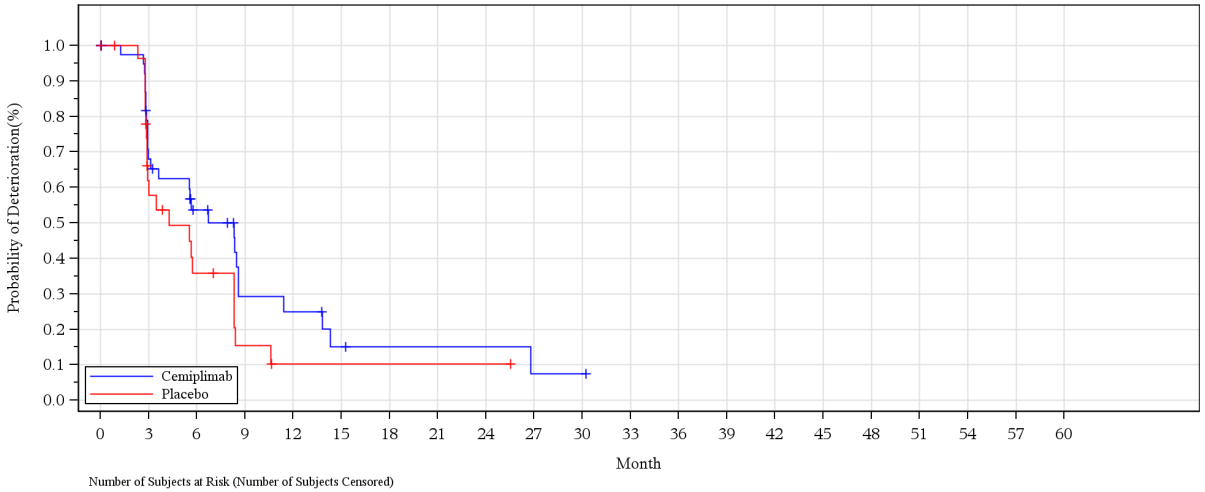
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	95 (17)	67 (19)	54 (20)	46 (23)	40 (28)	32 (34)	29 (35)	21 (41)	18 (43)	11 (49)	10 (50)	7 (52)	6 (53)	3 (54)	3 (54)	2 (55)	2 (55)	1 (56)	1 (56)	0 (57)
Placebo	177 (0)	102 (26)	77 (40)	54 (46)	34 (57)	26 (63)	21 (68)	19 (70)	15 (74)	14 (74)	13 (75)	12 (76)	7 (80)	7 (80)	2 (85)	2 (85)	2 (85)	2 (85)	0 (87)	0 (87)	0 (87)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	25 (6)	16 (10)	7 (13)	6 (13)	3 (14)	2 (15)	2 (15)	2 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	29 (0)	15 (4)	8 (5)	3 (6)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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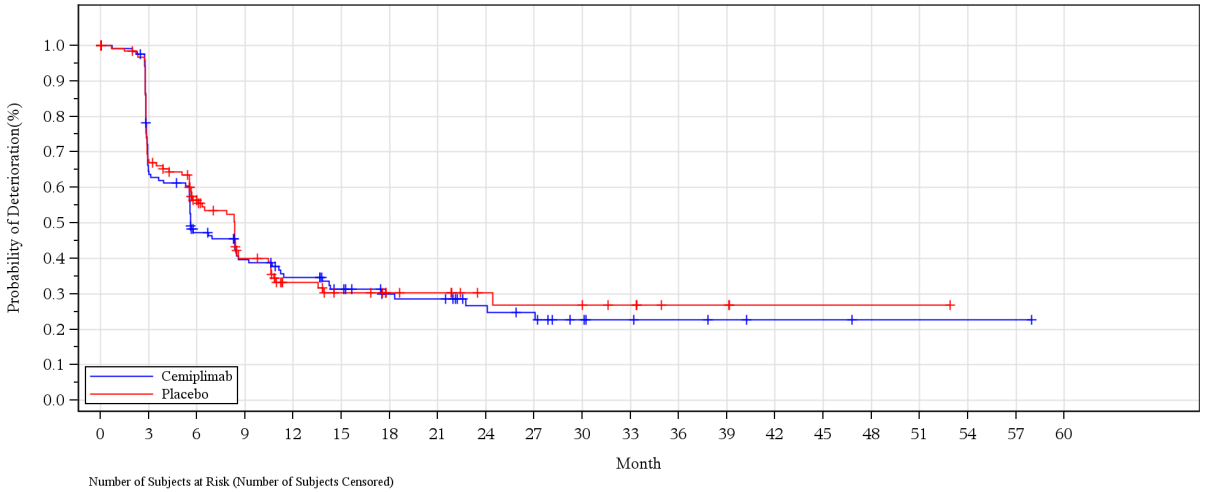
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



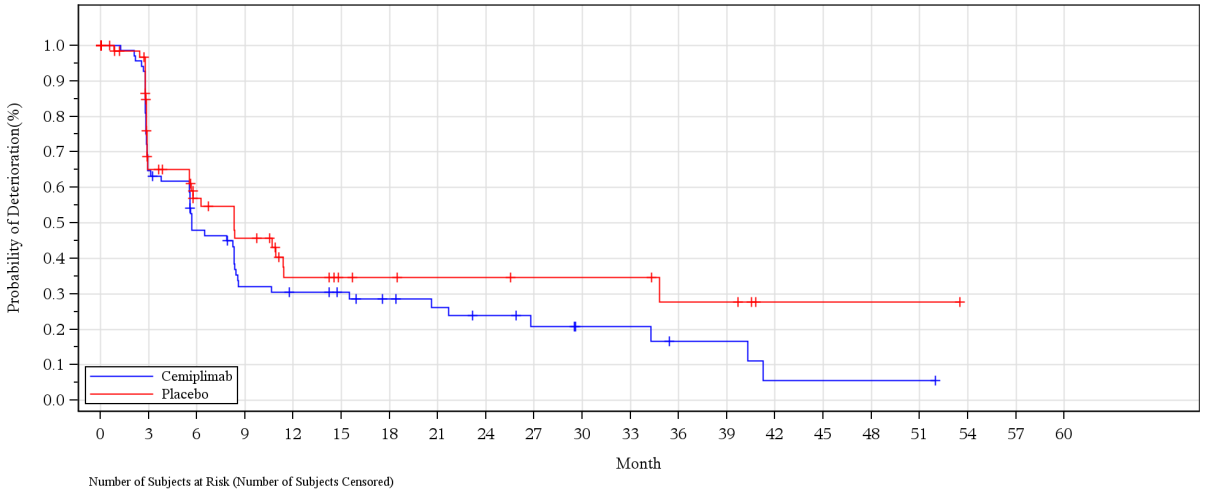
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	76 (15)	52 (19)	41 (22)	34 (24)	27 (28)	21 (33)	20 (33)	14 (38)	12 (39)	7 (43)	5 (45)	4 (46)	3 (47)	2 (48)	2 (48)	1 (49)	1 (49)	1 (49)	1 (49)	0 (50)
Placebo	131 (0)	82 (10)	59 (20)	37 (26)	23 (34)	18 (37)	14 (41)	13 (42)	9 (46)	8 (46)	7 (47)	6 (48)	3 (51)	3 (51)	1 (53)	1 (53)	1 (53)	1 (53)	0 (54)	0 (54)	0 (54)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	44 (8)	31 (10)	20 (11)	18 (12)	16 (14)	13 (16)	11 (17)	9 (18)	7 (19)	5 (21)	5 (21)	3 (22)	3 (22)	1 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)
Placebo	75 (0)	35 (20)	26 (25)	20 (26)	12 (30)	9 (33)	8 (34)	7 (35)	7 (35)	6 (36)	6 (36)	6 (36)	4 (37)	4 (37)	1 (40)	1 (40)	1 (40)	1 (40)	0 (41)	0 (41)	0 (41)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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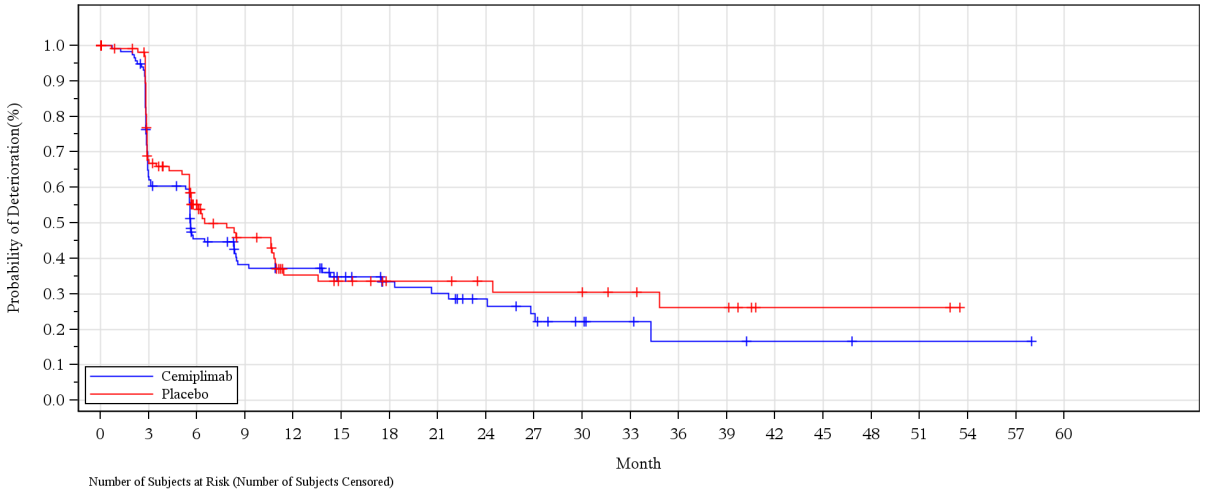
Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



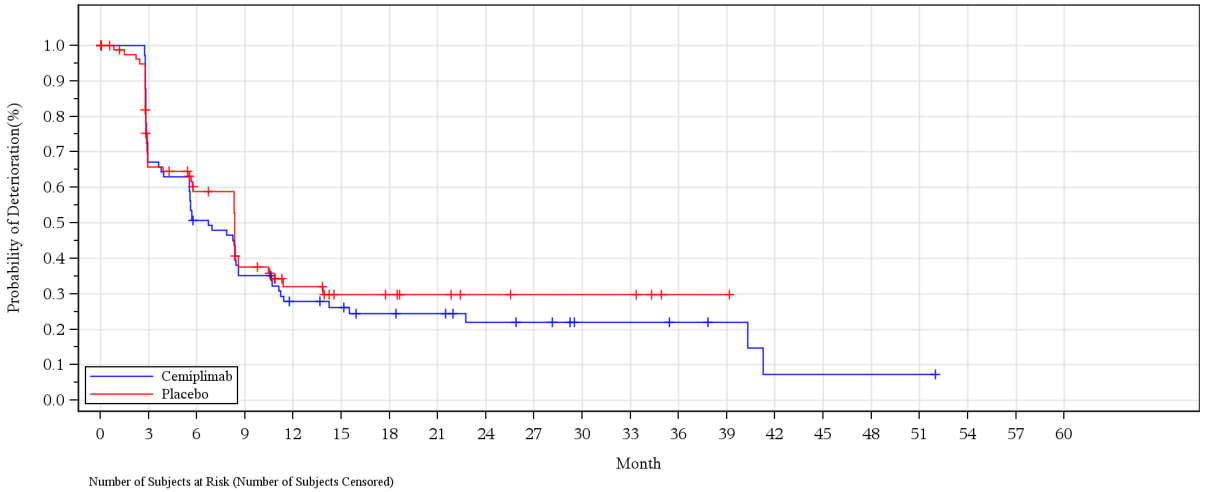
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	71 (12)	47 (17)	36 (21)	34 (22)	27 (27)	21 (32)	19 (32)	14 (36)	11 (37)	7 (40)	5 (42)	3 (43)	3 (43)	2 (44)	2 (44)	1 (45)	1 (45)	1 (45)	1 (45)	0 (46)
Placebo	117 (0)	68 (16)	45 (27)	33 (32)	20 (38)	17 (40)	13 (44)	13 (44)	11 (46)	10 (46)	9 (47)	8 (48)	6 (49)	6 (49)	2 (53)	2 (53)	2 (53)	2 (53)	0 (55)	0 (55)	0 (55)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.7 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Fatigue Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



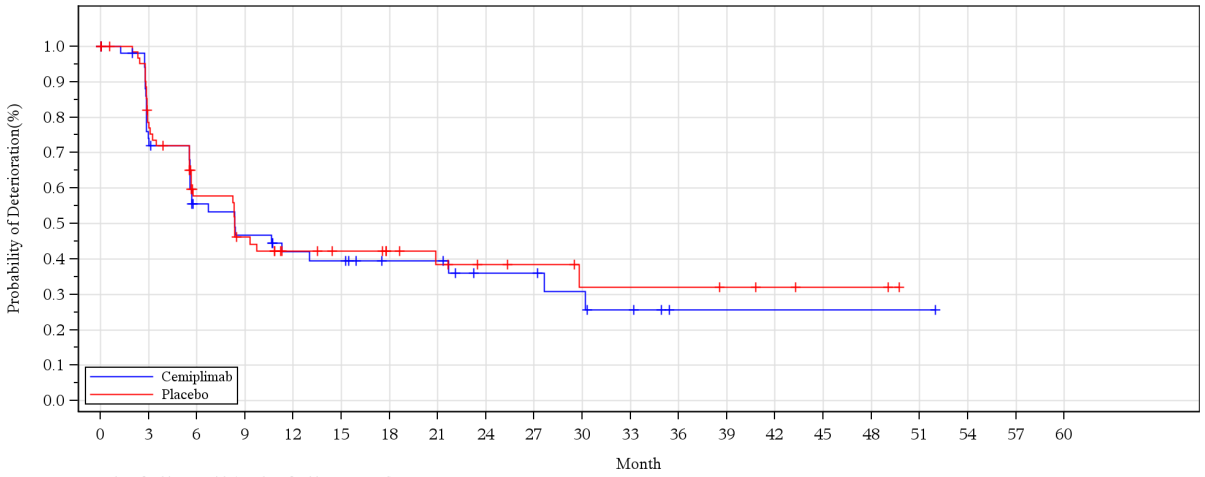
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	49 (11)	36 (12)	25 (12)	18 (14)	16 (15)	13 (17)	12 (18)	9 (20)	8 (21)	5 (24)	5 (24)	4 (25)	3 (26)	1 (26)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)
Placebo	89 (0)	49 (14)	40 (18)	24 (20)	15 (26)	10 (30)	9 (31)	7 (33)	5 (35)	4 (36)	4 (36)	4 (36)	1 (39)	1 (39)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)	0 (40)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



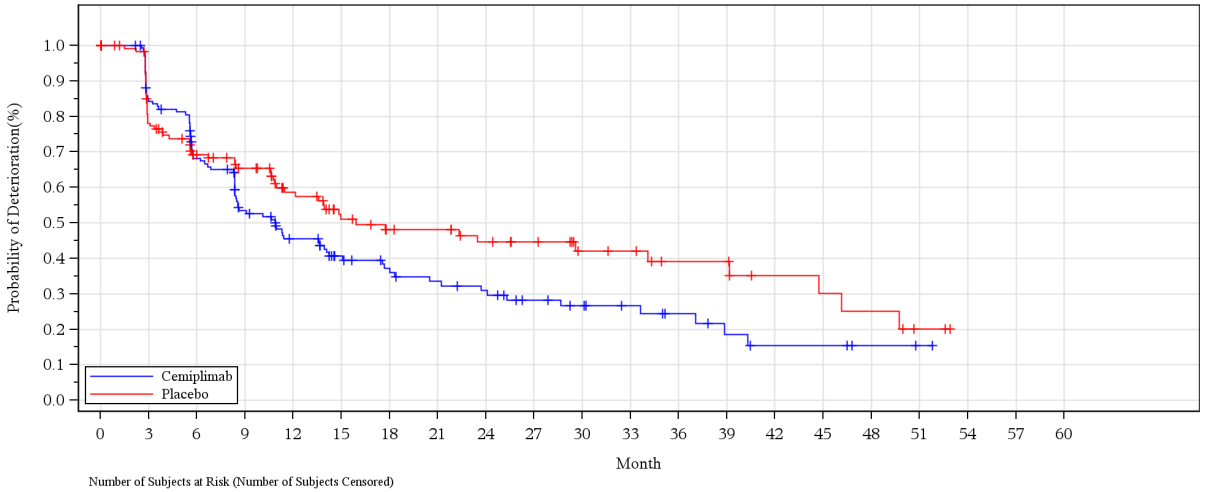
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	37 (6)	25 (9)	21 (9)	17 (11)	16 (11)	12 (15)	12 (15)	8 (18)	8 (18)	6 (19)	4 (20)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	0 (24)	0 (24)	0 (24)
Placebo	65 (0)	47 (5)	30 (10)	23 (11)	17 (15)	15 (17)	12 (20)	10 (21)	8 (23)	7 (24)	5 (25)	5 (25)	5 (25)	4 (26)	3 (27)	2 (28)	2 (28)	0 (30)	0 (30)	0 (30)	0 (30)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



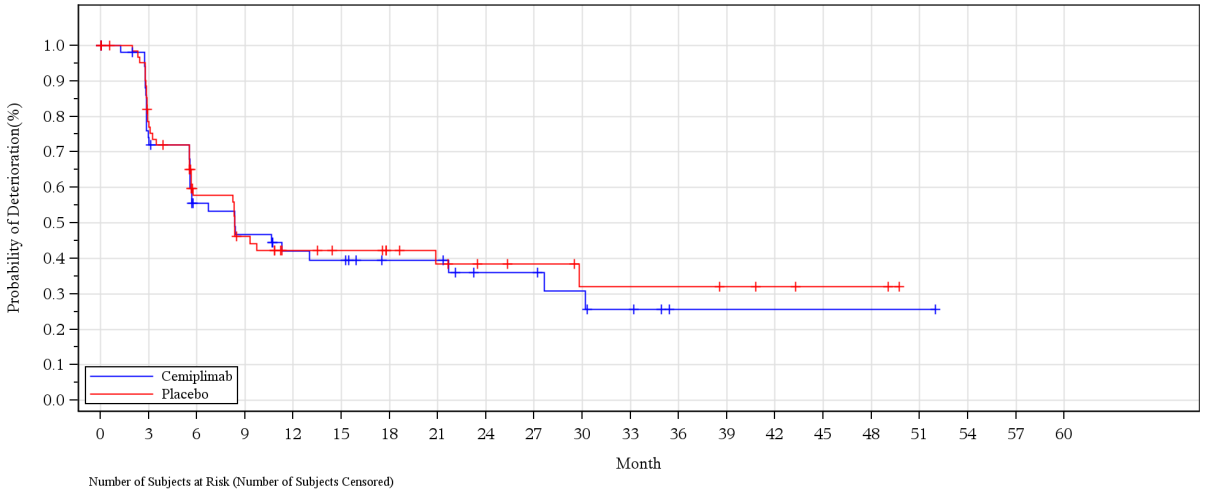
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	112 (20)	87 (24)	63 (30)	49 (35)	37 (42)	31 (45)	27 (46)	24 (47)	18 (51)	15 (53)	12 (56)	9 (58)	6 (59)	4 (60)	4 (60)	2 (62)	1 (63)	0 (64)	0 (64)	0 (64)
Placebo	141 (0)	92 (23)	73 (32)	64 (37)	49 (46)	37 (52)	31 (56)	30 (57)	25 (60)	22 (63)	16 (68)	15 (69)	11 (72)	11 (72)	7 (75)	6 (75)	5 (75)	2 (77)	0 (79)	0 (79)	0 (79)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



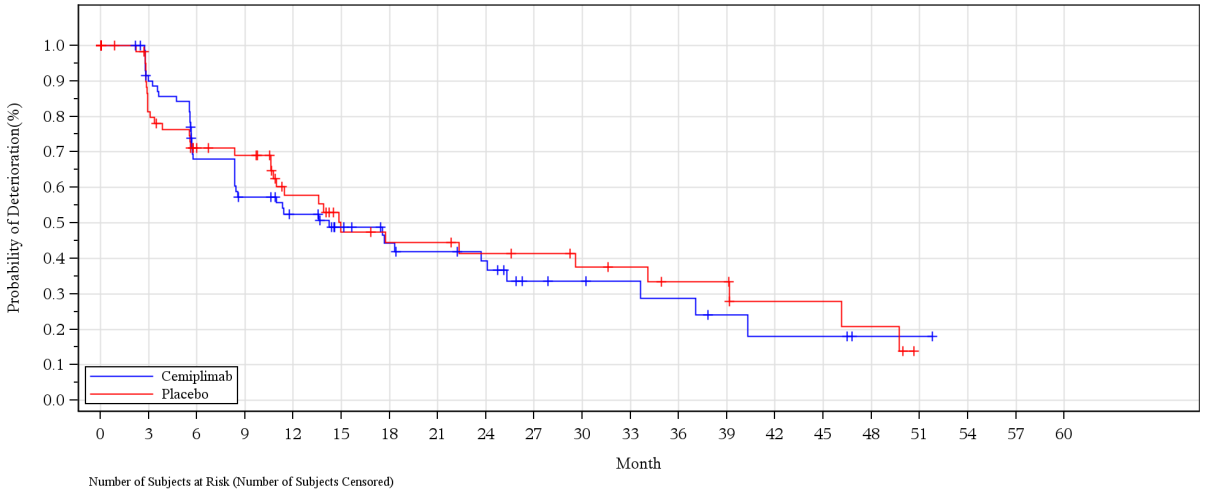
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	37 (6)	25 (9)	21 (9)	17 (11)	16 (11)	12 (15)	12 (15)	8 (18)	8 (18)	6 (19)	4 (20)	1 (23)	1 (23)	1 (23)	1 (23)	1 (23)	0 (24)	0 (24)	0 (24)
Placebo	65 (0)	47 (5)	30 (10)	23 (11)	17 (15)	15 (17)	12 (20)	10 (21)	8 (23)	7 (24)	5 (25)	5 (25)	5 (25)	4 (26)	3 (27)	2 (28)	2 (28)	0 (30)	0 (30)	0 (30)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	62 (11)	45 (13)	37 (14)	31 (17)	24 (22)	19 (25)	17 (26)	15 (27)	9 (31)	8 (32)	7 (33)	6 (33)	4 (34)	3 (34)	3 (34)	1 (36)	1 (36)	0 (37)	0 (37)	0 (37)
Placebo	69 (0)	48 (10)	37 (15)	35 (16)	24 (22)	17 (25)	15 (26)	15 (26)	13 (27)	12 (28)	10 (29)	9 (30)	7 (31)	7 (31)	4 (33)	4 (33)	3 (33)	0 (35)	0 (35)	0 (35)	0 (35)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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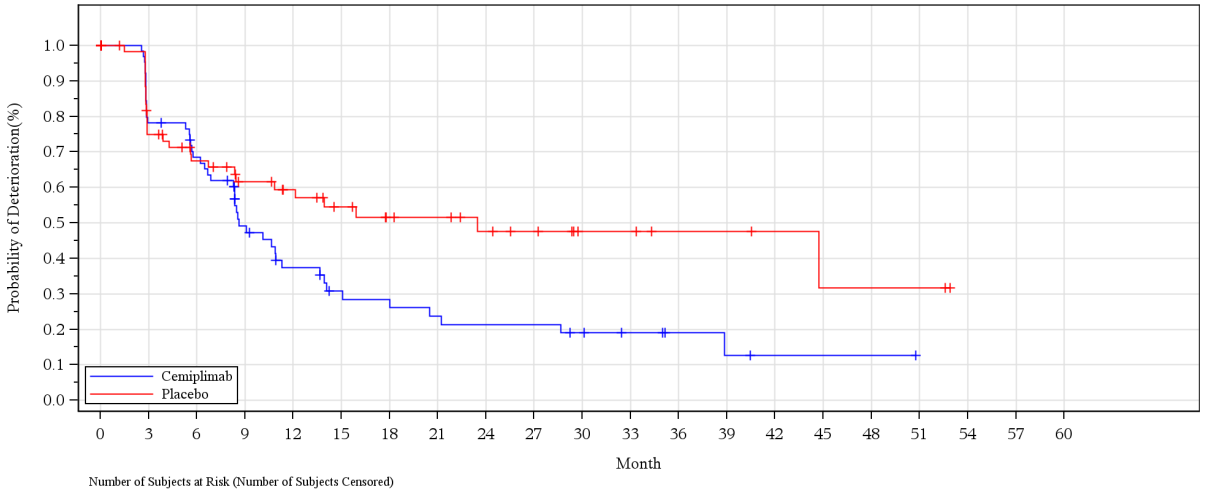
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	50 (9)	42 (11)	26 (16)	18 (18)	13 (20)	12 (20)	10 (20)	9 (20)	9 (20)	7 (21)	5 (23)	3 (25)	2 (25)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	72 (0)	44 (13)	36 (17)	29 (21)	25 (24)	20 (27)	16 (30)	15 (31)	12 (33)	10 (35)	6 (39)	6 (39)	4 (41)	4 (41)	3 (42)	2 (42)	2 (42)	2 (42)	0 (44)	0 (44)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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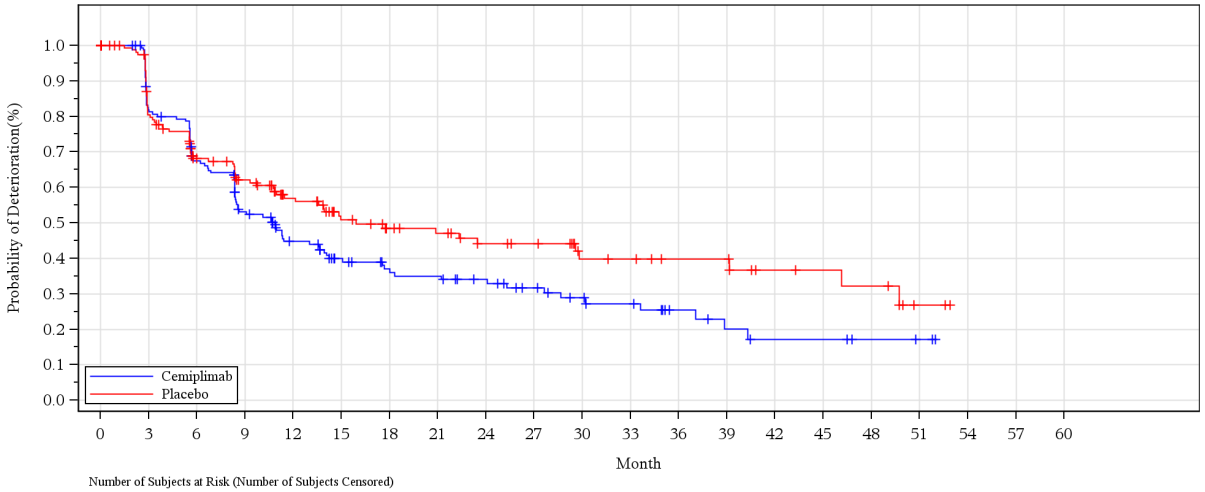
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	126 (20)	101 (23)	75 (28)	57 (35)	44 (42)	37 (46)	35 (46)	30 (50)	24 (54)	19 (57)	16 (59)	10 (64)	7 (65)	5 (66)	5 (66)	3 (68)	2 (69)	0 (71)	0 (71)	0 (71)
Placebo	174 (0)	122 (22)	92 (34)	79 (39)	60 (52)	46 (60)	37 (67)	34 (69)	28 (73)	26 (75)	18 (81)	17 (82)	14 (85)	14 (85)	9 (89)	8 (90)	7 (90)	2 (94)	0 (96)	0 (96)	0 (96)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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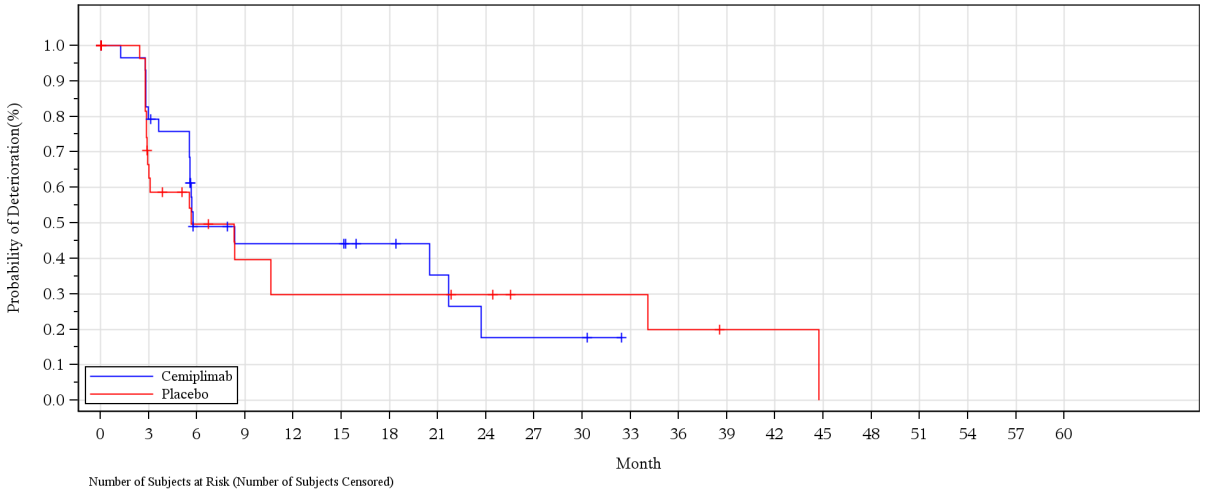
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Gender group: Female



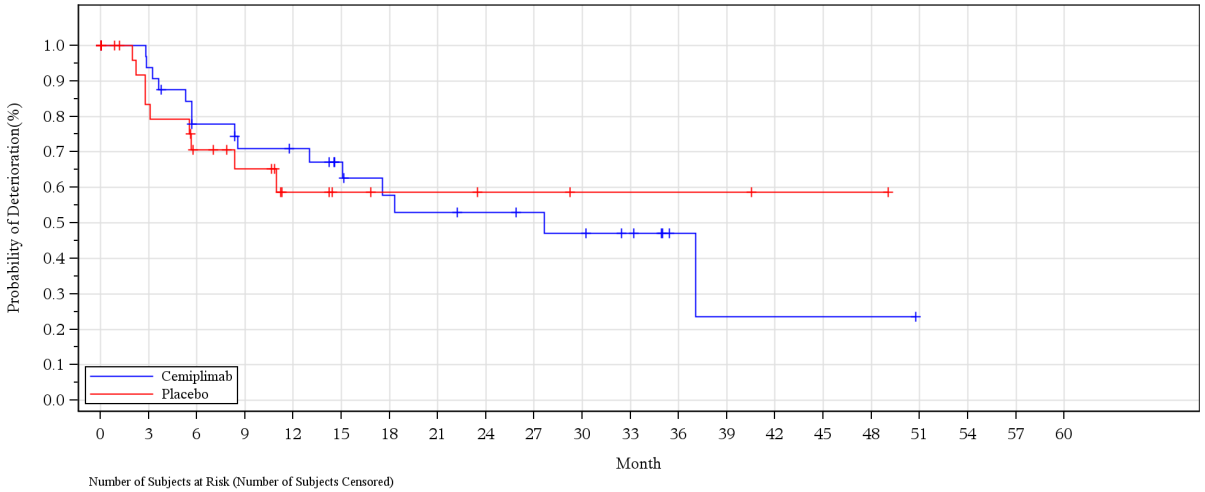
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	23 (6)	11 (10)	9 (11)	9 (11)	9 (11)	6 (14)	4 (15)	2 (15)	2 (15)	2 (15)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)	0 (17)
Placebo	32 (0)	17 (6)	11 (8)	8 (9)	6 (9)	6 (9)	6 (9)	6 (9)	5 (10)	3 (12)	3 (12)	3 (12)	2 (12)	1 (13)	1 (13)	0 (13)	0 (13)	0 (13)	0 (13)	0 (13)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (5)	23 (7)	20 (8)	19 (9)	15 (12)	12 (13)	11 (13)	10 (14)	9 (15)	8 (15)	6 (17)	2 (21)	1 (21)	1 (21)	1 (21)	1 (21)	0 (22)	0 (22)	0 (22)	0 (22)
Placebo	31 (0)	20 (7)	15 (9)	12 (11)	7 (15)	5 (17)	4 (18)	4 (18)	3 (19)	3 (19)	2 (20)	2 (20)	2 (20)	2 (20)	1 (21)	1 (21)	1 (21)	0 (22)	0 (22)	0 (22)	0 (22)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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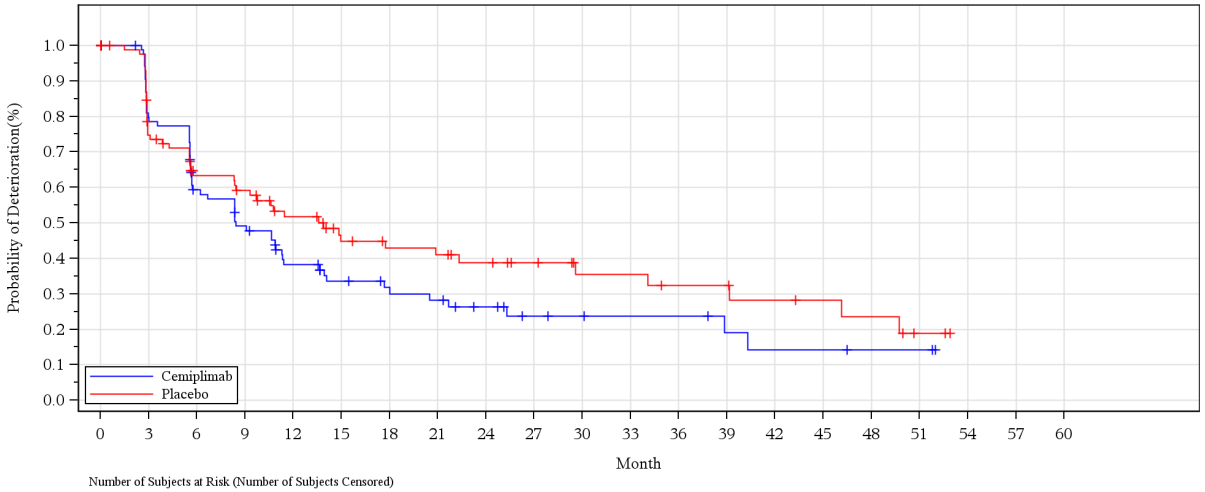
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



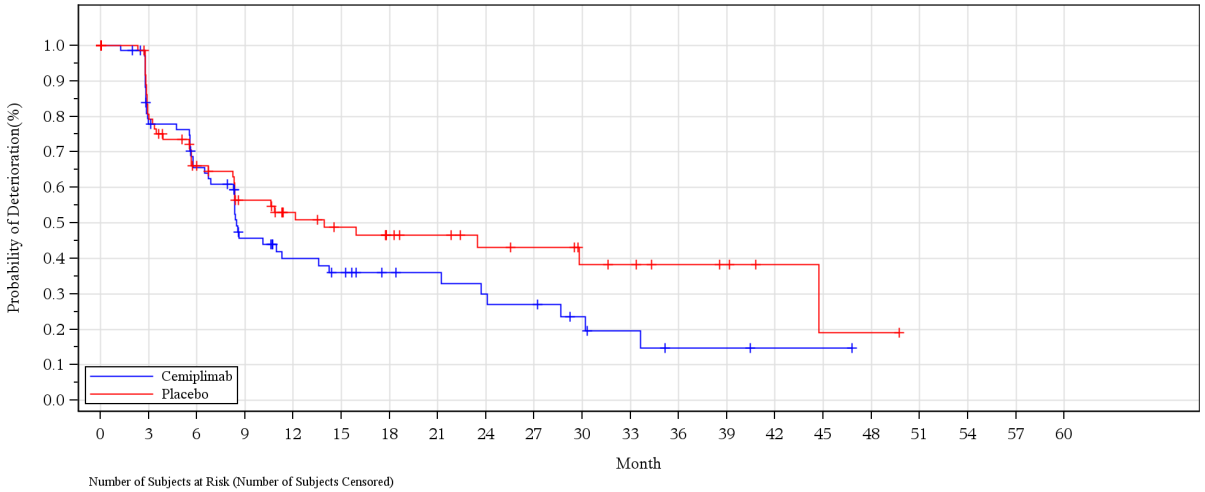
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	67 (6)	47 (9)	38 (10)	27 (13)	21 (16)	18 (18)	16 (18)	12 (21)	8 (24)	7 (25)	6 (26)	6 (26)	4 (27)	3 (27)	3 (27)	2 (28)	2 (28)	0 (30)	0 (30)	0 (30)
Placebo	90 (0)	61 (8)	46 (14)	42 (15)	33 (19)	25 (23)	22 (25)	21 (25)	18 (27)	15 (30)	11 (33)	11 (33)	9 (34)	9 (34)	7 (35)	6 (36)	5 (36)	2 (38)	0 (40)	0 (40)	0 (40)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



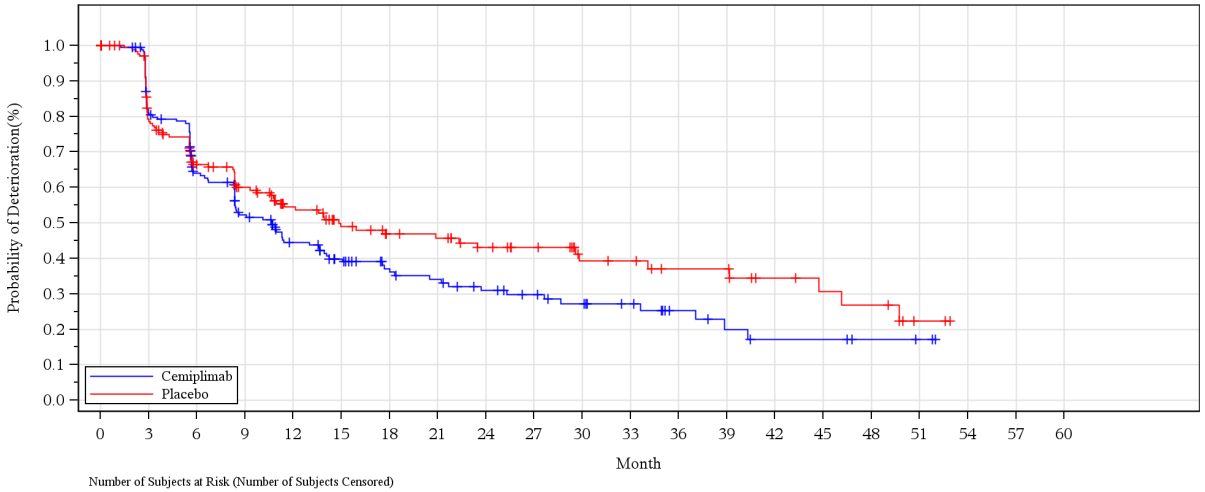
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	52 (15)	42 (17)	26 (21)	20 (24)	17 (25)	13 (29)	12 (30)	10 (30)	9 (30)	6 (32)	4 (33)	2 (34)	2 (34)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)	0 (36)
Placebo	85 (0)	58 (13)	42 (19)	33 (22)	26 (27)	22 (29)	17 (33)	15 (35)	12 (37)	11 (38)	8 (40)	7 (41)	5 (43)	4 (44)	2 (46)	1 (46)	1 (46)	0 (47)	0 (47)	0 (47)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	136 (21)	101 (28)	78 (33)	60 (40)	48 (46)	38 (53)	34 (54)	28 (57)	24 (60)	20 (62)	16 (66)	10 (71)	7 (72)	5 (73)	5 (73)	3 (75)	2 (76)	0 (78)	0 (78)	0 (78)
Placebo	189 (0)	128 (27)	96 (39)	81 (45)	62 (57)	49 (64)	41 (70)	39 (71)	32 (76)	28 (80)	20 (86)	19 (87)	15 (90)	15 (90)	10 (94)	8 (95)	7 (95)	2 (99)	0 (101)	0 (101)	0 (101)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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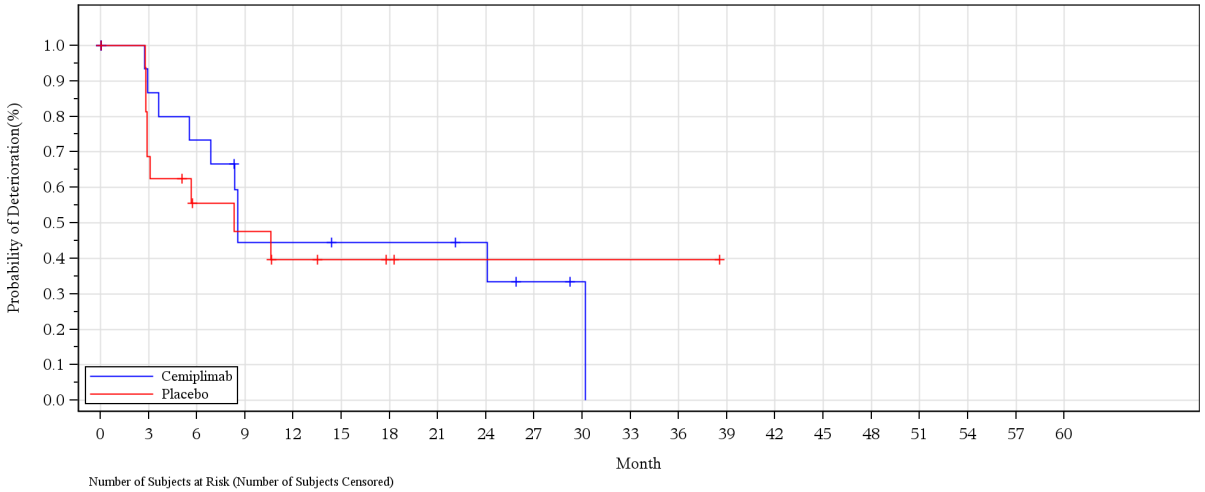
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	13 (5)	11 (5)	6 (6)	6 (6)	5 (7)	5 (7)	5 (7)	4 (8)	2 (9)	1 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)
Placebo	17 (0)	11 (1)	7 (3)	6 (3)	4 (4)	3 (5)	2 (6)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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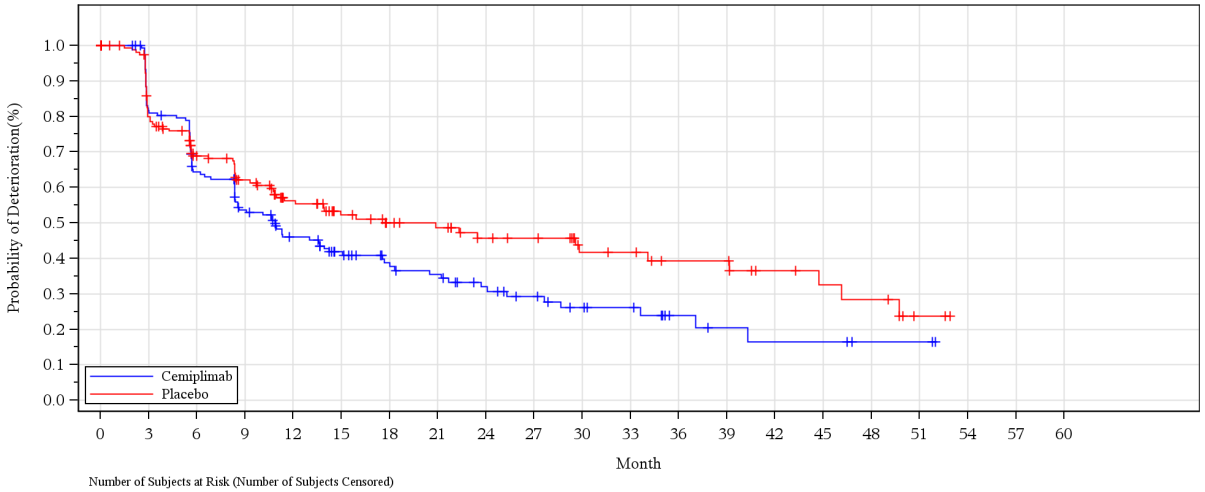
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	120 (19)	92 (22)	73 (26)	57 (32)	45 (39)	36 (45)	32 (46)	25 (50)	20 (53)	15 (56)	13 (58)	7 (63)	5 (64)	4 (64)	4 (64)	2 (66)	2 (66)	0 (68)	0 (68)	0 (68)
Placebo	177 (0)	122 (24)	93 (37)	79 (42)	60 (54)	48 (62)	40 (68)	37 (70)	30 (75)	28 (77)	20 (83)	19 (84)	15 (87)	15 (87)	10 (91)	8 (92)	7 (92)	2 (96)	0 (98)	0 (98)	0 (98)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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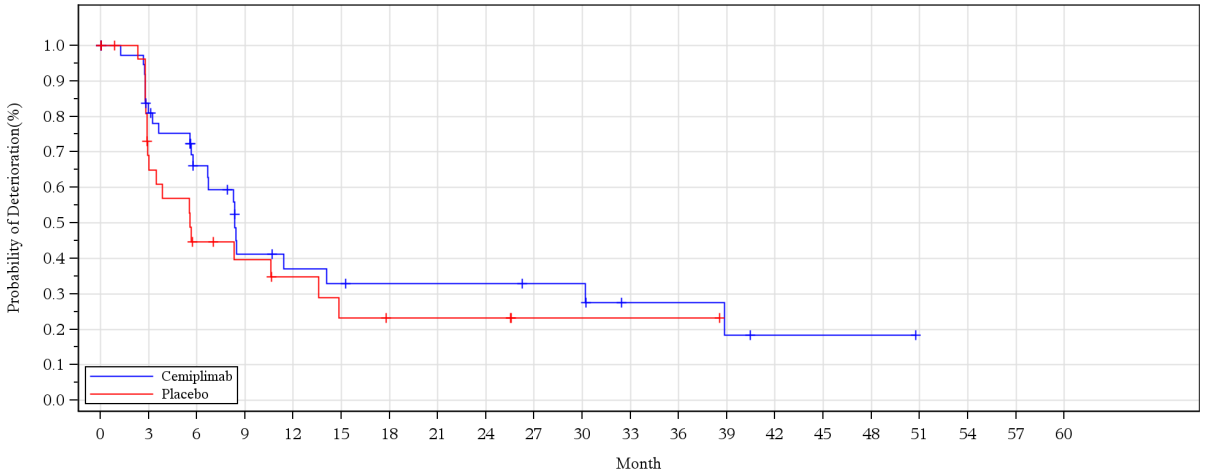
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



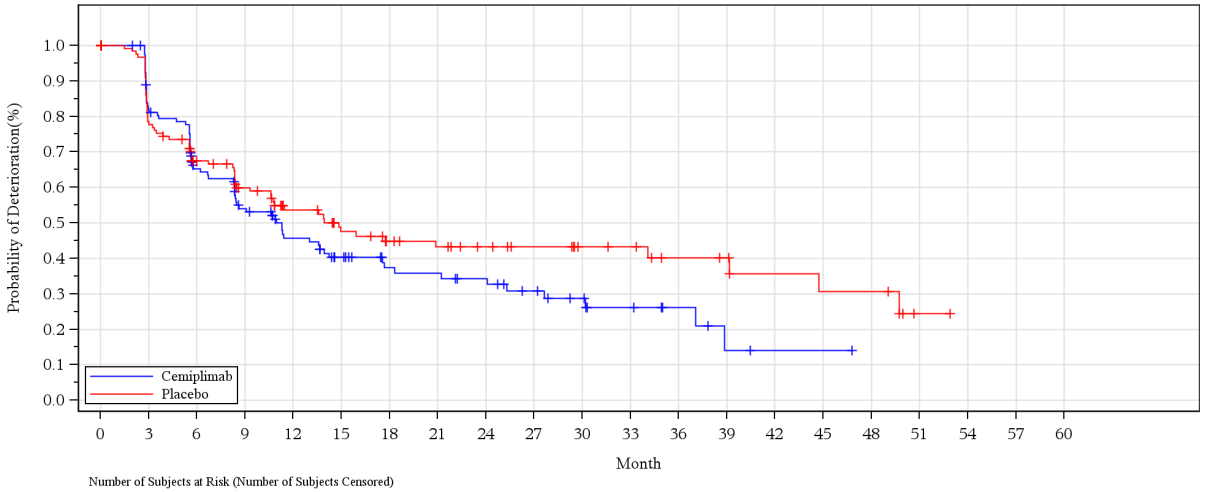
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (7)	20 (11)	11 (13)	9 (14)	8 (14)	7 (15)	7 (15)	7 (15)	6 (16)	6 (16)	3 (18)	3 (18)	2 (18)	1 (19)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	29 (0)	17 (4)	10 (5)	8 (6)	6 (7)	4 (7)	3 (8)	3 (8)	3 (8)	1 (10)	1 (10)	1 (10)	1 (10)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)	0 (11)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



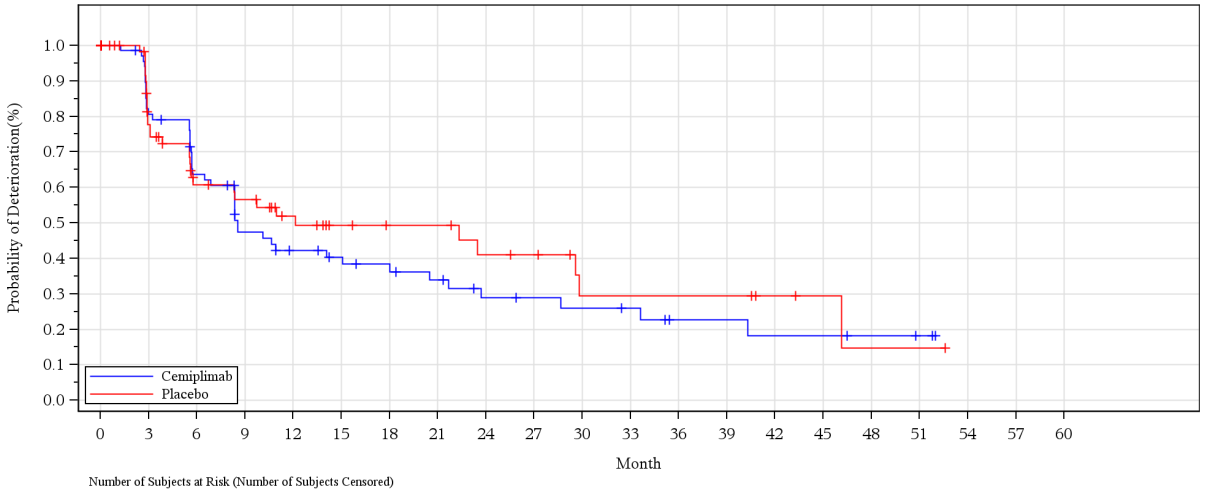
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	95 (17)	71 (22)	56 (25)	43 (30)	33 (35)	25 (41)	24 (41)	21 (43)	16 (46)	12 (49)	8 (52)	5 (55)	2 (56)	1 (57)	1 (57)	0 (58)	0 (58)	0 (58)	0 (58)	0 (58)
Placebo	131 (0)	95 (10)	73 (19)	60 (24)	46 (32)	37 (36)	30 (41)	27 (43)	23 (47)	20 (50)	16 (54)	15 (55)	11 (58)	10 (59)	7 (61)	6 (61)	6 (61)	1 (65)	0 (66)	0 (66)	0 (66)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



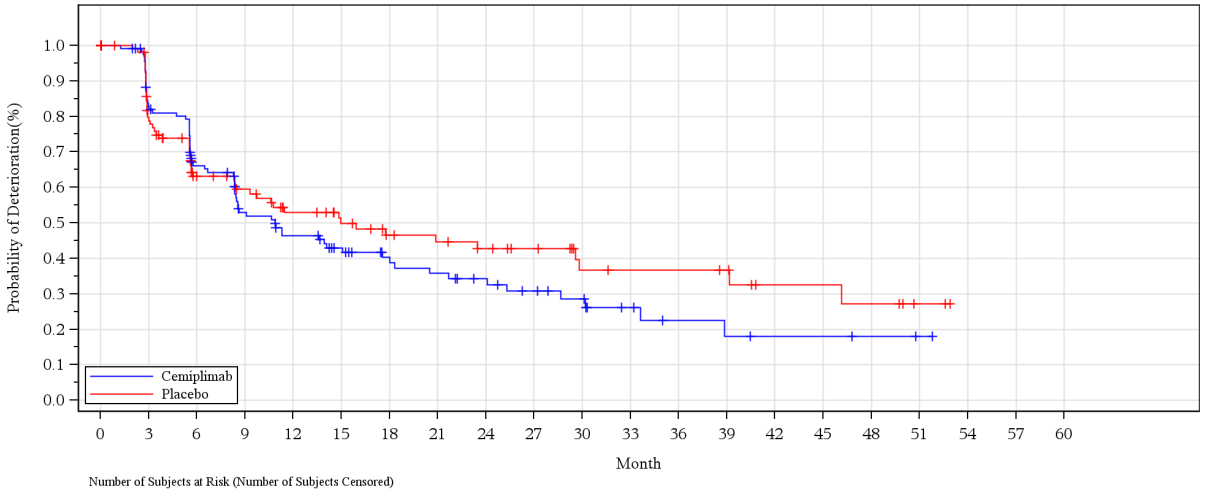
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	54 (9)	41 (11)	28 (14)	23 (16)	20 (18)	18 (19)	15 (20)	11 (22)	10 (23)	9 (23)	8 (24)	5 (26)	5 (26)	4 (26)	4 (26)	3 (27)	2 (28)	0 (30)	0 (30)	0 (30)
Placebo	75 (0)	44 (18)	30 (23)	27 (24)	20 (29)	15 (33)	13 (35)	13 (35)	10 (36)	9 (37)	5 (39)	5 (39)	5 (39)	5 (39)	3 (41)	2 (42)	1 (42)	1 (42)	0 (43)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	91 (15)	68 (20)	50 (25)	42 (27)	34 (32)	27 (37)	24 (37)	20 (40)	16 (42)	13 (44)	8 (48)	5 (50)	4 (50)	3 (51)	3 (51)	2 (52)	1 (53)	0 (54)	0 (54)	0 (54)
Placebo	117 (0)	81 (15)	54 (26)	48 (29)	38 (34)	32 (38)	26 (42)	24 (43)	21 (45)	18 (48)	12 (52)	11 (53)	11 (53)	10 (54)	6 (57)	6 (57)	5 (57)	2 (60)	0 (62)	0 (62)	0 (62)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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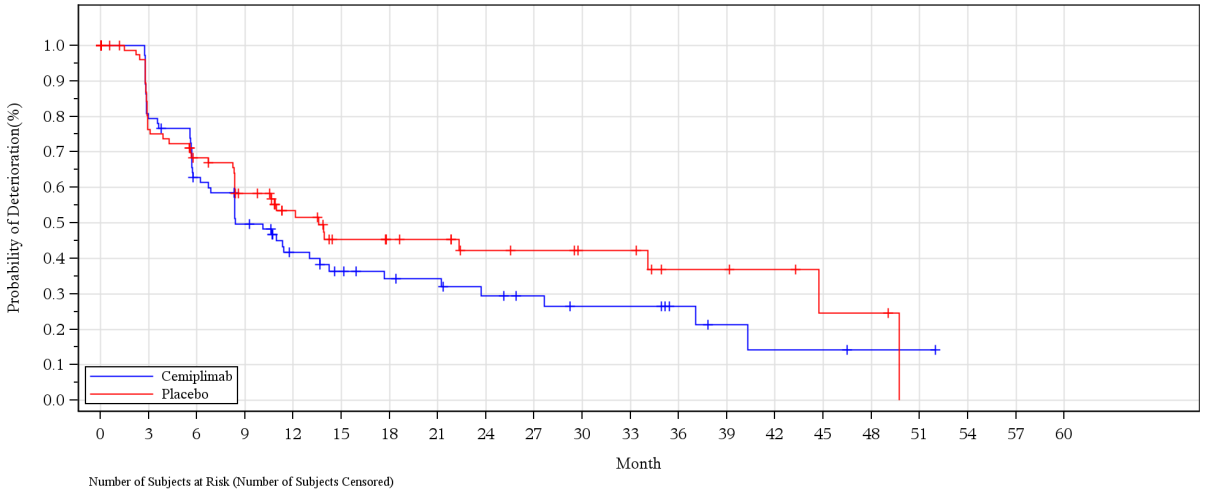
Figure 14.2.8.1.8 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Pain Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



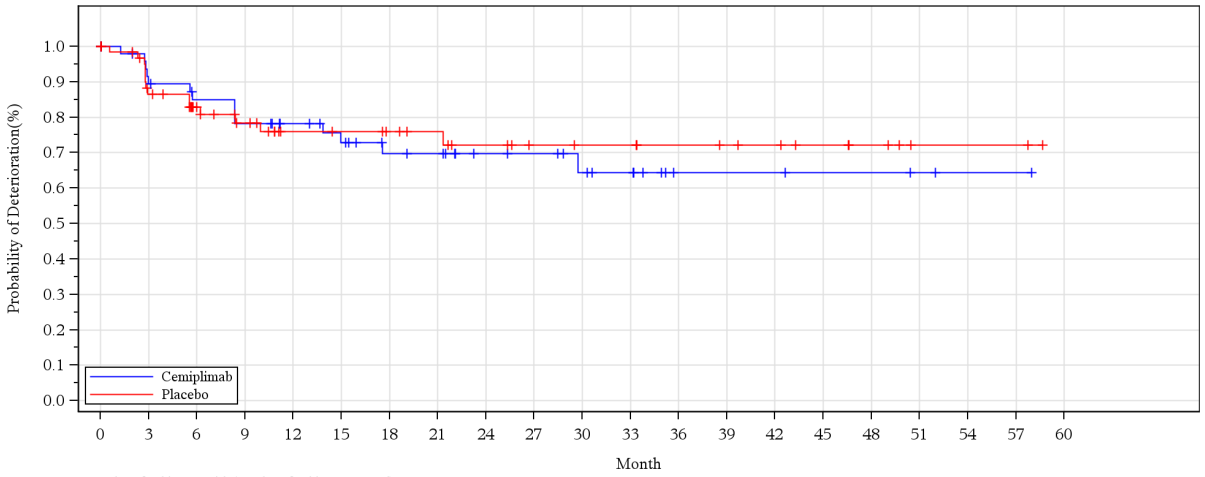
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	58 (11)	44 (13)	34 (14)	24 (19)	19 (21)	16 (23)	15 (24)	12 (25)	10 (27)	8 (28)	8 (28)	5 (31)	3 (32)	2 (32)	2 (32)	1 (33)	1 (33)	0 (34)	0 (34)	0 (34)
Placebo	89 (0)	58 (13)	49 (16)	39 (19)	28 (27)	20 (31)	17 (34)	16 (35)	12 (38)	11 (39)	9 (41)	9 (41)	5 (44)	5 (44)	4 (45)	2 (46)	2 (46)	0 (47)	0 (47)	0 (47)	0 (47)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 1: <65



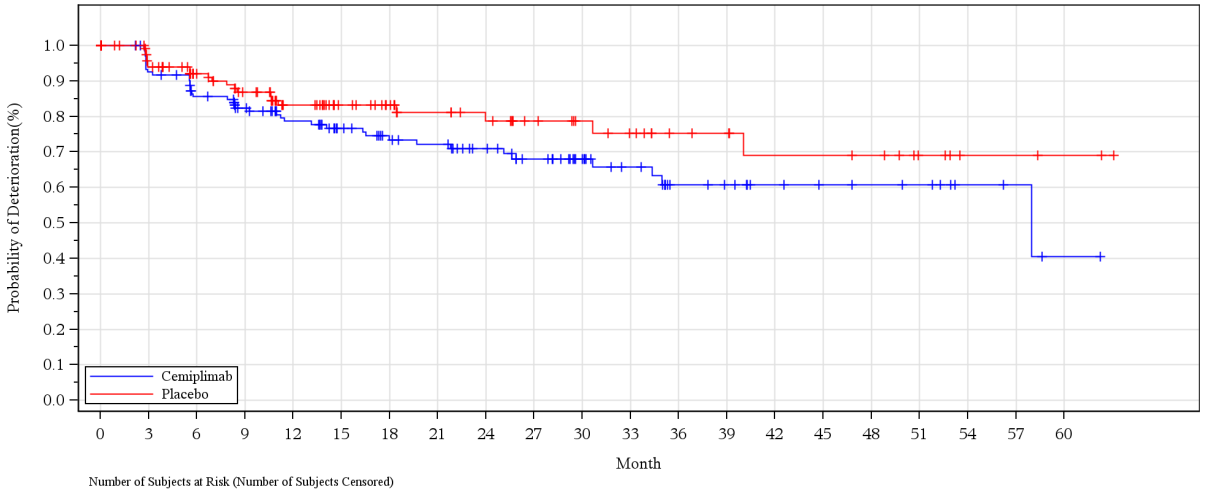
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	42 (9)	38 (11)	35 (11)	31 (15)	27 (17)	22 (21)	21 (22)	16 (27)	15 (28)	12 (30)	10 (32)	4 (38)	4 (38)	4 (38)	3 (39)	3 (39)	2 (40)	1 (41)	1 (41)	0 (42)
Placebo	65 (0)	50 (7)	40 (15)	33 (20)	25 (27)	24 (28)	22 (30)	20 (32)	17 (34)	14 (37)	13 (38)	13 (38)	11 (40)	10 (41)	9 (42)	7 (44)	5 (46)	2 (49)	2 (49)	2 (49)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 1: >=65



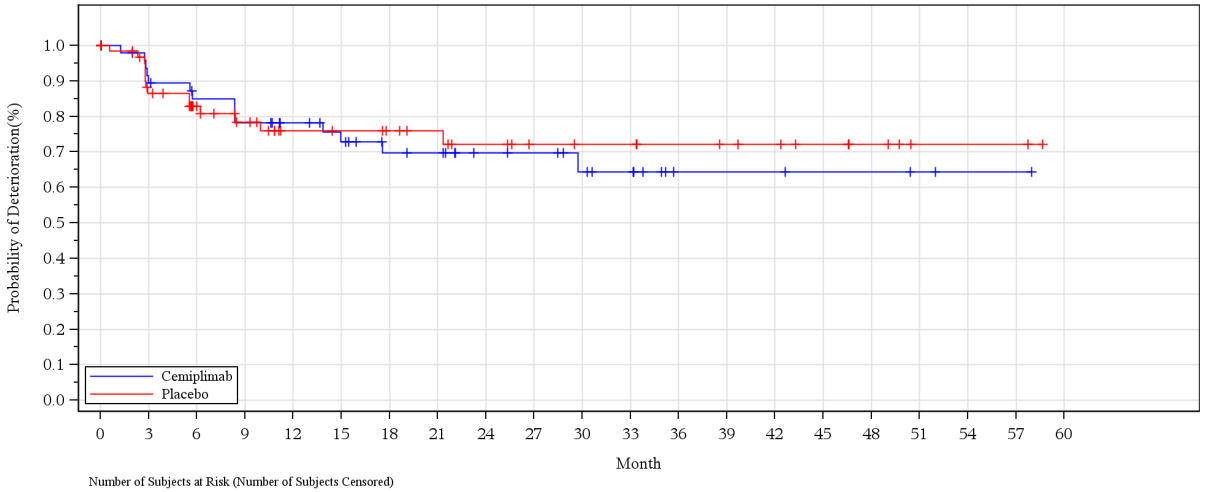
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	123 (20)	109 (25)	96 (34)	84 (42)	72 (52)	63 (58)	60 (60)	52 (67)	44 (73)	34 (83)	27 (89)	18 (96)	16 (98)	12 (102)	10 (104)	9 (105)	8 (106)	4 (110)	3 (111)	1 (112)
Placebo	141 (0)	108 (26)	90 (42)	78 (49)	62 (62)	50 (74)	43 (81)	37 (86)	33 (89)	27 (95)	23 (99)	20 (101)	15 (106)	14 (107)	11 (109)	11 (109)	10 (110)	6 (114)	3 (117)	3 (117)	2 (118)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 2: <65



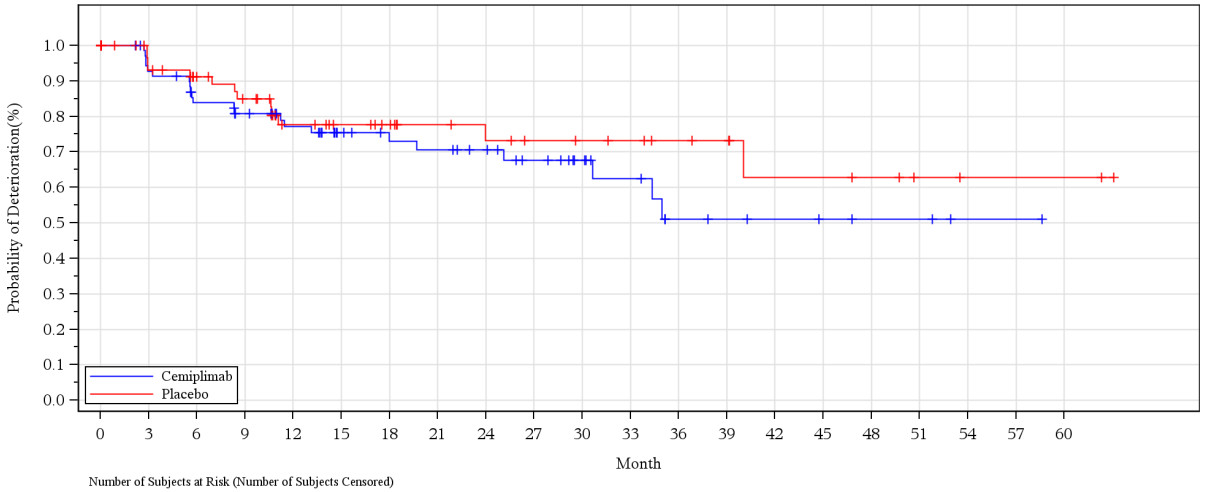
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	42 (9)	38 (11)	35 (11)	31 (15)	27 (17)	22 (21)	21 (22)	16 (27)	15 (28)	12 (30)	10 (32)	4 (38)	4 (38)	4 (38)	3 (39)	3 (39)	2 (40)	1 (41)	1 (41)	0 (42)
Placebo	65 (0)	50 (7)	40 (15)	33 (20)	25 (27)	24 (28)	22 (30)	20 (32)	17 (34)	14 (37)	13 (38)	13 (38)	11 (40)	10 (41)	9 (42)	7 (44)	5 (46)	2 (49)	2 (49)	2 (49)	0 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



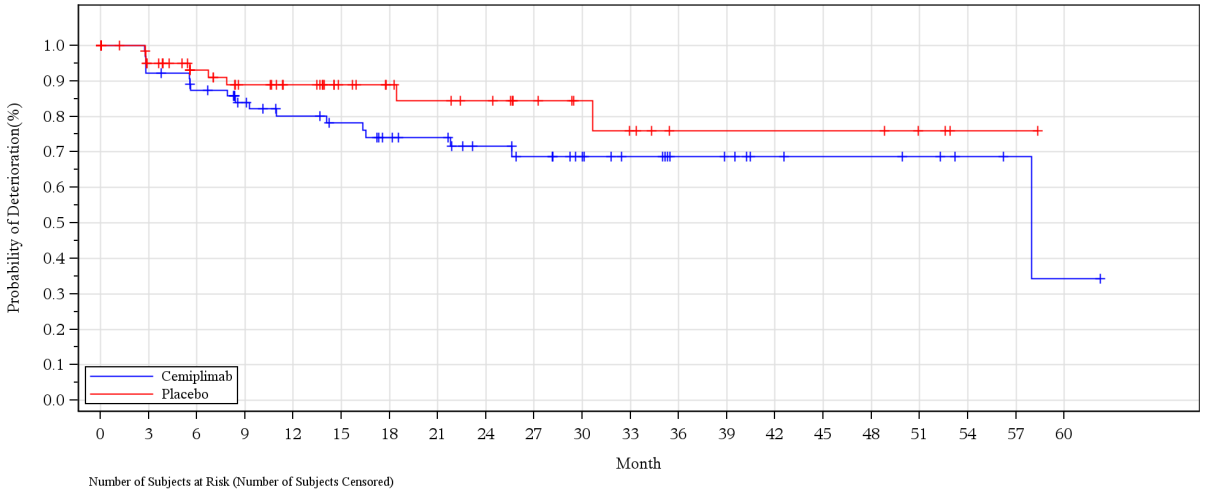
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	64 (11)	55 (14)	50 (17)	43 (22)	34 (30)	30 (33)	29 (33)	26 (36)	21 (40)	16 (45)	12 (48)	7 (51)	6 (52)	5 (53)	4 (54)	3 (55)	3 (55)	1 (57)	1 (57)	0 (58)
Placebo	69 (0)	53 (12)	45 (19)	40 (21)	29 (29)	25 (33)	22 (36)	18 (40)	16 (41)	14 (43)	13 (44)	12 (45)	10 (47)	9 (48)	6 (50)	6 (50)	5 (51)	3 (53)	2 (54)	2 (54)	2 (54)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Age group 2: >=75



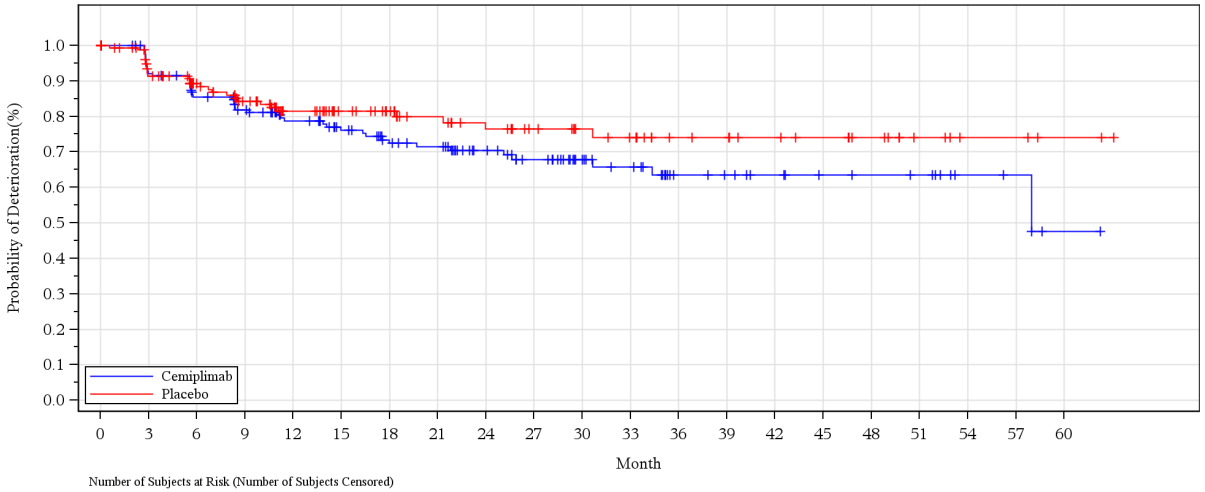
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	59 (9)	54 (11)	46 (17)	41 (20)	38 (22)	33 (25)	31 (27)	26 (31)	23 (33)	18 (38)	15 (41)	11 (45)	10 (46)	7 (49)	6 (50)	6 (50)	5 (51)	3 (53)	2 (54)	1 (54)
Placebo	72 (0)	55 (14)	45 (23)	38 (28)	33 (33)	25 (41)	21 (45)	19 (46)	17 (48)	13 (52)	10 (55)	8 (56)	5 (59)	5 (59)	5 (59)	5 (59)	5 (59)	3 (61)	1 (63)	1 (63)	0 (64)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Gender group: Male



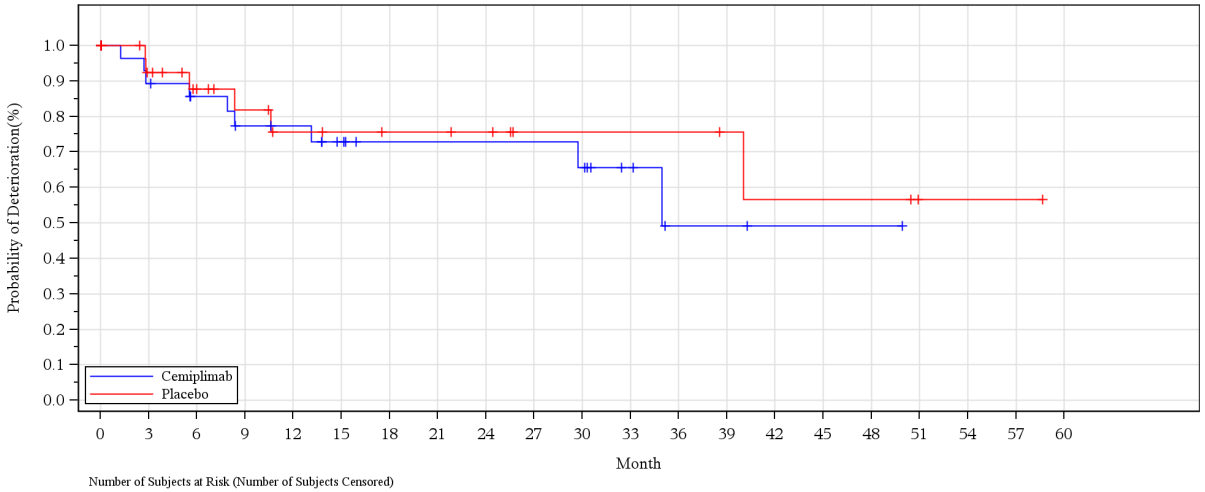
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	140 (22)	126 (26)	113 (34)	98 (45)	86 (54)	75 (61)	71 (64)	58 (76)	49 (83)	37 (95)	32 (99)	20 (110)	18 (112)	15 (115)	12 (118)	11 (119)	10 (120)	5 (125)	4 (126)	1 (128)
Placebo	174 (0)	135 (26)	112 (46)	97 (55)	76 (73)	64 (85)	56 (93)	48 (100)	42 (104)	36 (110)	31 (115)	28 (117)	21 (124)	20 (125)	17 (128)	15 (130)	12 (133)	7 (138)	4 (141)	4 (141)	2 (143)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Gender group: Female



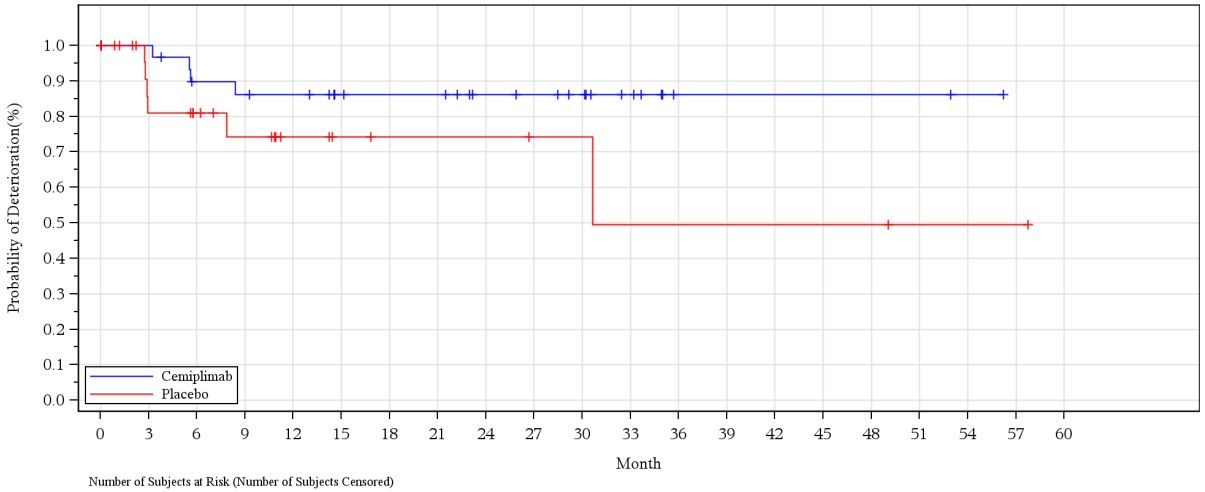
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	25 (7)	21 (10)	18 (11)	17 (12)	13 (15)	10 (18)	10 (18)	10 (18)	10 (18)	9 (18)	5 (22)	2 (24)	2 (24)	1 (25)	1 (25)	1 (25)	0 (26)	0 (26)	0 (26)	0 (26)
Placebo	32 (0)	23 (7)	18 (11)	14 (14)	11 (16)	10 (17)	9 (18)	9 (18)	8 (19)	5 (22)	5 (22)	5 (22)	5 (22)	4 (23)	3 (23)	3 (23)	3 (23)	1 (25)	1 (25)	1 (25)	0 (26)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



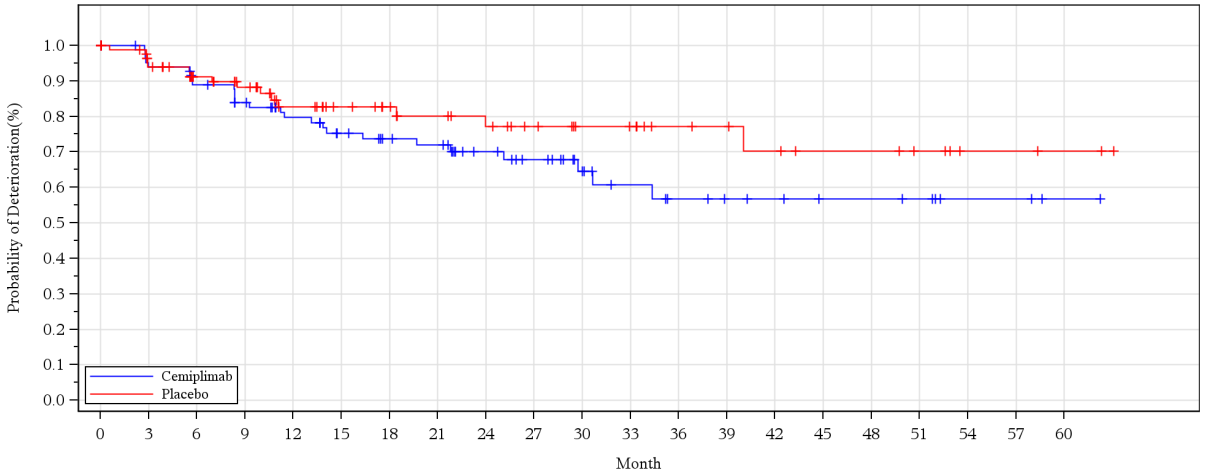
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	30 (7)	25 (9)	24 (9)	23 (10)	19 (14)	18 (15)	18 (15)	14 (19)	13 (20)	11 (22)	7 (26)	2 (31)	2 (31)	2 (31)	2 (31)	2 (31)	2 (31)	1 (32)	0 (33)	0 (33)
Placebo	31 (0)	17 (10)	14 (13)	11 (15)	7 (19)	5 (21)	4 (22)	4 (22)	4 (22)	3 (23)	3 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	77 (8)	71 (10)	64 (13)	56 (18)	48 (23)	43 (27)	41 (28)	32 (36)	27 (40)	19 (47)	15 (50)	12 (52)	10 (54)	9 (55)	7 (57)	7 (57)	6 (58)	3 (61)	3 (61)	1 (63)
Placebo	90 (0)	75 (10)	62 (21)	55 (26)	43 (35)	37 (41)	33 (45)	29 (48)	26 (50)	22 (54)	18 (58)	17 (59)	13 (63)	12 (64)	10 (65)	8 (67)	8 (67)	6 (69)	3 (72)	3 (72)	2 (73)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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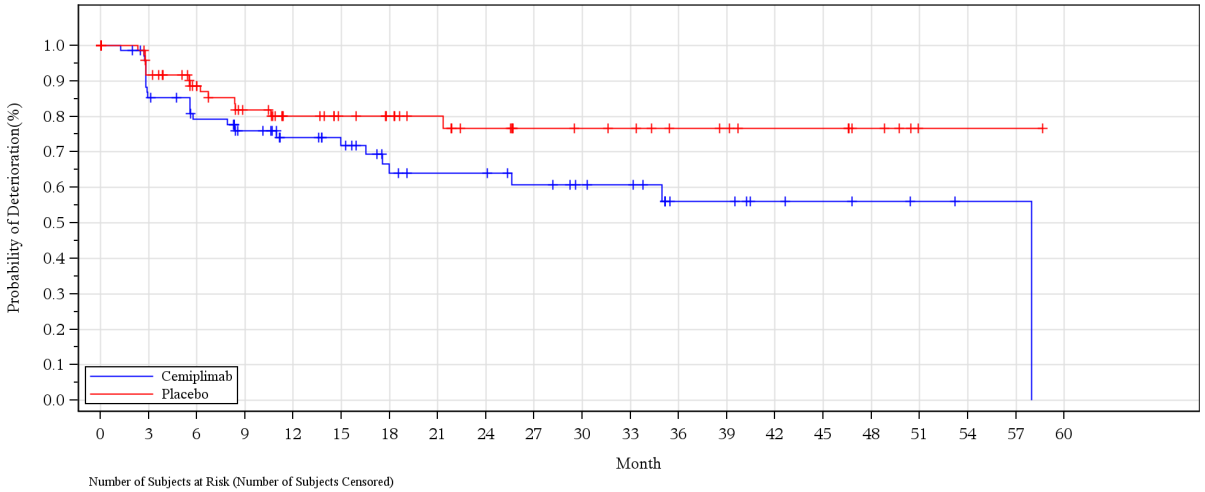
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	58 (14)	51 (17)	43 (23)	36 (29)	32 (32)	24 (37)	22 (39)	22 (39)	19 (41)	16 (44)	15 (45)	8 (51)	8 (51)	5 (54)	4 (55)	3 (56)	2 (57)	1 (58)	1 (58)	0 (58)
Placebo	85 (0)	66 (13)	54 (23)	45 (28)	37 (35)	32 (40)	28 (44)	24 (48)	20 (51)	16 (55)	15 (56)	14 (57)	11 (60)	10 (61)	8 (63)	8 (63)	5 (66)	1 (70)	1 (70)	1 (70)	0 (71)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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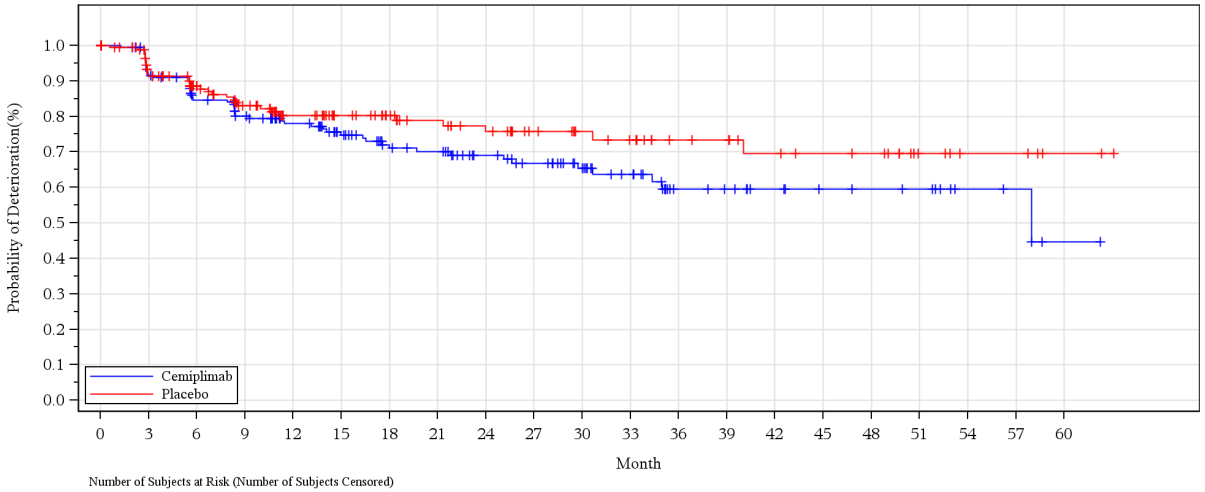
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	151 (24)	133 (31)	120 (37)	105 (49)	89 (61)	75 (71)	72 (73)	61 (83)	54 (88)	44 (97)	36 (104)	21 (117)	19 (119)	15 (123)	12 (126)	11 (127)	10 (128)	5 (133)	4 (134)	1 (136)
Placebo	189 (0)	143 (32)	118 (53)	99 (65)	78 (83)	67 (94)	59 (102)	52 (108)	46 (112)	38 (120)	33 (125)	30 (127)	23 (134)	22 (135)	18 (138)	16 (140)	15 (141)	8 (148)	5 (151)	5 (151)	2 (154)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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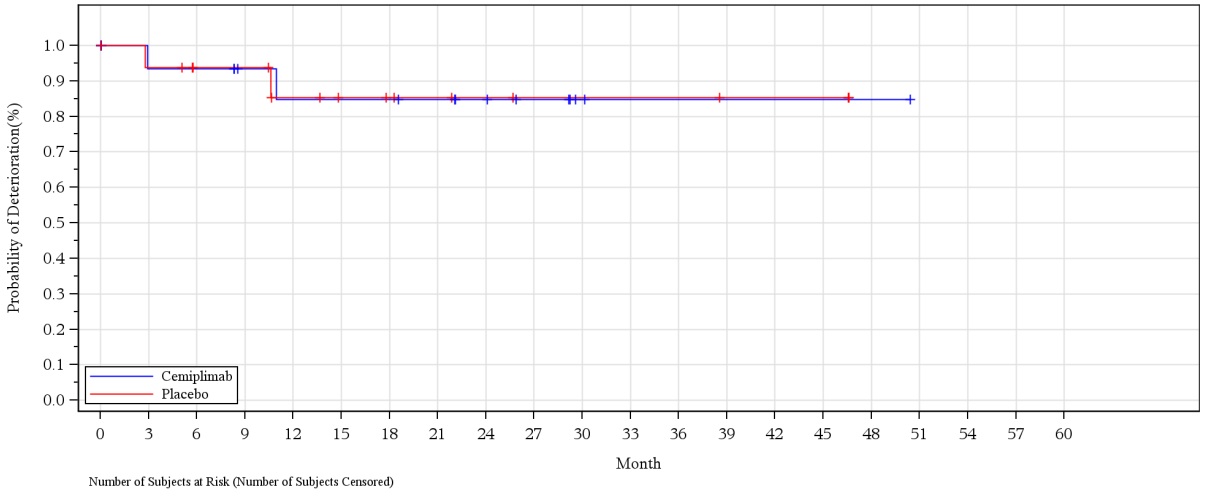
Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Race: Non-white



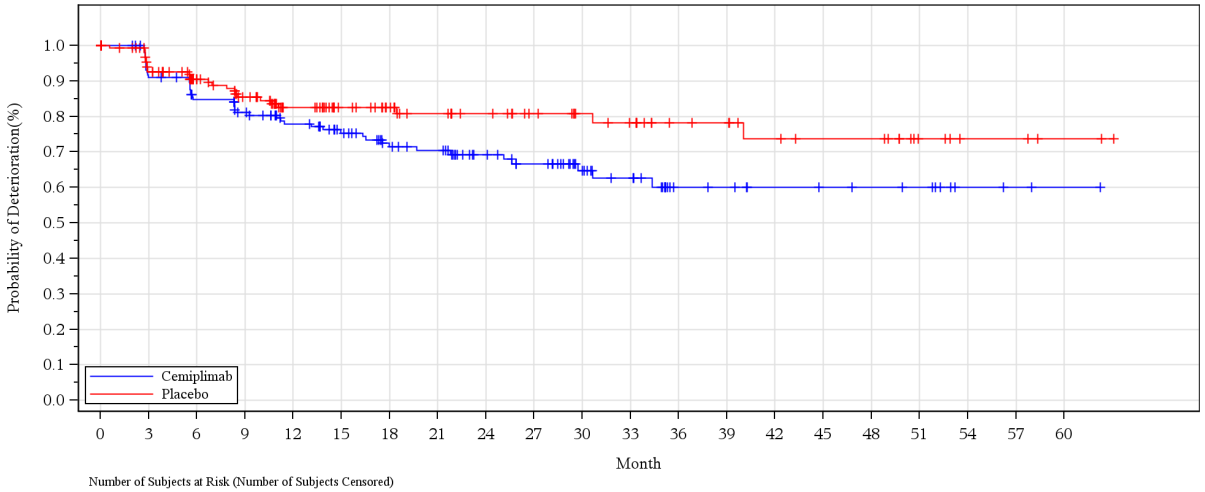
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	14 (5)	14 (5)	11 (8)	10 (8)	10 (8)	10 (8)	9 (9)	7 (11)	5 (13)	2 (16)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)	0 (18)	0 (18)	0 (18)
Placebo	17 (0)	15 (1)	12 (4)	12 (4)	9 (6)	7 (8)	6 (9)	5 (10)	4 (11)	3 (12)	3 (12)	3 (12)	3 (12)	2 (13)	2 (13)	2 (13)	0 (15)	0 (15)	0 (15)	0 (15)	0 (15)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



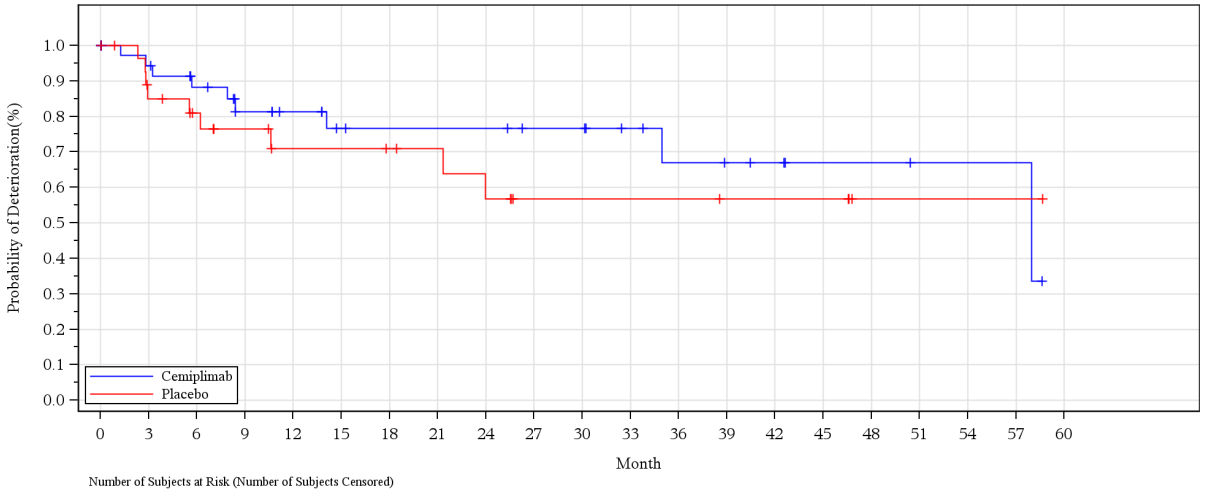
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	132 (21)	119 (25)	109 (30)	96 (39)	84 (48)	71 (57)	67 (60)	54 (72)	47 (77)	34 (89)	28 (94)	15 (106)	14 (107)	11 (110)	10 (111)	9 (112)	8 (113)	3 (118)	2 (119)	1 (120)
Placebo	177 (0)	136 (30)	112 (51)	96 (61)	75 (79)	62 (92)	54 (100)	47 (106)	42 (111)	36 (117)	31 (122)	28 (124)	21 (131)	20 (132)	16 (135)	14 (137)	14 (137)	7 (144)	4 (147)	4 (147)	2 (149)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



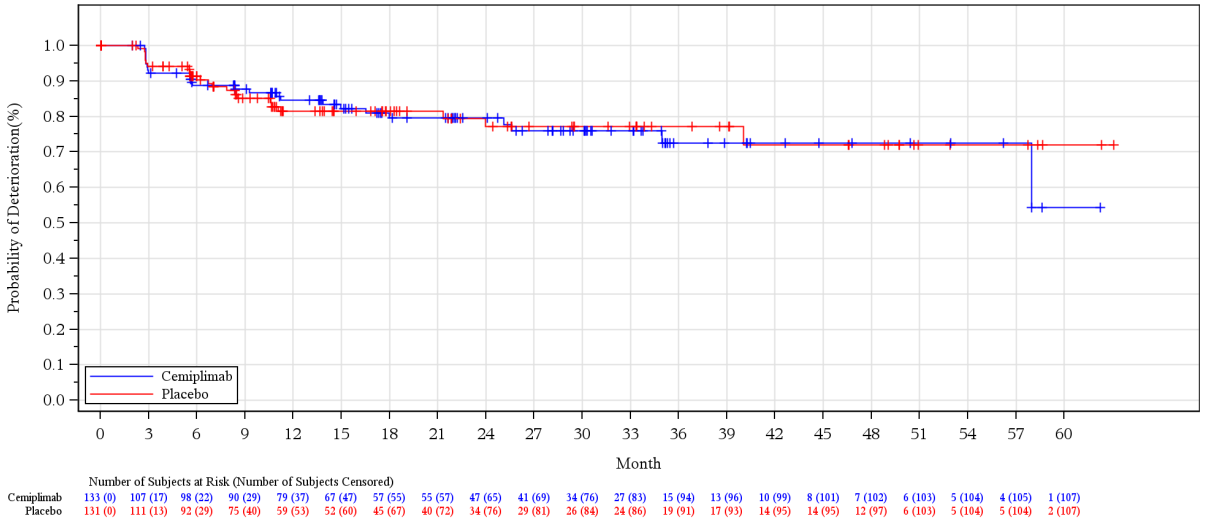
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	33 (8)	28 (11)	22 (15)	19 (18)	15 (21)	14 (22)	14 (22)	14 (22)	12 (24)	12 (24)	9 (27)	7 (28)	6 (29)	5 (30)	3 (32)	3 (32)	2 (33)	2 (33)	2 (33)	0 (34)
Placebo	29 (0)	22 (3)	18 (6)	15 (8)	12 (10)	12 (10)	11 (11)	10 (12)	8 (12)	5 (15)	5 (15)	5 (15)	5 (15)	4 (16)	4 (16)	4 (16)	1 (19)	1 (19)	1 (19)	1 (19)	0 (20)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

ECOG status: 0



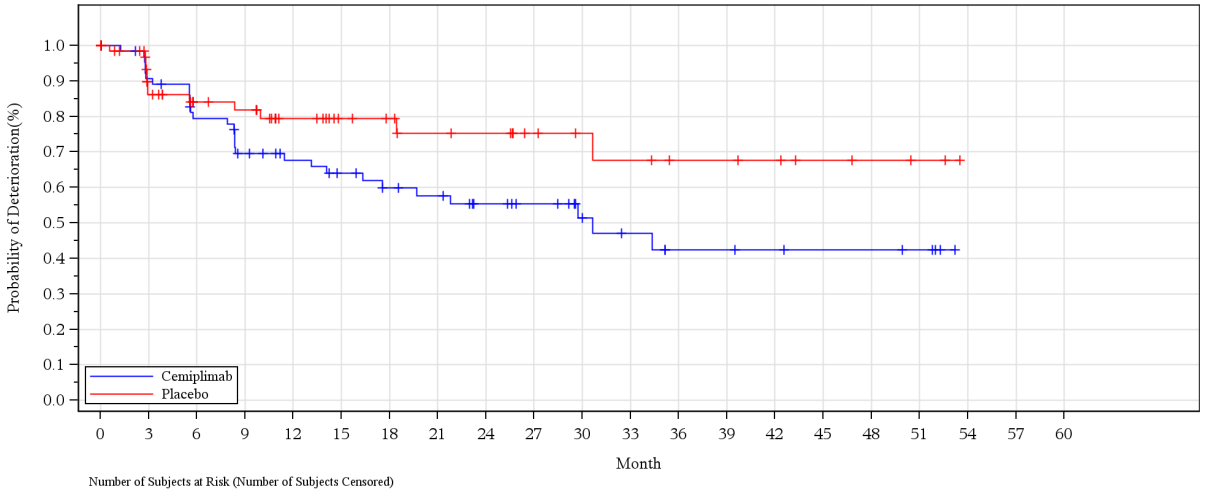
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	107 (17)	98 (22)	90 (29)	79 (37)	67 (47)	57 (55)	55 (57)	47 (65)	41 (69)	34 (76)	27 (83)	15 (94)	13 (96)	10 (99)	8 (101)	7 (102)	6 (103)	5 (104)	4 (105)	1 (107)
Placebo	131 (0)	111 (13)	92 (29)	75 (40)	59 (53)	52 (60)	45 (67)	40 (72)	34 (76)	29 (81)	26 (84)	24 (86)	19 (91)	17 (93)	14 (95)	14 (95)	12 (97)	6 (103)	5 (104)	5 (104)	2 (107)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

ECOG status: 1



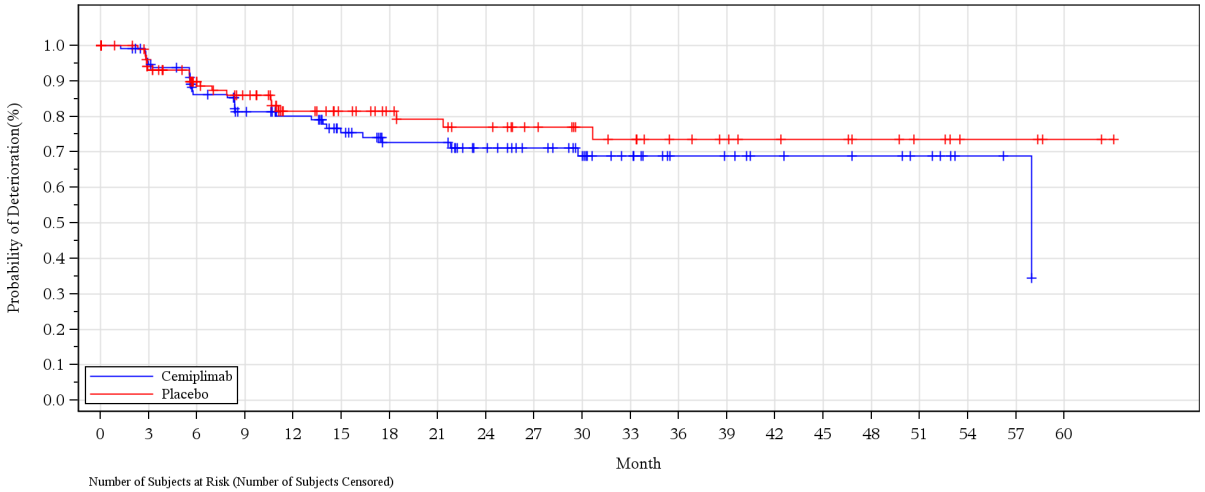
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	58 (12)	49 (14)	41 (16)	36 (20)	32 (22)	28 (24)	26 (25)	21 (29)	18 (32)	12 (37)	10 (38)	7 (40)	7 (40)	6 (41)	5 (42)	5 (42)	4 (43)	0 (47)	0 (47)	0 (47)
Placebo	75 (0)	47 (20)	38 (28)	36 (29)	28 (36)	22 (42)	20 (44)	17 (46)	16 (47)	12 (51)	10 (53)	9 (53)	7 (55)	7 (55)	6 (56)	4 (58)	3 (59)	2 (60)	0 (62)	0 (62)	0 (62)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

High risk feature: Nodal



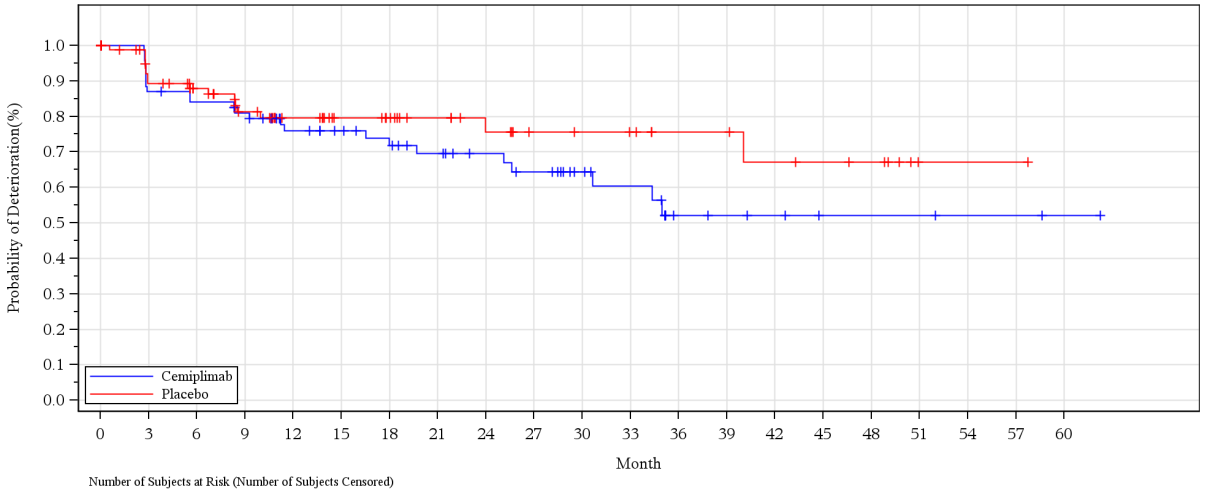
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	105 (14)	90 (20)	78 (27)	72 (32)	60 (40)	50 (48)	50 (48)	41 (56)	35 (62)	28 (68)	22 (74)	15 (81)	14 (82)	11 (85)	10 (86)	9 (87)	7 (89)	3 (93)	2 (94)	0 (95)
Placebo	117 (0)	92 (18)	73 (34)	64 (40)	49 (52)	43 (58)	37 (64)	34 (66)	31 (68)	26 (73)	22 (77)	20 (78)	16 (82)	14 (84)	12 (86)	11 (87)	9 (89)	7 (91)	4 (94)	4 (94)	2 (96)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

Figure 14.2.8.1.9 Time to First Deterioration (Excluding Death) - EORTC QLQ-C30 Financial Difficulties Scale by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	60 (15)	57 (16)	53 (18)	43 (25)	39 (29)	35 (31)	31 (34)	27 (38)	24 (39)	18 (45)	15 (47)	7 (53)	6 (54)	5 (55)	3 (57)	3 (57)	3 (57)	2 (58)	2 (58)	1 (59)
Placebo	89 (0)	66 (15)	57 (23)	47 (29)	38 (37)	31 (44)	28 (47)	23 (52)	19 (55)	15 (59)	14 (60)	13 (61)	10 (64)	10 (64)	8 (65)	7 (66)	6 (67)	1 (72)	1 (72)	1 (72)	0 (73)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FAS: Full analysis set; GHS: Global Heath Status; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable; QoL: Quality of Life.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:18 SAS Linux 9.4)

2.8 EQ 5D 3L VAS

2.8.1 1. Datenschnitt

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: <65
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	27 (48.2%)	30 (46.2%)
Number of censored cases	n (%)	29 (51.8%)	35 (53.8%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	3 (5.4%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (30.4%)	29 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 5.59]	5.55 [2.79, 5.65]
	Median [95% CI]	8.34 [3.02, 25.59]	9.33 [5.65, 38.90]
	Q3 [95% CI]	NYR [16.59, NC]	NYR [30.69, NC]
	p-value[b][d]		0.278
	HR [95 % CI][c][d]		1.35 [0.77, 2.35]
	Heterogeneity p-value[e][d]		0.6325

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	72 (47.1%)	54 (38.3%)
Number of censored cases	n (%)	81 (52.9%)	87 (61.7%)
No baseline score	n (%)	15 (9.8%)	17 (12.1%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	58 (37.9%)	61 (43.3%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.65]	3.84 [2.86, 5.62]
	Median [95% CI]	12.52 [8.34, 22.97]	14.36 [8.41, 23.95]
	Q3 [95% CI]	37.06 [27.73, NC]	NYR [NC, NC]
	p-value[b][d]		0.561
	HR [95 % CI][c][d]		1.11 [0.77, 1.59]
	Heterogeneity p-value[e][d]		0.6325

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	27 (48.2%)	30 (46.2%)
Number of censored cases	n (%)	29 (51.8%)	35 (53.8%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	3 (5.4%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (30.4%)	29 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.86 [2.79, 5.59]	5.55 [2.79, 5.65]
	Median [95% CI]	8.34 [3.02, 25.59]	9.33 [5.65, 38.90]
	Q3 [95% CI]	NYR [16.59, NC]	NYR [30.69, NC]
	p-value[b][d]		0.278
	HR [95 % CI][c][d]		1.35 [0.77, 2.35]
	Heterogeneity p-value[e][d]		0.3550

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	35 (43.8%)	30 (43.5%)
Number of censored cases	n (%)	45 (56.3%)	39 (56.5%)
No baseline score	n (%)	8 (10.0%)	9 (13.0%)
No post-baseline score	n (%)	3 (3.8%)	1 (1.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	34 (42.5%)	29 (42.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.89, 8.34]	3.09 [2.86, 8.31]
	Median [95% CI]	22.97 [8.34, 30.62]	14.06 [5.59, 22.47]
	Q3 [95% CI]	37.06 [27.17, NC]	NYR [17.77, NC]
	p-value[b][d]		0.492
	HR [95 % CI][c][d]		0.83 [0.49, 1.41]
	Heterogeneity p-value[e][d]		0.3550

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	37 (50.7%)	24 (33.3%)
Number of censored cases	n (%)	36 (49.3%)	48 (66.7%)
No baseline score	n (%)	7 (9.6%)	8 (11.1%)
No post-baseline score	n (%)	5 (6.8%)	7 (9.7%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	24 (32.9%)	32 (44.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.83, 5.65]	3.88 [2.83, 8.34]
	Median [95% CI]	10.97 [5.65, 14.23]	21.65 [6.51, NC]
	Q3 [95% CI]	28.85 [14.23, NC]	NYR [NC, NC]
	p-value[b][d]		0.342
	HR [95 % CI][c][d]		1.28 [0.75, 2.20]
	Heterogeneity p-value[e][d]		0.3550

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	84 (48.3%)	70 (40.2%)
Number of censored cases	n (%)	90 (51.7%)	104 (59.8%)
No baseline score	n (%)	20 (11.5%)	17 (9.8%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	64 (36.8%)	76 (43.7%)
Time to first deterioration (months)	Q1 [95% CI]	3.09 [2.86, 5.59]	3.48 [2.86, 5.62]
	Median [95% CI]	11.27 [8.34, 19.58]	13.90 [8.38, 38.90]
	Q3 [95% CI]	37.06 [27.73, NC]	NYR [38.90, NC]
	p-value[b][d]		0.402
	HR [95 % CI][c][d]		1.14 [0.82, 1.57]
	Heterogeneity p-value[e][d]		0.7241

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	15 (42.9%)	14 (43.8%)
Number of censored cases	n (%)	20 (57.1%)	18 (56.3%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	5 (14.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	11 (31.4%)	14 (43.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.79, 8.31]	5.55 [2.79, 7.06]
	Median [95% CI]	13.90 [5.55, NC]	17.77 [5.65, NC]
	Q3 [95% CI]	NYR [13.90, NC]	NYR [17.77, NC]
	p-value[b][d]		0.294
	HR [95 % CI][c][d]		1.56 [0.68, 3.57]
	Heterogeneity p-value[e][d]		0.7241

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	14 (37.8%)	12 (38.7%)
Number of censored cases	n (%)	23 (62.2%)	19 (61.3%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (45.9%)	14 (45.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.86, 22.97]	2.79 [1.18, 5.65]
	Median [95% CI]	27.07 [11.27, NC]	11.27 [3.09, NC]
	Q3 [95% CI]	37.06 [37.06, NC]	NYR [11.27, NC]
	p-value[b][d]		0.215
	HR [95 % CI][c][d]		0.60 [0.27, 1.34]
	Heterogeneity p-value[e][d]		0.1140

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	46 (51.1%)	36 (40.0%)
Number of censored cases	n (%)	44 (48.9%)	54 (60.0%)
No baseline score	n (%)	7 (7.8%)	6 (6.7%)
No post-baseline score	n (%)	4 (4.4%)	5 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	33 (36.7%)	43 (47.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.86, 5.98]	5.55 [2.89, 9.33]
	Median [95% CI]	10.91 [8.31, 19.58]	17.74 [9.95, NC]
	Q3 [95% CI]	30.62 [21.68, NC]	NYR [NC, NC]
	p-value[b][d]		0.256
	HR [95 % CI][c][d]		1.29 [0.83, 1.99]
	Heterogeneity p-value[e][d]		0.1140

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	39 (47.6%)	36 (42.4%)
Number of censored cases	n (%)	43 (52.4%)	49 (57.6%)
No baseline score	n (%)	13 (15.9%)	11 (12.9%)
No post-baseline score	n (%)	5 (6.1%)	4 (4.7%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	25 (30.5%)	33 (38.8%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.79, 5.59]	3.48 [2.79, 5.62]
	Median [95% CI]	8.31 [5.59, 13.90]	8.41 [5.65, 30.69]
	Q3 [95% CI]	28.85 [13.80, NC]	NYR [30.69, NC]
	p-value[b][d]		0.240
	HR [95 % CI][c][d]		1.30 [0.83, 2.06]
	Heterogeneity p-value[e][d]		0.1140

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: White
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	91 (48.1%)	72 (38.1%)
Number of censored cases	n (%)	98 (51.9%)	117 (61.9%)
No baseline score	n (%)	20 (10.6%)	21 (11.1%)
No post-baseline score	n (%)	9 (4.8%)	10 (5.3%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	69 (36.5%)	85 (45.0%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.89, 5.59]	5.55 [2.89, 5.65]
	Median [95% CI]	12.52 [8.34, 21.68]	17.74 [9.95, 30.69]
	Q3 [95% CI]	37.06 [27.73, NC]	NYR [38.90, NC]
	p-value[b][d]		0.197
	HR [95 % CI][c][d]		1.23 [0.89, 1.68]
	Heterogeneity p-value[e][d]		0.3877

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	8 (40.0%)	12 (70.6%)
Number of censored cases	n (%)	12 (60.0%)	5 (29.4%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	6 (30.0%)	5 (29.4%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.79, 10.97]	3.09 [2.79, 5.65]
	Median [95% CI]	10.97 [2.83, NC]	5.65 [2.83, 8.41]
	Q3 [95% CI]	NYR [5.68, NC]	8.41 [5.65, NC]
	p-value[b][d]		0.912
	HR [95 % CI][c][d]		0.94 [0.33, 2.73]
	Heterogeneity p-value[e][d]		0.3877

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	79 (47.6%)	68 (38.4%)
Number of censored cases	n (%)	87 (52.4%)	109 (61.6%)
No baseline score	n (%)	20 (12.0%)	21 (11.9%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	62 (37.3%)	79 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	3.09 [2.89, 5.59]	3.25 [2.86, 5.62]
	Median [95% CI]	12.52 [8.34, 22.97]	14.36 [9.82, 38.90]
	Q3 [95% CI]	31.54 [27.17, NC]	NYR [NC, NC]
	p-value[b][d]		0.239
	HR [95 % CI][c][d]		1.21 [0.87, 1.68]
	Heterogeneity p-value[e][d]		0.5889

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	20 (46.5%)	16 (55.2%)
Number of censored cases	n (%)	23 (53.5%)	13 (44.8%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	6 (14.0%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	13 (30.2%)	11 (37.9%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.66, 6.24]	5.55 [2.79, 6.41]
	Median [95% CI]	11.30 [5.55, 45.70]	8.31 [5.55, 21.65]
	Q3 [95% CI]	45.70 [13.80, NC]	23.95 [8.31, NC]
	p-value[b][d]		0.946
	HR [95 % CI][c][d]		1.02 [0.52, 2.01]
	Heterogeneity p-value[e][d]		0.5889

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	59 (44.4%)	53 (40.5%)
Number of censored cases	n (%)	74 (55.6%)	78 (59.5%)
No baseline score	n (%)	16 (12.0%)	12 (9.2%)
No post-baseline score	n (%)	7 (5.3%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	51 (38.3%)	59 (45.0%)
Time to first deterioration (months)	Q1 [95% CI]	3.09 [2.86, 5.65]	5.59 [2.86, 5.82]
	Median [95% CI]	13.80 [8.34, 27.73]	11.60 [8.34, NC]
	Q3 [95% CI]	45.70 [28.85, NC]	NYR [NC, NC]
	p-value[b][d]		0.497
	HR [95 % CI][c][d]		1.13 [0.78, 1.65]
	Heterogeneity p-value[e][d]		0.9617

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	40 (52.6%)	31 (41.3%)
Number of censored cases	n (%)	36 (47.4%)	44 (58.7%)
No baseline score	n (%)	8 (10.5%)	9 (12.0%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	24 (31.6%)	31 (41.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.83, 5.59]	2.89 [2.83, 3.84]
	Median [95% CI]	10.91 [5.59, 19.58]	14.06 [3.84, 22.47]
	Q3 [95% CI]	30.62 [19.58, NC]	NYR [21.65, NC]
	p-value[b][d]		0.627
	HR [95 % CI][c][d]		1.12 [0.68, 1.85]
	Heterogeneity p-value[e][d]		0.9617

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	66 (52.8%)	47 (40.2%)
Number of censored cases	n (%)	59 (47.2%)	70 (59.8%)
No baseline score	n (%)	11 (8.8%)	13 (11.1%)
No post-baseline score	n (%)	9 (7.2%)	3 (2.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	39 (31.2%)	54 (46.2%)
Time to first deterioration (months)	Q1 [95% CI]	3.09 [2.86, 5.59]	5.09 [2.86, 5.65]
	Median [95% CI]	10.91 [5.68, 14.23]	11.60 [8.31, NC]
	Q3 [95% CI]	27.73 [19.58, NC]	NYR [38.90, NC]
	p-value[b][d]		0.079
	HR [95 % CI][c][d]		1.40 [0.95, 2.05]
	Heterogeneity p-value[e][d]		0.1572

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	33 (39.3%)	37 (41.6%)
Number of censored cases	n (%)	51 (60.7%)	52 (58.4%)
No baseline score	n (%)	13 (15.5%)	8 (9.0%)
No post-baseline score	n (%)	2 (2.4%)	7 (7.9%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	36 (42.9%)	36 (40.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 8.31]	3.88 [2.83, 5.65]
	Median [95% CI]	22.97 [8.31, NC]	14.06 [5.82, 30.69]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [23.95, NC]
	p-value[b][d]		0.583
	HR [95 % CI][c][d]		0.88 [0.54, 1.42]
	Heterogeneity p-value[e][d]		0.1572

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: <65
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	27 (48.2%)	30 (46.2%)
Number of censored participants, n (%)	29 (51.8%)	35 (53.8%)
Proportionality Test p-value[a][b]	0.5324	
Hazard ratio(interaction)	1.283 (0.586, 2.809)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	72 (47.1%)	54 (38.3%)
Number of censored participants, n (%)	81 (52.9%)	87 (61.7%)
Proportionality Test p-value[a][b]	0.3136	
Hazard ratio(interaction)	0.775 (0.472, 1.272)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	27 (48.2%)	30 (46.2%)
Number of censored participants, n (%)	29 (51.8%)	35 (53.8%)
Proportionality Test p-value[a][b]	0.5324	
Hazard ratio(interaction)	1.283 (0.586, 2.809)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	35 (43.8%)	30 (43.5%)
Number of censored participants, n (%)	45 (56.3%)	39 (56.5%)
Proportionality Test p-value[a][b]	0.4825	
Hazard ratio(interaction)	1.311 (0.616, 2.792)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	37 (50.7%)	24 (33.3%)
Number of censored participants, n (%)	36 (49.3%)	48 (66.7%)
Proportionality Test p-value[a][b]	0.1269	
Hazard ratio(interaction)	0.513 (0.217, 1.209)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	84 (48.3%)	70 (40.2%)
Number of censored participants, n (%)	90 (51.7%)	104 (59.8%)
Proportionality Test p-value[a][b]	0.2227	
Hazard ratio(interaction)	0.765 (0.497, 1.177)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	15 (42.9%)	14 (43.8%)
Number of censored participants, n (%)	20 (57.1%)	18 (56.3%)
Proportionality Test p-value[a][b]	0.7443	
Hazard ratio(interaction)	1.208 (0.388, 3.766)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	14 (37.8%)	12 (38.7%)
Number of censored participants, n (%)	23 (62.2%)	19 (61.3%)
Proportionality Test p-value[a][b]	0.1391	
Hazard ratio(interaction)	0.348 (0.086, 1.409)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	46 (51.1%)	36 (40.0%)
Number of censored participants, n (%)	44 (48.9%)	54 (60.0%)
Proportionality Test p-value[a][b]	0.7725	
Hazard ratio(interaction)	0.914 (0.495, 1.685)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	39 (47.6%)	36 (42.4%)
Number of censored participants, n (%)	43 (52.4%)	49 (57.6%)
Proportionality Test p-value[a][b]	0.6978	
Hazard ratio(interaction)	0.897 (0.519, 1.551)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: White
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	91 (48.1%)	72 (38.1%)
Number of censored participants, n (%)	98 (51.9%)	117 (61.9%)
Proportionality Test p-value[a][b]	0.2320	
Hazard ratio(interaction)	0.787 (0.531, 1.166)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	8 (40.0%)	12 (70.6%)
Number of censored participants, n (%)	12 (60.0%)	5 (29.4%)
Proportionality Test p-value[a][b]	0.8435	
Hazard ratio(interaction)	1.265 (0.123, 13.020)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	79 (47.6%)	68 (38.4%)
Number of censored participants, n (%)	87 (52.4%)	109 (61.6%)
Proportionality Test p-value[a][b]	0.0827	
Hazard ratio(interaction)	0.680 (0.440, 1.051)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	20 (46.5%)	16 (55.2%)
Number of censored participants, n (%)	23 (53.5%)	13 (44.8%)
Proportionality Test p-value[a][b]	0.4494	
Hazard ratio(interaction)	1.380 (0.599, 3.181)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	59 (44.4%)	53 (40.5%)
Number of censored participants, n (%)	74 (55.6%)	78 (59.5%)
Proportionality Test p-value[a][b]	0.7440	
Hazard ratio(interaction)	0.921 (0.563, 1.508)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	40 (52.6%)	31 (41.3%)
Number of censored participants, n (%)	36 (47.4%)	44 (58.7%)
Proportionality Test p-value[a][b]	0.1840	
Hazard ratio(interaction)	0.609 (0.293, 1.266)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	66 (52.8%)	47 (40.2%)
Number of censored participants, n (%)	59 (47.2%)	70 (59.8%)
Proportionality Test p-value[a][b]	0.0476	
Hazard ratio(interaction)	0.585 (0.344, 0.994)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

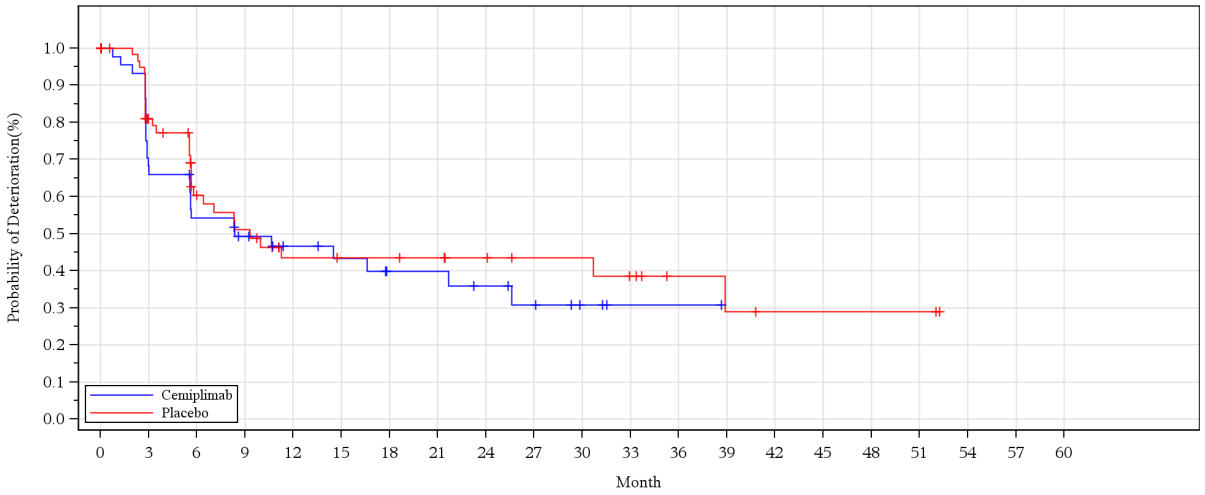
High risk feature: Non-Nodal
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	33 (39.3%)	37 (41.6%)
Number of censored participants, n (%)	51 (60.7%)	52 (58.4%)
Proportionality Test p-value[a][b]	0.8712	
Hazard ratio(interaction)	1.050 (0.581, 1.899)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 1: <65



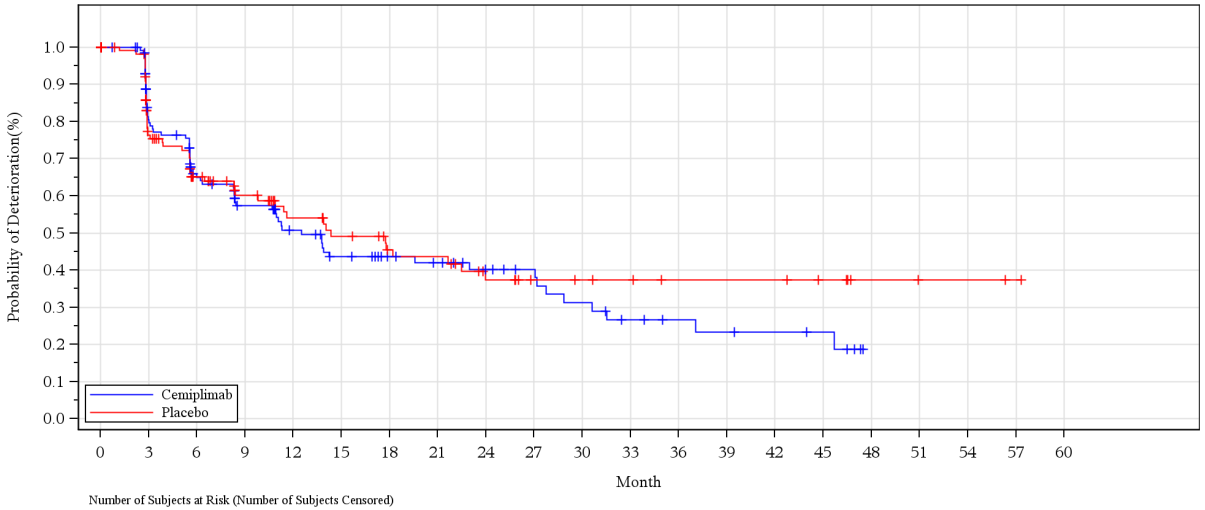
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	30 (12)	23 (13)	19 (15)	15 (18)	13 (19)	10 (21)	10 (21)	8 (22)	6 (23)	3 (26)	1 (28)	1 (28)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)
Placebo	65 (0)	42 (12)	27 (17)	22 (18)	15 (22)	14 (23)	14 (23)	13 (24)	11 (26)	9 (28)	9 (28)	7 (29)	4 (32)	3 (32)	2 (33)	2 (33)	2 (33)	2 (33)	0 (35)	0 (35)	0 (35)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 1: >=65



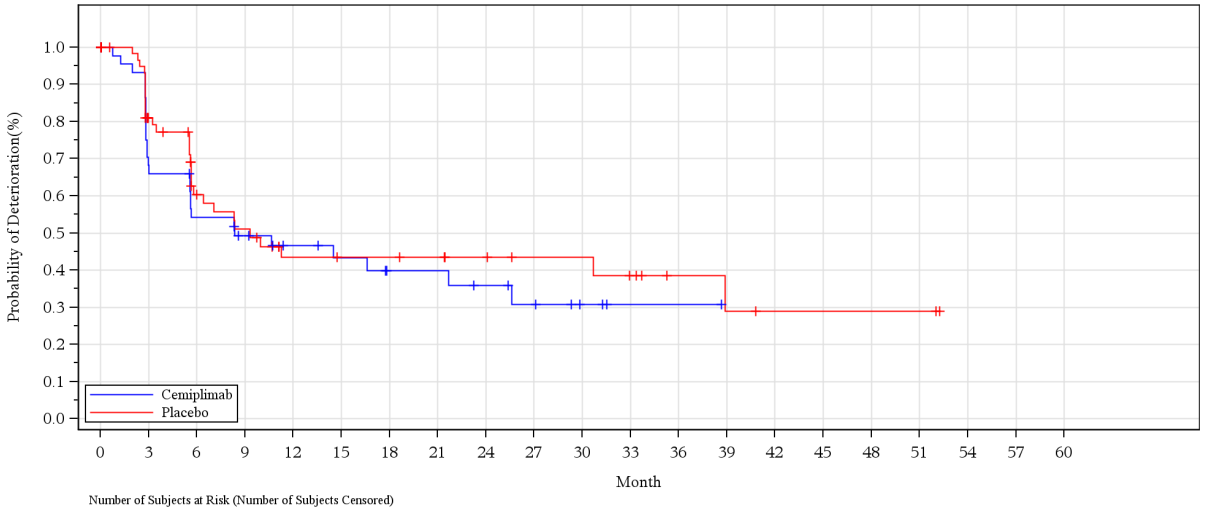
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	96 (33)	71 (40)	57 (46)	44 (53)	35 (56)	29 (62)	26 (64)	21 (68)	18 (71)	14 (71)	10 (73)	8 (75)	7 (75)	6 (76)	5 (77)	0 (81)	0 (81)	0 (81)	0 (81)	0 (81)
Placebo	141 (0)	79 (36)	58 (46)	45 (55)	35 (61)	30 (63)	24 (67)	23 (67)	16 (71)	12 (75)	11 (76)	10 (77)	8 (79)	8 (79)	8 (79)	6 (81)	3 (84)	2 (85)	2 (85)	1 (86)	0 (87)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	30 (12)	23 (13)	19 (15)	15 (18)	13 (19)	10 (21)	10 (21)	8 (22)	6 (23)	3 (26)	1 (28)	1 (28)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)	0 (29)
Placebo	65 (0)	42 (12)	27 (17)	22 (18)	15 (22)	14 (23)	14 (23)	13 (24)	11 (26)	9 (28)	9 (28)	7 (29)	4 (32)	3 (32)	2 (33)	2 (33)	2 (33)	2 (33)	0 (35)	0 (35)	0 (35)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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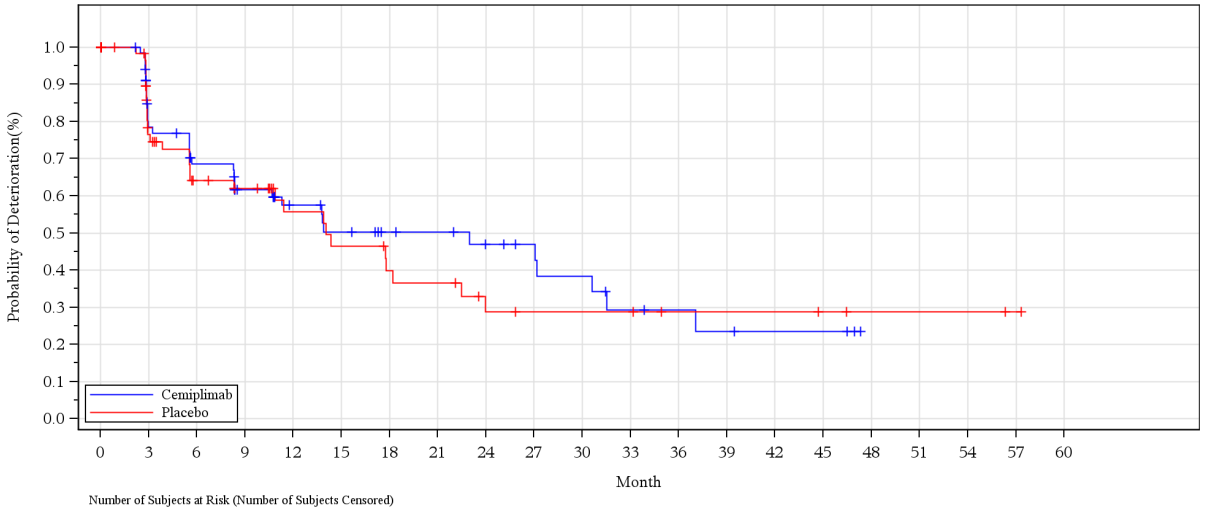
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



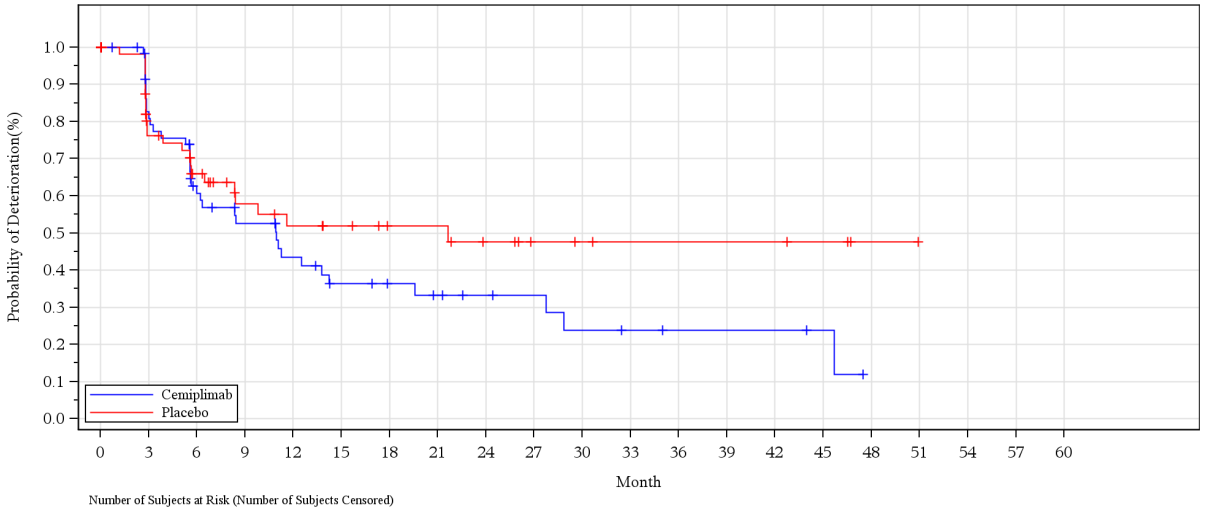
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	49 (17)	40 (20)	32 (24)	25 (29)	21 (30)	17 (34)	16 (35)	13 (37)	11 (39)	9 (39)	6 (40)	5 (41)	4 (41)	3 (42)	3 (42)	0 (45)	0 (45)	0 (45)	0 (45)	0 (45)
Placebo	69 (0)	40 (16)	29 (21)	25 (24)	18 (29)	15 (29)	12 (30)	11 (30)	7 (32)	6 (33)	6 (33)	6 (33)	4 (35)	4 (35)	4 (35)	3 (36)	2 (37)	2 (37)	2 (37)	1 (38)	0 (39)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=75



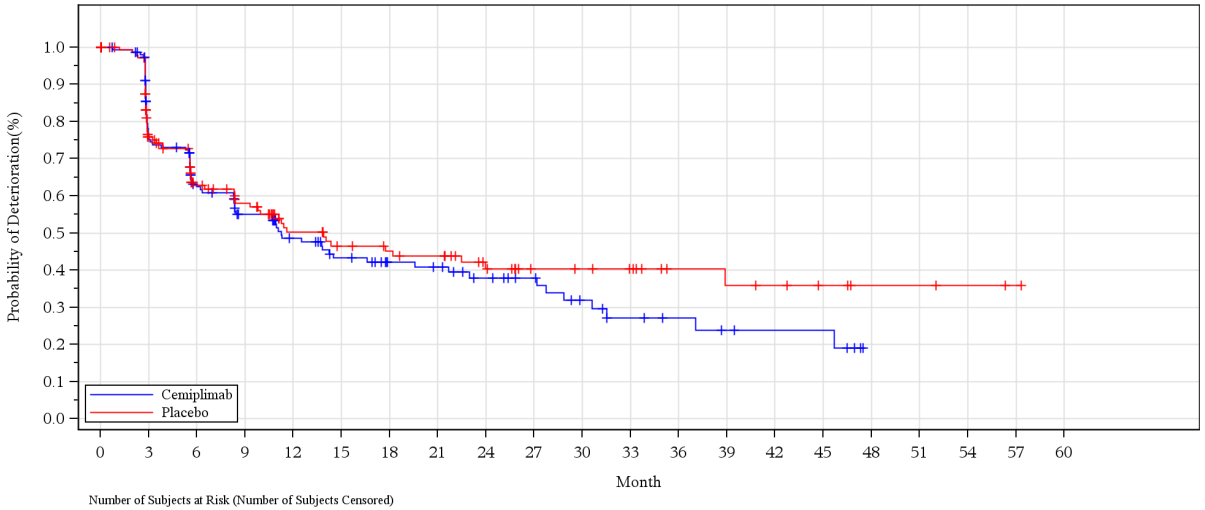
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	47 (16)	31 (20)	25 (22)	19 (24)	14 (26)	12 (28)	10 (29)	8 (31)	7 (32)	5 (32)	4 (33)	3 (34)	3 (34)	3 (34)	2 (35)	0 (36)	0 (36)	0 (36)	0 (36)	0 (36)
Placebo	72 (0)	39 (20)	29 (25)	20 (31)	17 (32)	15 (34)	12 (37)	12 (37)	9 (39)	6 (42)	5 (43)	4 (44)	4 (44)	4 (44)	4 (44)	3 (45)	1 (47)	0 (48)	0 (48)	0 (48)	0 (48)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	106 (35)	79 (43)	64 (49)	49 (57)	40 (61)	32 (68)	30 (69)	24 (73)	20 (77)	14 (80)	10 (82)	8 (84)	6 (85)	5 (86)	5 (86)	0 (90)	0 (90)	0 (90)	0 (90)	0 (90)
Placebo	174 (0)	99 (41)	70 (54)	59 (60)	42 (70)	36 (73)	33 (75)	31 (76)	23 (82)	17 (88)	16 (89)	14 (91)	9 (96)	8 (96)	7 (97)	5 (99)	3 (101)	3 (101)	2 (102)	1 (103)	0 (104)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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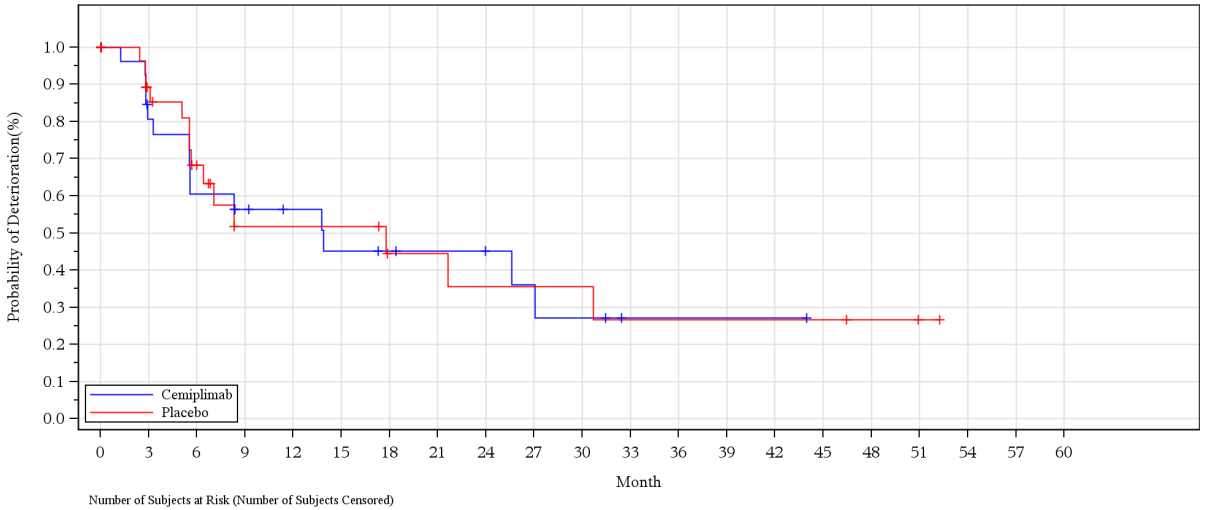
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	20 (10)	15 (10)	12 (12)	10 (14)	8 (14)	7 (15)	6 (16)	5 (17)	4 (17)	3 (17)	1 (19)	1 (19)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	32 (0)	22 (7)	15 (9)	8 (13)	8 (13)	8 (13)	5 (15)	5 (15)	4 (15)	4 (15)	4 (15)	3 (15)	3 (15)	3 (15)	3 (15)	3 (15)	2 (16)	1 (17)	0 (18)	0 (18)	0 (18)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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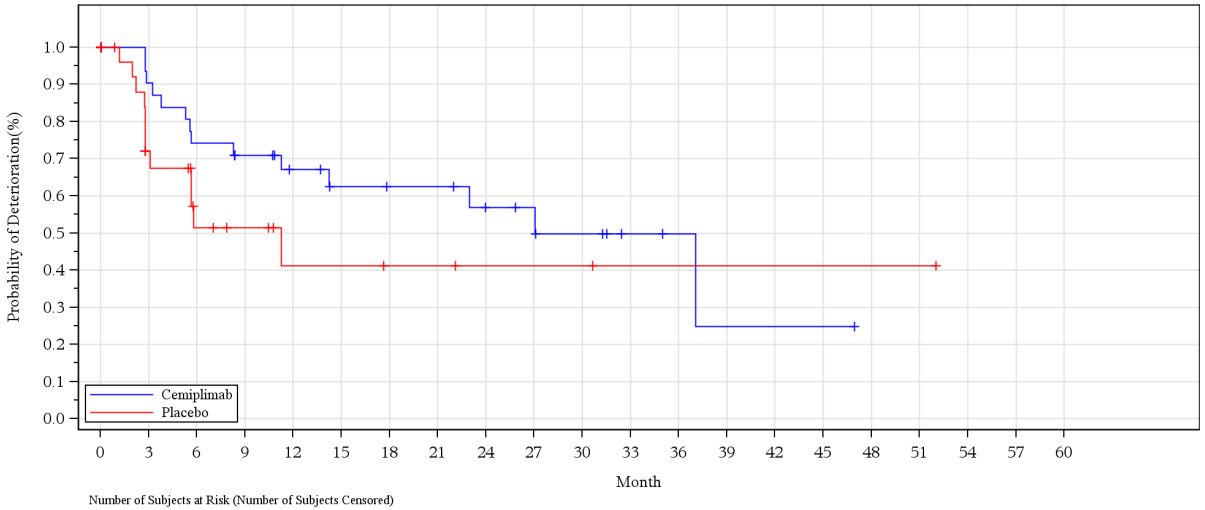
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	28 (6)	23 (6)	20 (8)	16 (11)	13 (13)	12 (14)	12 (14)	9 (16)	8 (17)	6 (18)	3 (21)	2 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	31 (0)	16 (8)	9 (11)	7 (13)	4 (15)	4 (15)	3 (16)	3 (16)	2 (17)	2 (17)	2 (17)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)	0 (19)	0 (19)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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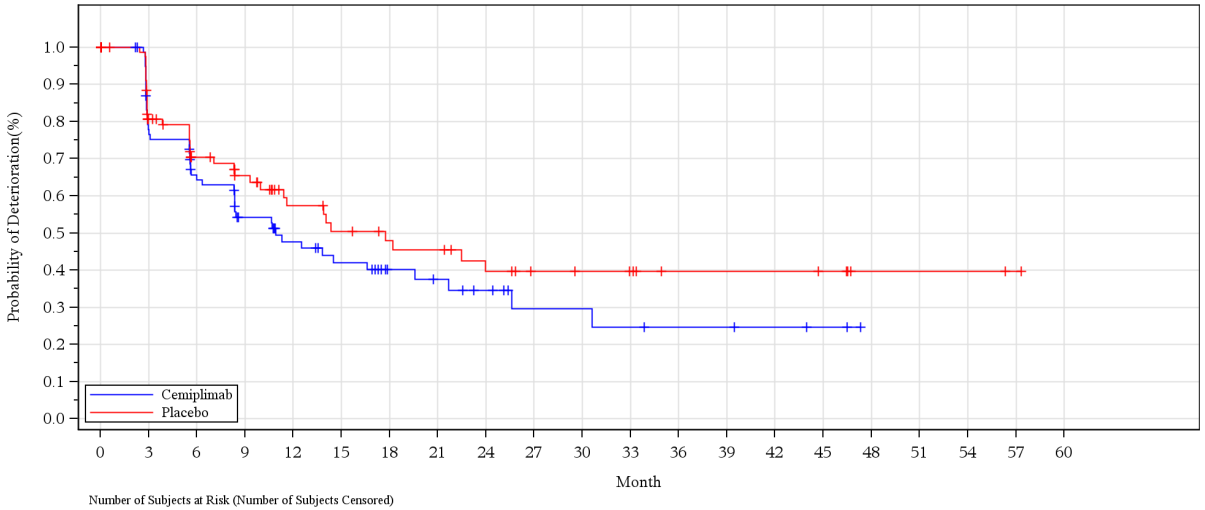
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	59 (14)	46 (17)	35 (21)	27 (25)	22 (27)	15 (33)	13 (34)	10 (36)	6 (39)	6 (39)	5 (39)	4 (40)	4 (40)	3 (41)	2 (42)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)
Placebo	90 (0)	58 (17)	44 (24)	37 (28)	26 (35)	22 (36)	19 (38)	18 (38)	14 (40)	11 (43)	10 (44)	9 (45)	6 (48)	6 (48)	6 (48)	5 (49)	2 (52)	2 (52)	2 (52)	1 (53)	0 (54)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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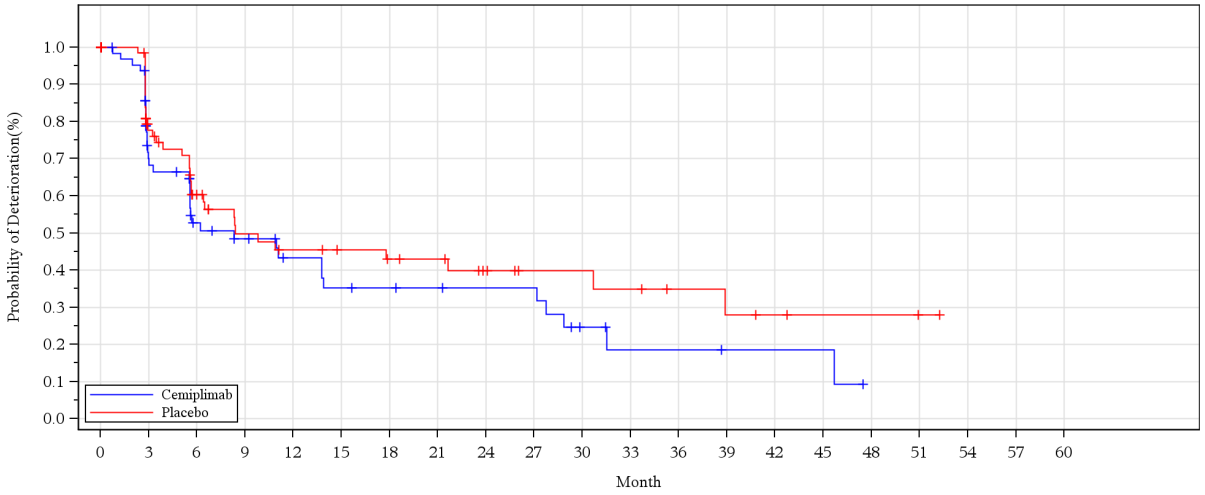
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	39 (25)	25 (30)	21 (32)	16 (35)	13 (35)	12 (36)	11 (37)	10 (38)	10 (38)	5 (40)	3 (41)	3 (41)	2 (42)	2 (42)	2 (42)	0 (43)	0 (43)	0 (43)	0 (43)	0 (43)
Placebo	85 (0)	47 (23)	32 (28)	23 (32)	20 (33)	18 (35)	16 (36)	15 (37)	11 (40)	8 (43)	8 (43)	7 (43)	5 (45)	4 (45)	3 (46)	2 (47)	2 (47)	1 (48)	0 (49)	0 (49)	0 (49)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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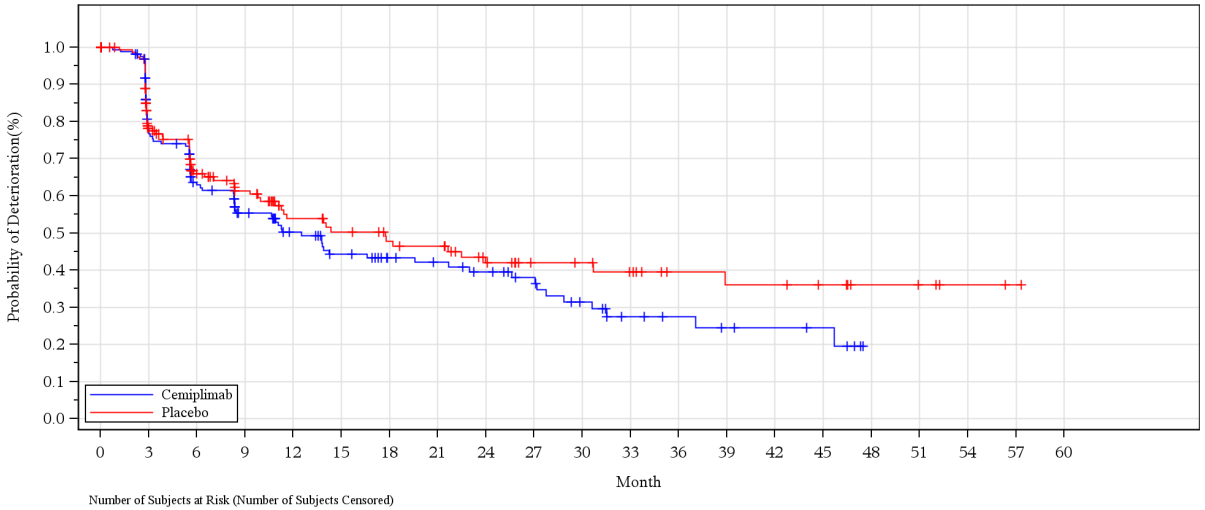
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Race: White



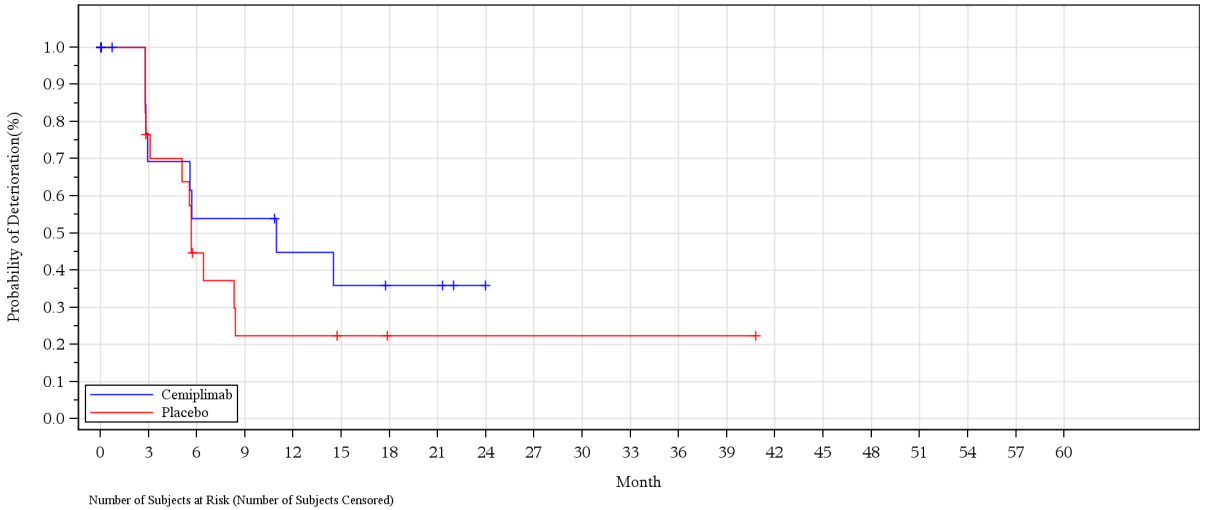
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	117 (38)	87 (46)	69 (54)	54 (63)	44 (67)	36 (74)	33 (76)	29 (78)	24 (82)	17 (85)	11 (89)	9 (91)	7 (92)	6 (93)	5 (94)	0 (98)	0 (98)	0 (98)	0 (98)	0 (98)
Placebo	189 (0)	109 (47)	79 (61)	64 (71)	47 (81)	42 (83)	37 (86)	35 (87)	26 (93)	20 (99)	19 (100)	16 (102)	11 (107)	10 (107)	10 (107)	8 (109)	5 (112)	4 (113)	2 (115)	1 (116)	0 (117)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Race: Non-white



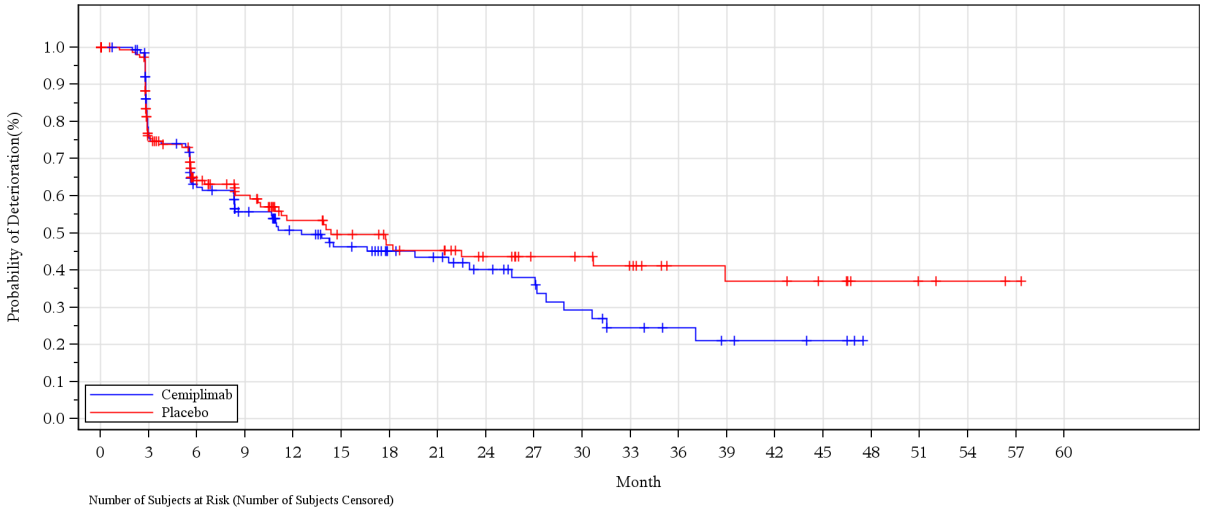
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	9 (7)	7 (7)	7 (7)	5 (8)	4 (8)	3 (9)	3 (9)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)
Placebo	17 (0)	12 (1)	6 (2)	3 (2)	3 (2)	2 (3)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)	0 (5)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	102 (33)	77 (39)	62 (46)	48 (55)	40 (59)	31 (67)	28 (69)	22 (73)	18 (76)	13 (77)	9 (79)	7 (81)	5 (82)	4 (83)	3 (84)	0 (87)	0 (87)	0 (87)	0 (87)	0 (87)
Placebo	177 (0)	102 (41)	72 (56)	59 (65)	44 (74)	38 (77)	33 (80)	31 (81)	24 (87)	19 (92)	18 (93)	15 (95)	10 (100)	9 (100)	9 (100)	7 (102)	4 (105)	3 (106)	2 (107)	1 (108)	0 (109)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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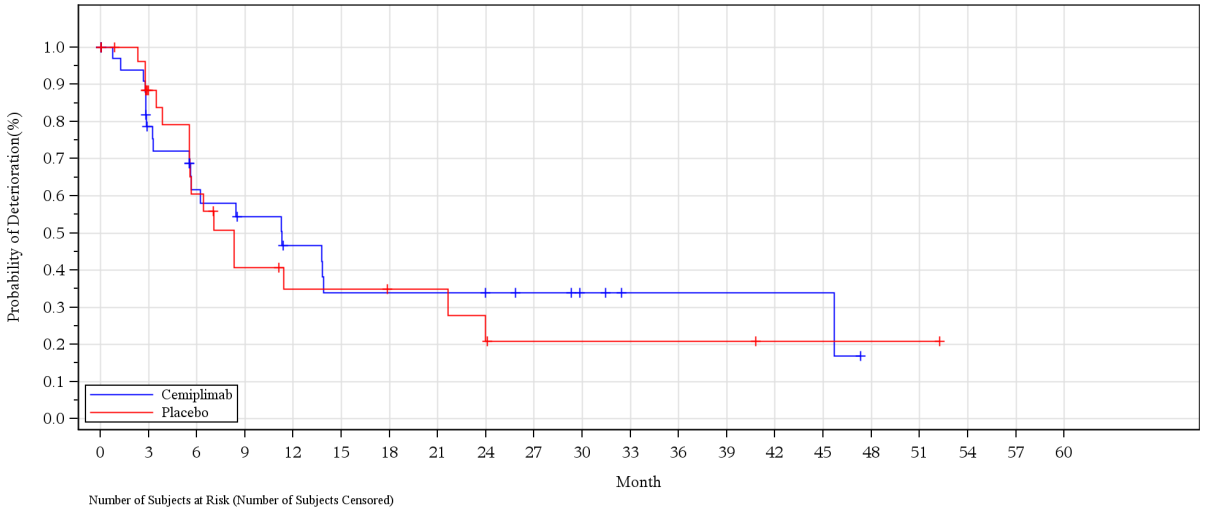
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	24 (12)	17 (14)	14 (15)	11 (16)	8 (16)	8 (16)	8 (16)	7 (17)	6 (18)	4 (20)	2 (22)	2 (22)	2 (22)	2 (22)	2 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	29 (0)	19 (7)	13 (7)	8 (8)	6 (9)	6 (9)	5 (10)	5 (10)	3 (10)	2 (11)	2 (11)	2 (11)	2 (11)	2 (11)	1 (12)	1 (12)	1 (12)	1 (12)	0 (13)	0 (13)	0 (13)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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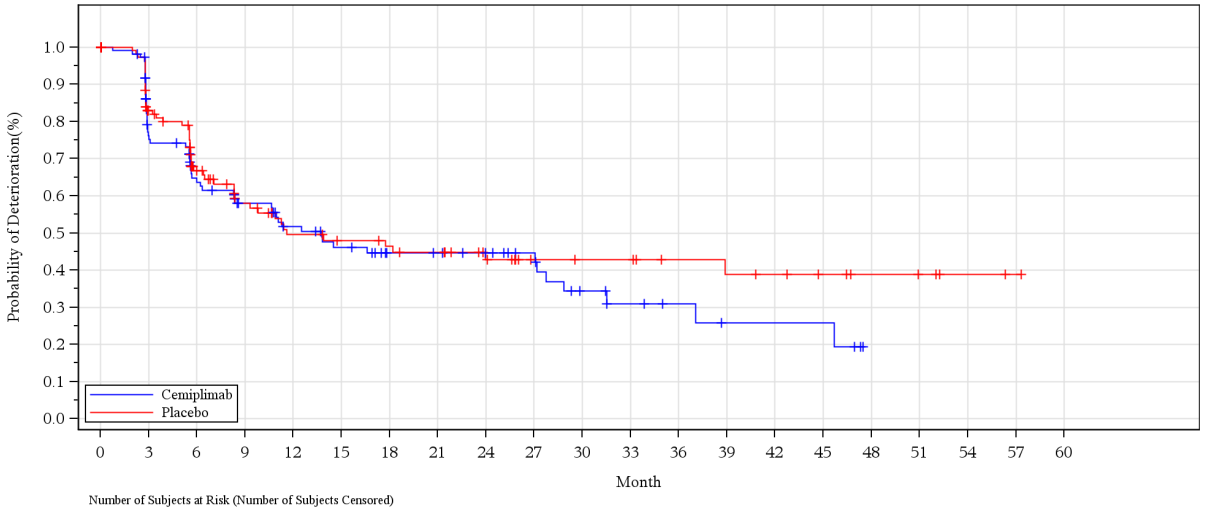
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 0



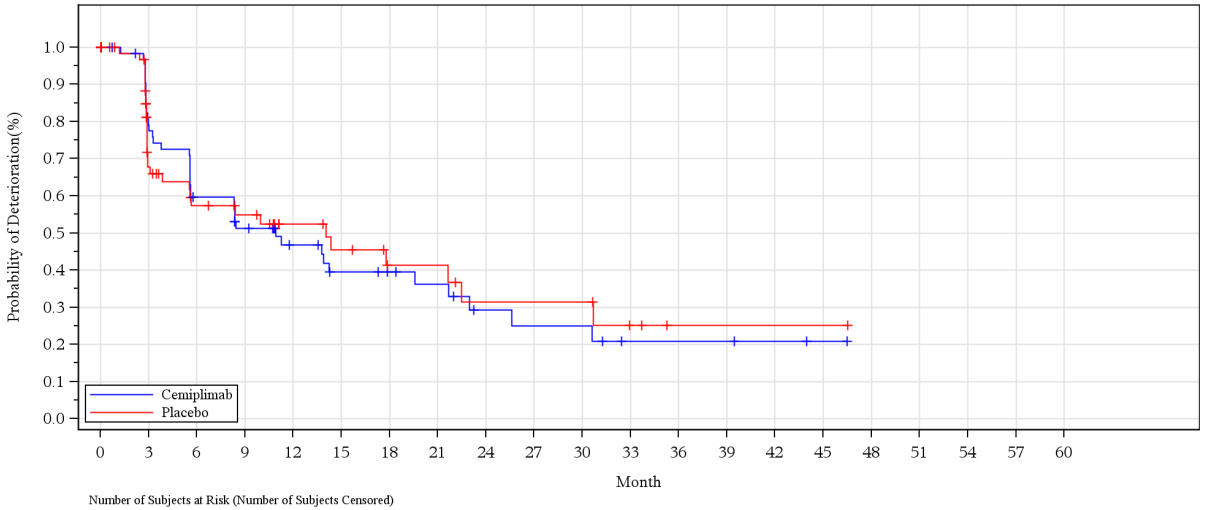
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	77 (31)	58 (38)	47 (44)	39 (47)	33 (49)	26 (55)	25 (56)	22 (59)	18 (63)	11 (66)	8 (68)	6 (70)	4 (71)	4 (71)	4 (71)	0 (74)	0 (74)	0 (74)	0 (74)	0 (74)
Placebo	131 (0)	86 (26)	59 (37)	44 (45)	34 (49)	31 (51)	29 (52)	27 (53)	21 (58)	15 (64)	14 (65)	14 (65)	11 (68)	10 (68)	9 (69)	7 (71)	5 (73)	4 (74)	2 (76)	1 (77)	0 (78)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	49 (14)	36 (15)	29 (17)	20 (24)	15 (26)	13 (28)	11 (29)	7 (31)	6 (31)	6 (31)	3 (33)	3 (33)	3 (33)	2 (34)	1 (35)	0 (36)	0 (36)	0 (36)	0 (36)	0 (36)
Placebo	75 (0)	35 (22)	26 (26)	23 (28)	16 (34)	13 (35)	9 (38)	9 (38)	6 (39)	6 (39)	6 (39)	3 (41)	1 (43)	1 (43)	1 (43)	1 (43)	0 (44)	0 (44)	0 (44)	0 (44)	0 (44)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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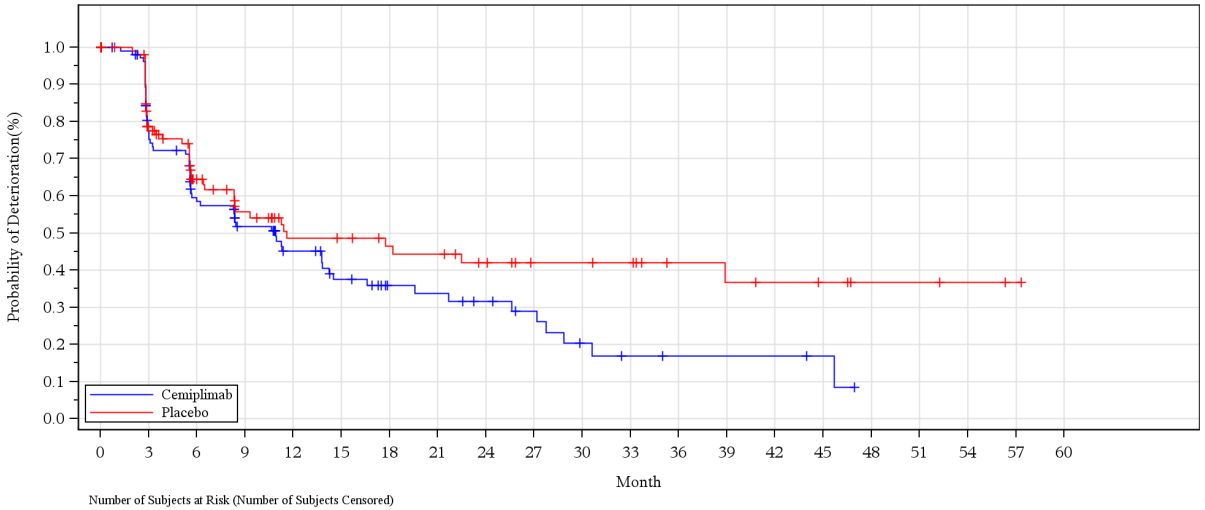
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Nodal



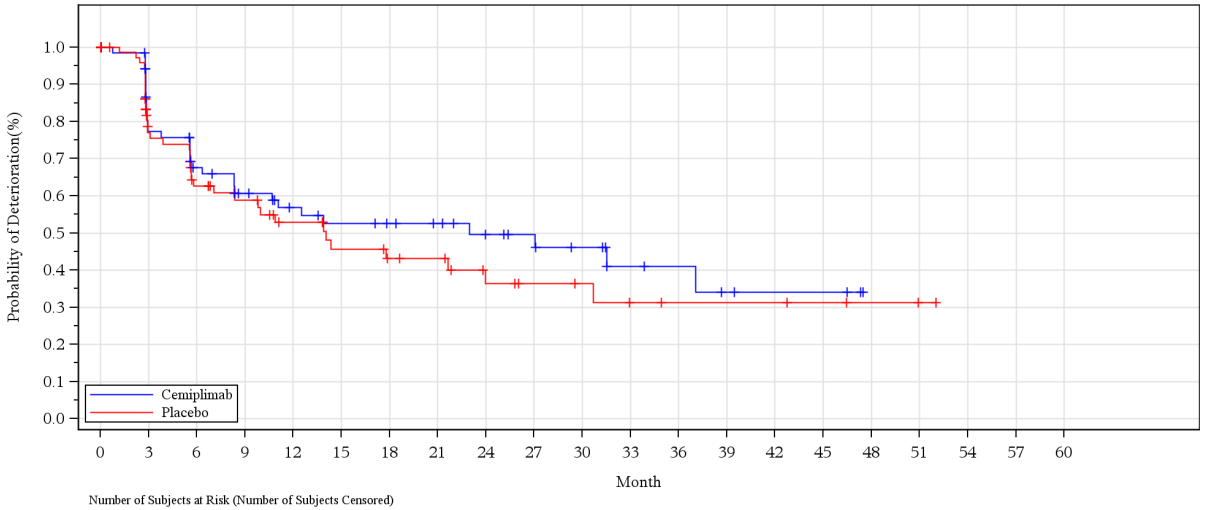
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	76 (26)	54 (30)	43 (35)	32 (41)	24 (44)	17 (50)	16 (50)	13 (52)	10 (54)	6 (55)	4 (56)	3 (57)	3 (57)	3 (57)	2 (58)	0 (59)	0 (59)	0 (59)	0 (59)	0 (59)
Placebo	117 (0)	72 (24)	48 (36)	36 (42)	26 (48)	25 (49)	22 (51)	21 (51)	17 (54)	13 (58)	13 (58)	12 (59)	8 (63)	7 (63)	6 (64)	5 (65)	3 (67)	3 (67)	2 (68)	1 (69)	0 (70)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	50 (19)	40 (23)	33 (26)	27 (30)	24 (31)	22 (33)	20 (35)	16 (38)	14 (40)	11 (42)	7 (45)	6 (46)	4 (47)	3 (48)	3 (48)	0 (51)	0 (51)	0 (51)	0 (51)	0 (51)
Placebo	89 (0)	49 (24)	37 (27)	31 (31)	24 (35)	19 (37)	16 (39)	15 (40)	10 (43)	8 (45)	7 (46)	5 (47)	4 (48)	4 (48)	4 (48)	3 (49)	2 (50)	1 (51)	0 (52)	0 (52)	0 (52)

Data cut-off as of October 4, 2024.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:17 SAS Linux 9.4)

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup (Full Analysis Set)

Age group 1: <65
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	18 (32.1%)	22 (33.8%)
Number of censored cases	n (%)	38 (67.9%)	43 (66.2%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	3 (5.4%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (46.4%)	37 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.89, 10.87]	8.31 [5.55, 8.44]
	Median [95% CI]	NYR [10.68, NC]	38.90 [8.41, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [38.90, NC]
	p-value[b][d]		0.983
	HR [95 % CI][c][d]		1.01 [0.53, 1.93]
	Heterogeneity p-value[e][d]		0.6272

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	53 (34.6%)	35 (24.8%)
Number of censored cases	n (%)	100 (65.4%)	106 (75.2%)
No baseline score	n (%)	15 (9.8%)	17 (12.1%)
No post-baseline score	n (%)	8 (5.2%)	8 (5.7%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	77 (50.3%)	80 (56.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 10.91]	8.34 [3.09, 17.77]
	Median [95% CI]	24.74 [15.21, NC]	NYR [18.20, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.330
	HR [95 % CI][c][d]		1.24 [0.80, 1.91]
	Heterogeneity p-value[e][d]		0.6272

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	18 (32.1%)	22 (33.8%)
Number of censored cases	n (%)	38 (67.9%)	43 (66.2%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	3 (5.4%)	2 (3.1%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	26 (46.4%)	37 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [2.89, 10.87]	8.31 [5.55, 8.44]
	Median [95% CI]	NYR [10.68, NC]	38.90 [8.41, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [38.90, NC]
	p-value[b][d]		0.983
	HR [95 % CI][c][d]		1.01 [0.53, 1.93]
	Heterogeneity p-value[e][d]		0.6546

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	25 (31.3%)	18 (26.1%)
Number of censored cases	n (%)	55 (68.8%)	51 (73.9%)
No baseline score	n (%)	8 (10.0%)	9 (13.0%)
No post-baseline score	n (%)	3 (3.8%)	1 (1.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	44 (55.0%)	41 (59.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [5.55, 19.81]	8.31 [2.92, 18.20]
	Median [95% CI]	27.17 [19.81, NC]	NYR [17.77, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.832
	HR [95 % CI][c][d]		1.06 [0.56, 2.01]
	Heterogeneity p-value[e][d]		0.6546

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	28 (38.4%)	17 (23.6%)
Number of censored cases	n (%)	45 (61.6%)	55 (76.4%)
No baseline score	n (%)	7 (9.6%)	8 (11.1%)
No post-baseline score	n (%)	5 (6.8%)	7 (9.7%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	33 (45.2%)	39 (54.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [3.29, 10.64]	8.34 [2.86, 22.21]
	Median [95% CI]	17.87 [10.64, NC]	NYR [14.65, NC]
	Q3 [95% CI]	NYR [35.29, NC]	NYR [NC, NC]
	p-value[b][d]		0.376
	HR [95 % CI][c][d]		1.32 [0.70, 2.48]
	Heterogeneity p-value[e][d]		0.6546

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	59 (33.9%)	48 (27.6%)
Number of censored cases	n (%)	115 (66.1%)	126 (72.4%)
No baseline score	n (%)	20 (11.5%)	17 (9.8%)
No post-baseline score	n (%)	6 (3.4%)	10 (5.7%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	89 (51.1%)	98 (56.3%)
Time to first deterioration (months)	Q1 [95% CI]	6.34 [5.59, 10.68]	8.31 [5.55, 9.95]
	Median [95% CI]	28.85 [15.21, NC]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.489
	HR [95 % CI][c][d]		1.14 [0.78, 1.68]
	Heterogeneity p-value[e][d]		0.6839

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	12 (34.3%)	9 (28.1%)
Number of censored cases	n (%)	23 (65.7%)	23 (71.9%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	5 (14.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	14 (40.0%)	19 (59.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [2.83, 13.90]	8.31 [3.09, 30.69]
	Median [95% CI]	19.81 [10.64, NC]	30.69 [8.31, NC]
	Q3 [95% CI]	NYR [29.73, NC]	NYR [30.69, NC]
	p-value[b][d]		0.399
	HR [95 % CI][c][d]		1.49 [0.58, 3.84]
	Heterogeneity p-value[e][d]		0.6839

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	7 (18.9%)	6 (19.4%)
Number of censored cases	n (%)	30 (81.1%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	2 (5.4%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	24 (64.9%)	20 (64.5%)
Time to first deterioration (months)	Q1 [95% CI]	37.06 [5.55, NC]	8.44 [1.18, NC]
	Median [95% CI]	37.06 [37.06, NC]	NYR [8.38, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.523
	HR [95 % CI][c][d]		0.69 [0.22, 2.16]
	Heterogeneity p-value[e][d]		0.4484

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	34 (37.8%)	23 (25.6%)
Number of censored cases	n (%)	56 (62.2%)	67 (74.4%)
No baseline score	n (%)	7 (7.8%)	6 (6.7%)
No post-baseline score	n (%)	4 (4.4%)	5 (5.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	45 (50.0%)	56 (62.2%)
Time to first deterioration (months)	Q1 [95% CI]	6.34 [5.55, 10.68]	13.54 [5.55, 22.21]
	Median [95% CI]	29.73 [10.91, NC]	NYR [18.20, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.256
	HR [95 % CI][c][d]		1.36 [0.80, 2.31]
	Heterogeneity p-value[e][d]		0.4484

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	30 (36.6%)	28 (32.9%)
Number of censored cases	n (%)	52 (63.4%)	57 (67.1%)
No baseline score	n (%)	13 (15.9%)	11 (12.9%)
No post-baseline score	n (%)	5 (6.1%)	4 (4.7%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	34 (41.5%)	41 (48.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.89, 10.68]	5.62 [3.25, 8.31]
	Median [95% CI]	13.90 [10.64, 28.85]	30.69 [8.31, NC]
	Q3 [95% CI]	NYR [24.08, NC]	NYR [38.90, NC]
	p-value[b][d]		0.540
	HR [95 % CI][c][d]		1.17 [0.70, 1.97]
	Heterogeneity p-value[e][d]		0.4484

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: White
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	65 (34.4%)	48 (25.4%)
Number of censored cases	n (%)	124 (65.6%)	141 (74.6%)
No baseline score	n (%)	20 (10.6%)	21 (11.1%)
No post-baseline score	n (%)	9 (4.8%)	10 (5.3%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	95 (50.3%)	109 (57.7%)
Time to first deterioration (months)	Q1 [95% CI]	6.34 [5.59, 10.68]	8.38 [5.59, 13.90]
	Median [95% CI]	29.73 [15.21, NC]	NYR [23.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.192
	HR [95 % CI][c][d]		1.28 [0.88, 1.87]
	Heterogeneity p-value[e][d]		0.1742

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	6 (30.0%)	9 (52.9%)
Number of censored cases	n (%)	14 (70.0%)	8 (47.1%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	2 (10.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	8 (40.0%)	8 (47.1%)
Time to first deterioration (months)	Q1 [95% CI]	12.63 [2.92, 24.08]	5.09 [2.79, 8.31]
	Median [95% CI]	24.08 [5.59, NC]	8.31 [3.09, NC]
	Q3 [95% CI]	NYR [17.87, NC]	NYR [8.31, NC]
	p-value[b][d]		0.158
	HR [95 % CI][c][d]		0.38 [0.10, 1.49]
	Heterogeneity p-value[e][d]		0.1742

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	58 (34.9%)	48 (27.1%)
Number of censored cases	n (%)	108 (65.1%)	129 (72.9%)
No baseline score	n (%)	20 (12.0%)	21 (11.9%)
No post-baseline score	n (%)	5 (3.0%)	8 (4.5%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	83 (50.0%)	99 (55.9%)
Time to first deterioration (months)	Q1 [95% CI]	6.34 [5.55, 10.78]	8.34 [5.09, 10.64]
	Median [95% CI]	27.17 [17.87, NC]	NYR [18.20, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.331
	HR [95 % CI][c][d]		1.21 [0.82, 1.77]
	Heterogeneity p-value[e][d]		0.8551

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	13 (30.2%)	9 (31.0%)
Number of censored cases	n (%)	30 (69.8%)	20 (69.0%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	6 (14.0%)	2 (6.9%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	20 (46.5%)	18 (62.1%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [2.83, 13.90]	8.31 [5.55, 23.95]
	Median [95% CI]	NYR [8.57, NC]	23.95 [8.31, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [23.95, NC]
	p-value[b][d]		0.816
	HR [95 % CI][c][d]		1.11 [0.46, 2.64]
	Heterogeneity p-value[e][d]		0.8551

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	40 (30.1%)	37 (28.2%)
Number of censored cases	n (%)	93 (69.9%)	94 (71.8%)
No baseline score	n (%)	16 (12.0%)	12 (9.2%)
No post-baseline score	n (%)	7 (5.3%)	7 (5.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	70 (52.6%)	75 (57.3%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.62, 14.49]	8.34 [5.59, 10.64]
	Median [95% CI]	35.29 [24.08, NC]	NYR [14.65, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.742
	HR [95 % CI][c][d]		1.07 [0.68, 1.69]
	Heterogeneity p-value[e][d]		0.5015

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	31 (40.8%)	20 (26.7%)
Number of censored cases	n (%)	45 (59.2%)	55 (73.3%)
No baseline score	n (%)	8 (10.5%)	9 (12.0%)
No post-baseline score	n (%)	4 (5.3%)	3 (4.0%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	33 (43.4%)	42 (56.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.02, 8.44]	5.59 [2.89, 17.77]
	Median [95% CI]	19.81 [8.44, NC]	30.69 [17.77, NC]
	Q3 [95% CI]	NYR [29.73, NC]	NYR [30.69, NC]
	p-value[b][d]		0.206
	HR [95 % CI][c][d]		1.46 [0.81, 2.64]
	Heterogeneity p-value[e][d]		0.5015

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	45 (36.0%)	29 (24.8%)
Number of censored cases	n (%)	80 (64.0%)	88 (75.2%)
No baseline score	n (%)	11 (8.8%)	13 (11.1%)
No post-baseline score	n (%)	9 (7.2%)	3 (2.6%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	60 (48.0%)	72 (61.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.62 [5.55, 10.68]	8.31 [5.55, 18.20]
	Median [95% CI]	27.17 [13.80, NC]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [35.29, NC]	NYR [NC, NC]
	p-value[b][d]		0.072
	HR [95 % CI][c][d]		1.54 [0.96, 2.48]
	Heterogeneity p-value[e][d]		0.2115

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	26 (31.0%)	28 (31.5%)
Number of censored cases	n (%)	58 (69.0%)	61 (68.5%)
No baseline score	n (%)	13 (15.5%)	8 (9.0%)
No post-baseline score	n (%)	2 (2.4%)	7 (7.9%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	43 (51.2%)	45 (50.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.57 [5.59, 11.07]	5.78 [2.86, 8.44]
	Median [95% CI]	37.06 [11.07, NC]	30.69 [9.82, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.650
	HR [95 % CI][c][d]		0.89 [0.51, 1.52]
	Heterogeneity p-value[e][d]		0.2115

Data cut-off as of October 4, 2024.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: <65
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	18 (32.1%)	22 (33.8%)
Number of censored participants, n (%)	38 (67.9%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.7525	
Hazard ratio(interaction)	1.166 (0.448, 3.036)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	53 (34.6%)	35 (24.8%)
Number of censored participants, n (%)	100 (65.4%)	106 (75.2%)
Proportionality Test p-value[a][b]	0.0855	
Hazard ratio(interaction)	0.584 (0.317, 1.078)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	18 (32.1%)	22 (33.8%)
Number of censored participants, n (%)	38 (67.9%)	43 (66.2%)
Proportionality Test p-value[a][b]	0.7525	
Hazard ratio(interaction)	1.166 (0.448, 3.036)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	25 (31.3%)	18 (26.1%)
Number of censored participants, n (%)	55 (68.8%)	51 (73.9%)
Proportionality Test p-value[a][b]	0.2818	
Hazard ratio(interaction)	0.613 (0.252, 1.494)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	28 (38.4%)	17 (23.6%)
Number of censored participants, n (%)	45 (61.6%)	55 (76.4%)
Proportionality Test p-value[a][b]	0.2565	
Hazard ratio(interaction)	0.591 (0.238, 1.466)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	59 (33.9%)	48 (27.6%)
Number of censored participants, n (%)	115 (66.1%)	126 (72.4%)
Proportionality Test p-value[a][b]	0.1299	
Hazard ratio(interaction)	0.666 (0.393, 1.127)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	12 (34.3%)	9 (28.1%)
Number of censored participants, n (%)	23 (65.7%)	23 (71.9%)
Proportionality Test p-value[a][b]	0.5579	
Hazard ratio(interaction)	0.687 (0.196, 2.408)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	7 (18.9%)	6 (19.4%)
Number of censored participants, n (%)	30 (81.1%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.1508	
Hazard ratio(interaction)	0.222 (0.029, 1.730)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	34 (37.8%)	23 (25.6%)
Number of censored participants, n (%)	56 (62.2%)	67 (74.4%)
Proportionality Test p-value[a][b]	0.7304	
Hazard ratio(interaction)	0.880 (0.425, 1.822)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	30 (36.6%)	28 (32.9%)
Number of censored participants, n (%)	52 (63.4%)	57 (67.1%)
Proportionality Test p-value[a][b]	0.3643	
Hazard ratio(interaction)	0.732 (0.373, 1.436)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: White
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	65 (34.4%)	48 (25.4%)
Number of censored participants, n (%)	124 (65.6%)	141 (74.6%)
Proportionality Test p-value[a][b]	0.2765	
Hazard ratio(interaction)	0.762 (0.468, 1.243)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	6 (30.0%)	9 (52.9%)
Number of censored participants, n (%)	14 (70.0%)	8 (47.1%)
Proportionality Test p-value[a][b]	0.3460	
Hazard ratio(interaction)	0.242 (0.013, 4.631)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	58 (34.9%)	48 (27.1%)
Number of censored participants, n (%)	108 (65.1%)	129 (72.9%)
Proportionality Test p-value[a][b]	0.0414	
Hazard ratio(interaction)	0.589 (0.354, 0.980)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	13 (30.2%)	9 (31.0%)
Number of censored participants, n (%)	30 (69.8%)	20 (69.0%)
Proportionality Test p-value[a][b]	0.2638	
Hazard ratio(interaction)	2.194 (0.553, 8.706)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	40 (30.1%)	37 (28.2%)
Number of censored participants, n (%)	93 (69.9%)	94 (71.8%)
Proportionality Test p-value[a][b]	0.1758	
Hazard ratio(interaction)	0.661 (0.362, 1.204)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	31 (40.8%)	20 (26.7%)
Number of censored participants, n (%)	45 (59.2%)	55 (73.3%)
Proportionality Test p-value[a][b]	0.1586	
Hazard ratio(interaction)	0.532 (0.222, 1.279)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	45 (36.0%)	29 (24.8%)
Number of censored participants, n (%)	80 (64.0%)	88 (75.2%)
Proportionality Test p-value[a][b]	0.2174	
Hazard ratio(interaction)	0.665 (0.347, 1.272)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

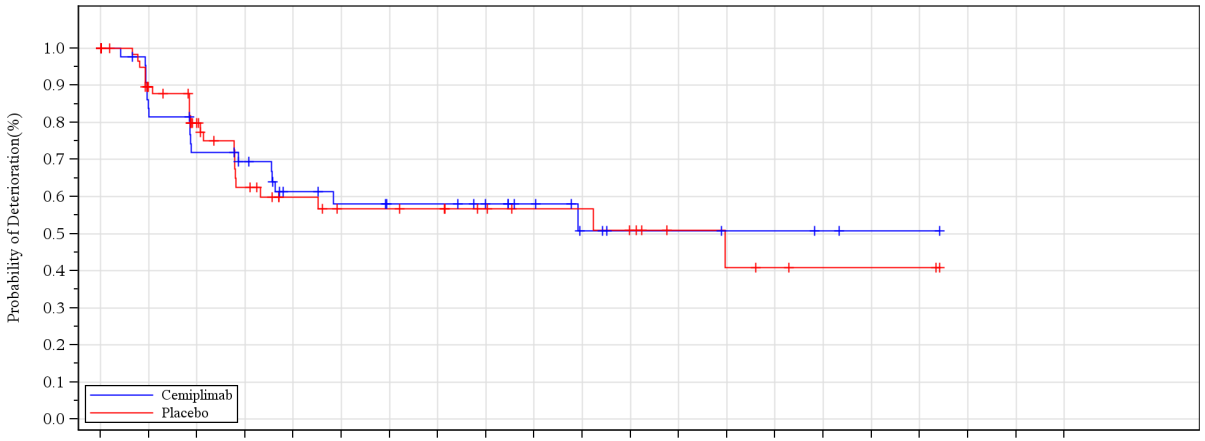
High risk feature: Non-Nodal
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	26 (31.0%)	28 (31.5%)
Number of censored participants, n (%)	58 (69.0%)	61 (68.5%)
Proportionality Test p-value[a][b]	0.1639	
Hazard ratio(interaction)	0.592 (0.283, 1.238)	

Data cut-off as of October 4, 2024.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: <65



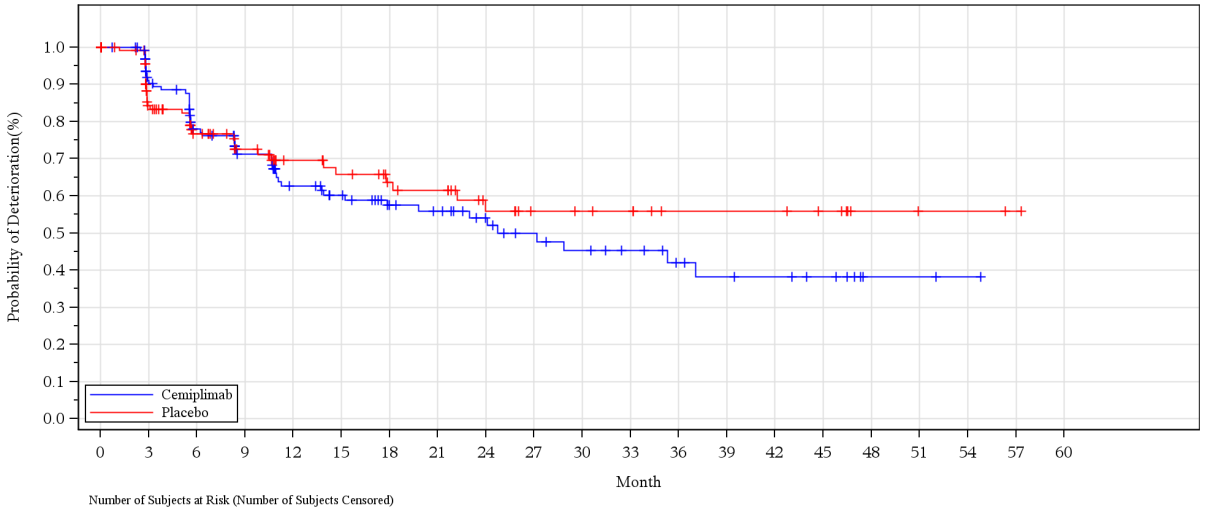
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	36 (13)	30 (14)	27 (16)	20 (20)	18 (21)	16 (23)	16 (23)	13 (26)	10 (29)	6 (32)	4 (34)	4 (34)	3 (35)	3 (35)	2 (36)	1 (37)	1 (37)	0 (38)	0 (38)	0 (38)
Placebo	65 (0)	47 (12)	36 (18)	25 (22)	19 (27)	16 (29)	16 (29)	15 (30)	12 (33)	10 (35)	10 (35)	8 (36)	5 (39)	4 (39)	3 (40)	2 (41)	2 (41)	2 (41)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

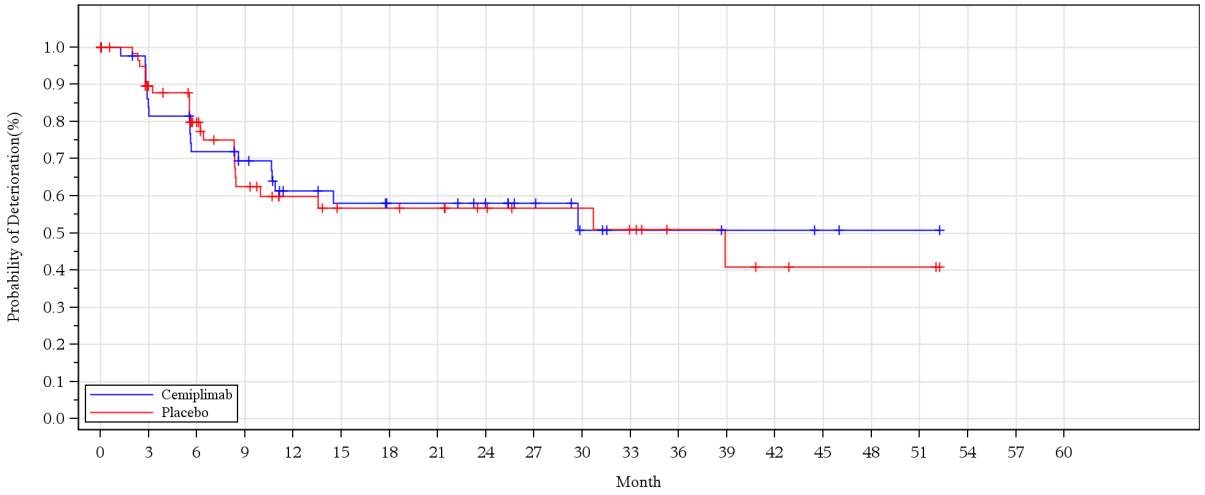
Cemiplimab	153 (0)	108 (34)	85 (42)	70 (50)	54 (58)	47 (63)	37 (71)	34 (73)	27 (79)	22 (82)	19 (83)	16 (86)	12 (89)	10 (90)	9 (91)	7 (93)	2 (98)	2 (98)	1 (99)	0 (100)	0 (100)
Placebo	141 (0)	85 (39)	63 (54)	50 (64)	39 (73)	35 (75)	29 (80)	27 (81)	19 (87)	15 (91)	14 (92)	13 (93)	9 (97)	9 (97)	9 (97)	7 (99)	3 (103)	2 (104)	2 (104)	1 (105)	0 (106)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

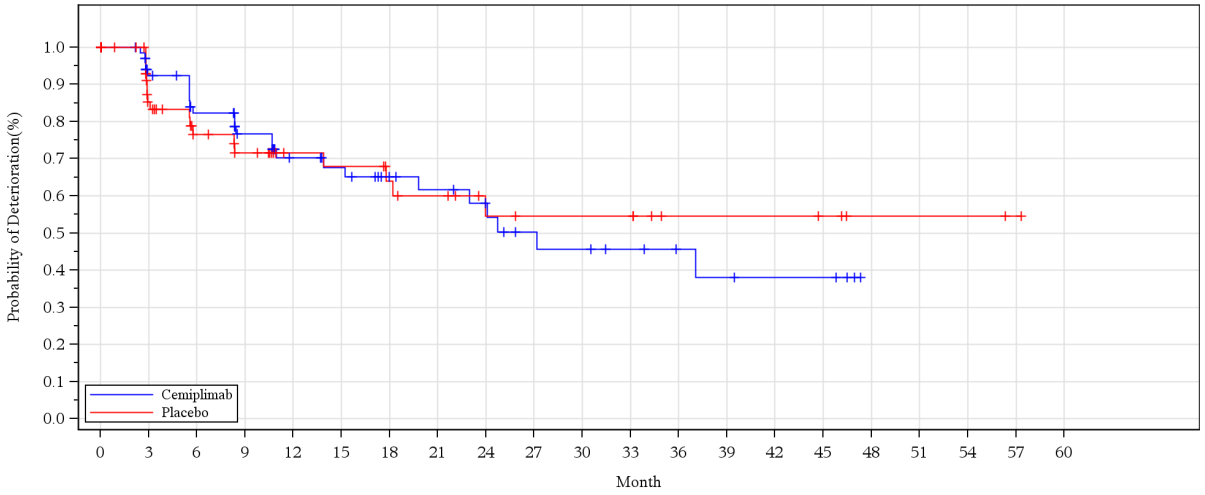
Cemiplimab	56 (0)	36 (13)	30 (14)	27 (16)	20 (20)	18 (21)	16 (23)	16 (23)	13 (26)	10 (29)	6 (32)	4 (34)	4 (34)	3 (35)	3 (35)	2 (36)	1 (37)	1 (37)	0 (38)	0 (38)	0 (38)
Placebo	65 (0)	47 (12)	36 (18)	25 (22)	19 (27)	16 (29)	16 (29)	15 (30)	12 (33)	10 (35)	10 (35)	8 (36)	5 (39)	4 (39)	3 (40)	2 (41)	2 (41)	2 (41)	0 (43)	0 (43)	0 (43)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

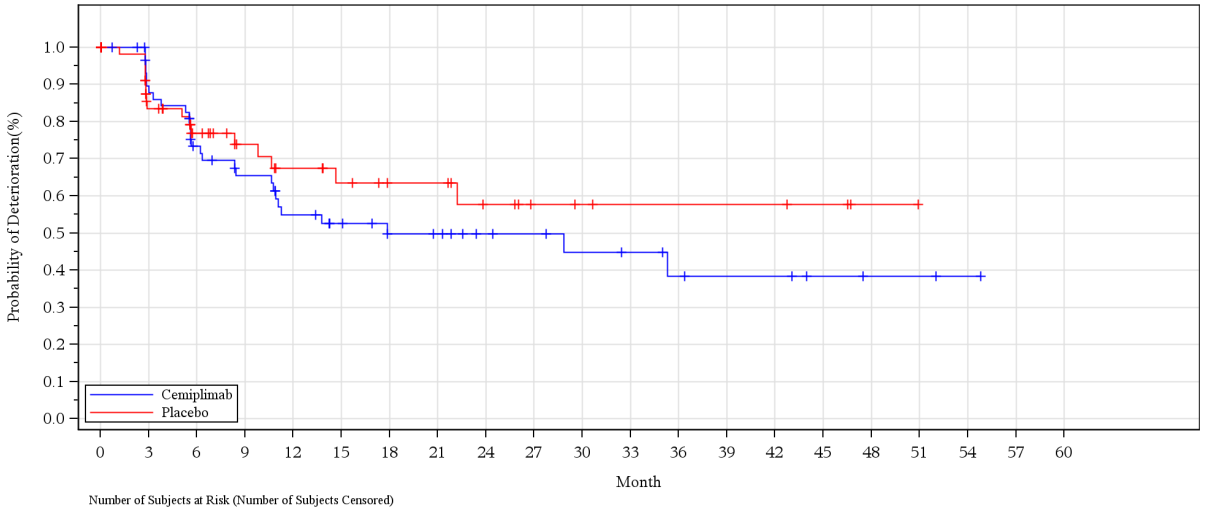
Cemiplimab	80 (0)	57 (18)	47 (22)	38 (28)	29 (34)	26 (36)	20 (41)	18 (42)	15 (44)	11 (46)	10 (46)	8 (48)	6 (50)	5 (50)	4 (51)	4 (51)	0 (55)	0 (55)	0 (55)	0 (55)	0 (55)
Placebo	69 (0)	43 (18)	32 (25)	27 (28)	20 (35)	19 (35)	16 (37)	14 (38)	10 (41)	9 (42)	9 (42)	9 (42)	5 (46)	5 (46)	5 (46)	4 (47)	2 (49)	2 (49)	2 (49)	1 (50)	0 (51)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

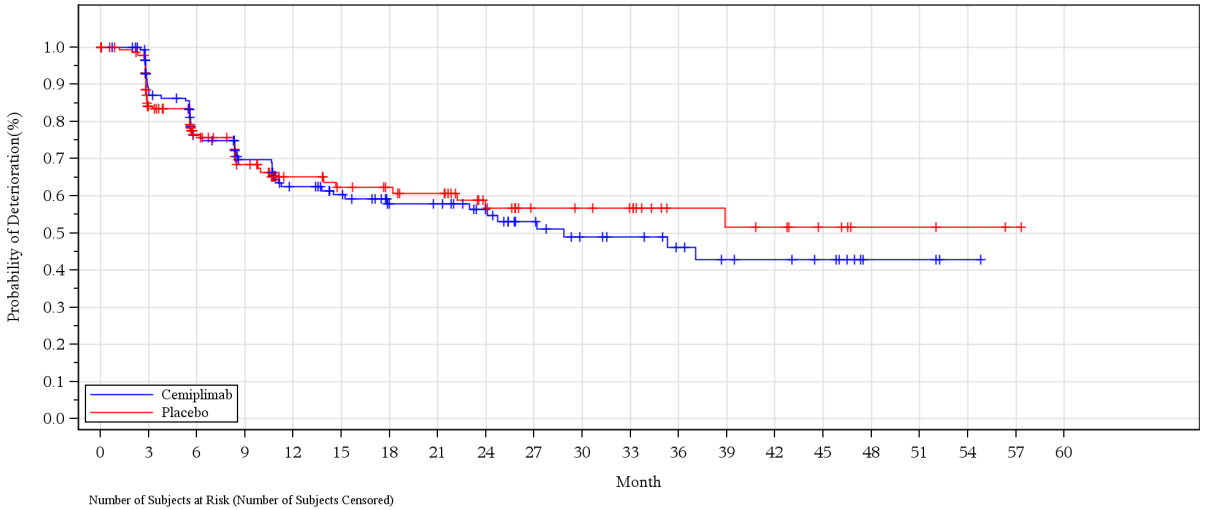
Cemiplimab	73 (0)	51 (16)	38 (20)	32 (22)	25 (24)	21 (27)	17 (30)	16 (31)	12 (35)	11 (36)	9 (37)	8 (38)	6 (39)	5 (40)	5 (40)	3 (42)	2 (43)	2 (43)	1 (44)	0 (45)	0 (45)
Placebo	72 (0)	42 (21)	31 (29)	23 (36)	19 (38)	16 (40)	13 (43)	13 (43)	9 (46)	6 (49)	5 (50)	4 (51)	4 (51)	4 (51)	4 (51)	3 (52)	1 (54)	0 (55)	0 (55)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Gender group: Male



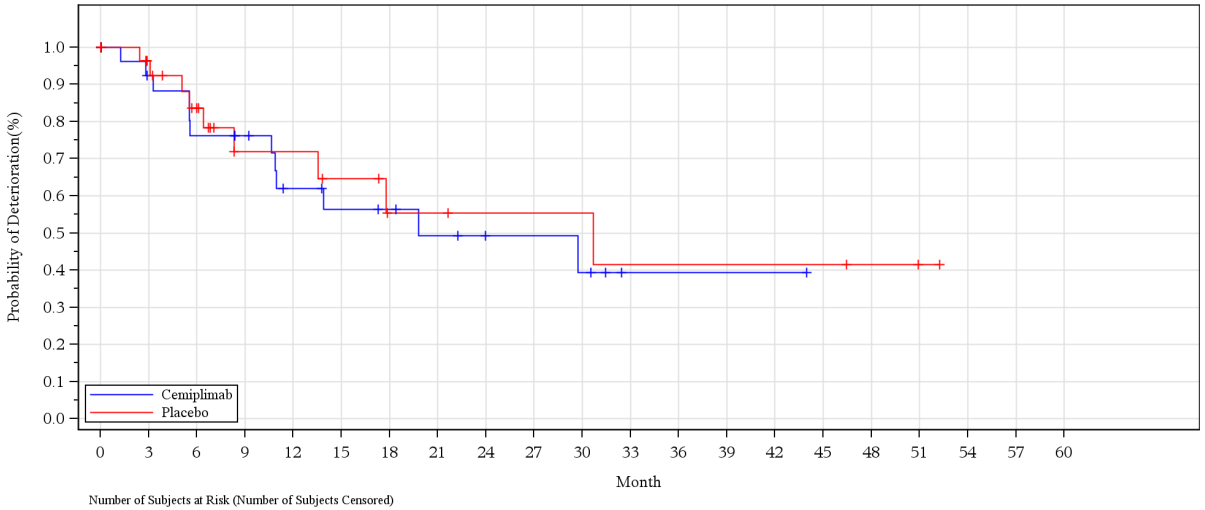
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	121 (37)	96 (46)	80 (54)	62 (64)	55 (69)	44 (78)	43 (79)	35 (86)	27 (92)	21 (96)	19 (98)	15 (101)	12 (103)	11 (104)	9 (106)	3 (112)	3 (112)	1 (114)	0 (115)	0 (115)
Placebo	174 (0)	108 (44)	81 (62)	65 (70)	48 (84)	43 (87)	40 (90)	37 (92)	27 (100)	21 (106)	20 (107)	18 (109)	11 (116)	10 (116)	9 (117)	6 (120)	3 (123)	3 (123)	2 (124)	1 (125)	0 (126)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

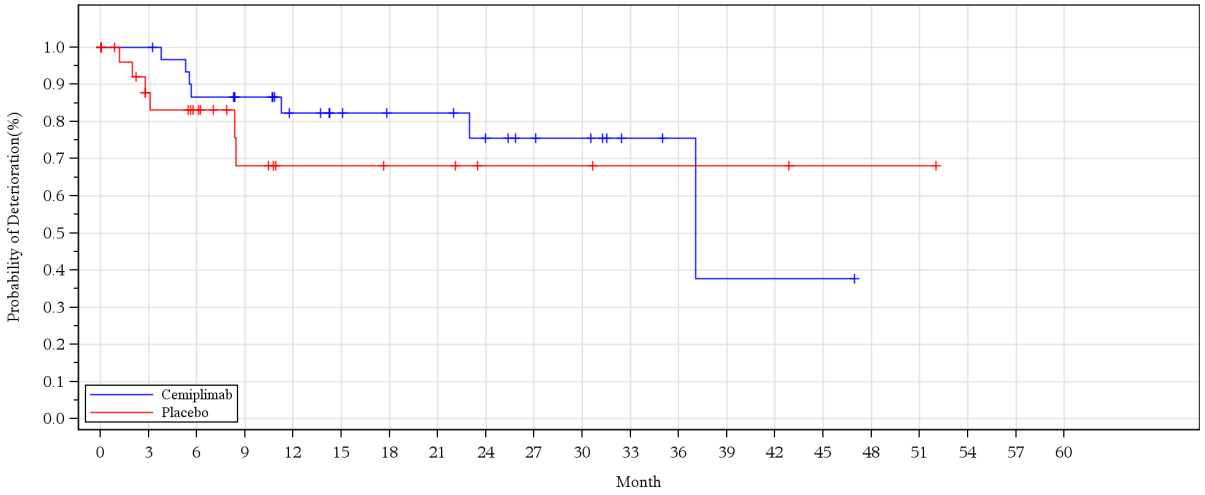
Cemiplimab	35 (0)	23 (10)	19 (10)	17 (12)	12 (14)	10 (15)	9 (16)	7 (17)	5 (19)	5 (19)	4 (19)	1 (22)	1 (22)	1 (22)	1 (22)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)	0 (23)
Placebo	32 (0)	24 (7)	18 (10)	10 (16)	10 (16)	8 (17)	5 (19)	5 (19)	4 (20)	4 (20)	4 (20)	3 (20)	3 (20)	3 (20)	3 (20)	3 (20)	2 (21)	1 (22)	0 (23)	0 (23)	0 (23)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

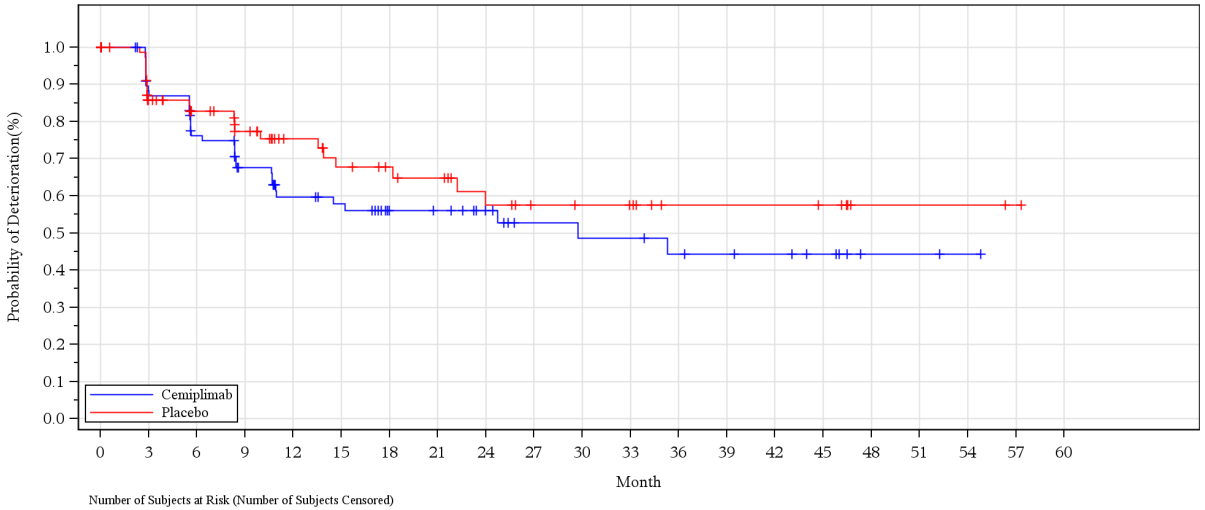
Cemiplimab	37 (0)	31 (6)	26 (7)	23 (10)	18 (14)	15 (17)	13 (19)	13 (19)	10 (21)	8 (23)	7 (24)	3 (28)	2 (29)	1 (29)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)	0 (30)	0 (30)
Placebo	31 (0)	19 (9)	15 (12)	9 (16)	6 (19)	6 (19)	5 (20)	5 (20)	3 (22)	3 (22)	3 (22)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)	0 (25)	0 (25)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

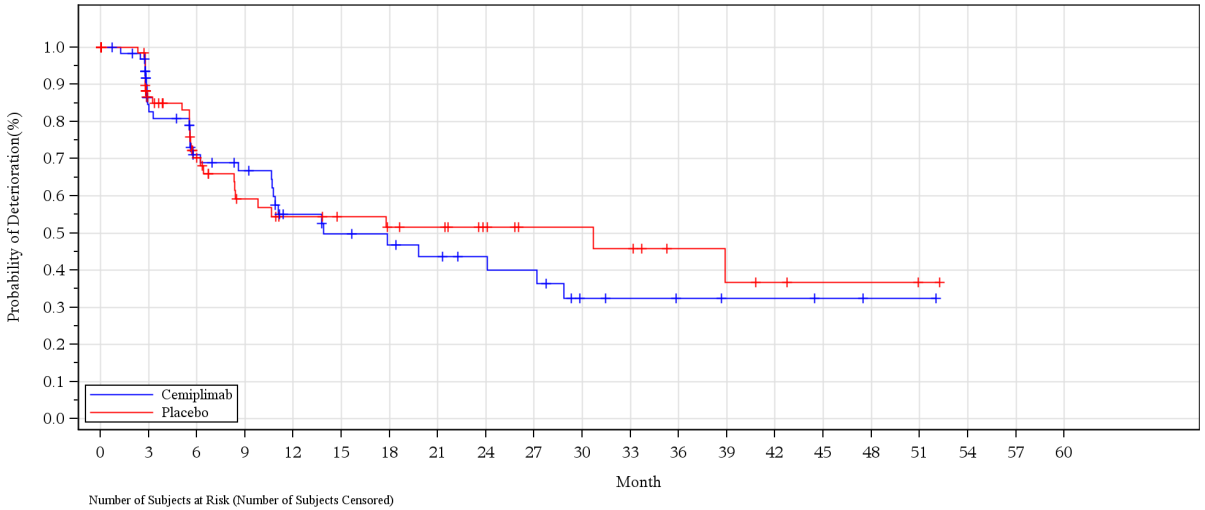
Cemiplimab	90 (0)	67 (14)	55 (17)	44 (22)	35 (26)	32 (28)	24 (35)	23 (36)	18 (41)	13 (45)	12 (45)	12 (45)	10 (46)	9 (47)	8 (48)	6 (50)	2 (54)	2 (54)	1 (55)	0 (56)	0 (56)
Placebo	90 (0)	61 (18)	49 (28)	41 (33)	31 (42)	26 (44)	23 (47)	21 (48)	16 (51)	13 (54)	12 (55)	11 (56)	7 (60)	7 (60)	7 (60)	6 (61)	2 (65)	2 (65)	2 (65)	1 (66)	0 (67)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

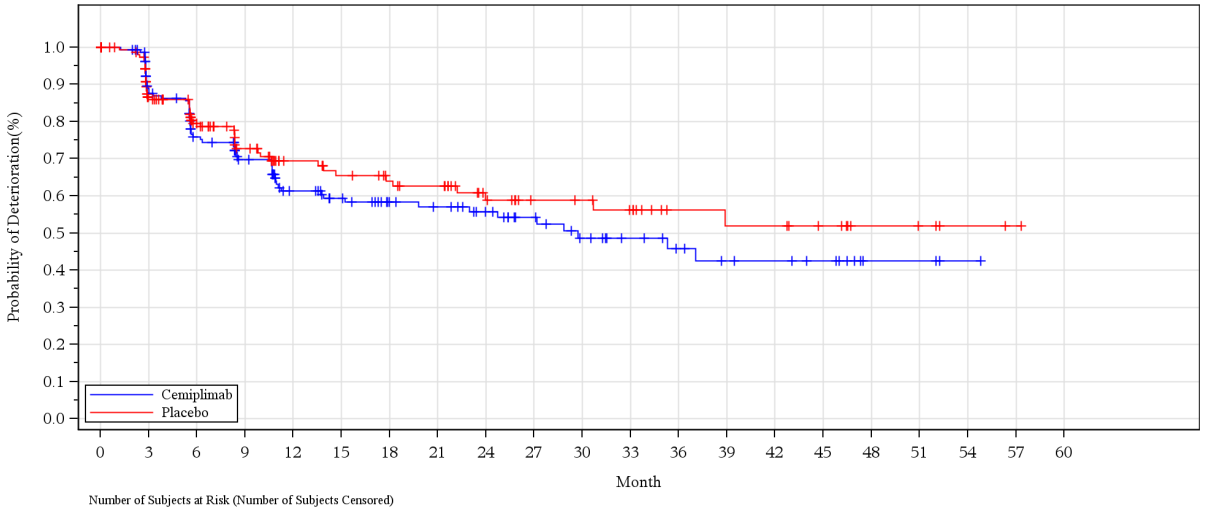
Cemiplimab	82 (0)	46 (27)	34 (32)	30 (34)	21 (38)	18 (39)	16 (40)	14 (41)	12 (43)	11 (43)	6 (46)	5 (47)	4 (48)	3 (49)	3 (49)	2 (50)	1 (51)	1 (51)	0 (52)	0 (52)	0 (52)
Placebo	85 (0)	52 (24)	35 (32)	25 (37)	21 (39)	19 (41)	17 (42)	16 (43)	12 (47)	9 (50)	9 (50)	8 (50)	5 (53)	4 (53)	3 (54)	2 (55)	2 (55)	1 (56)	0 (57)	0 (57)	0 (57)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

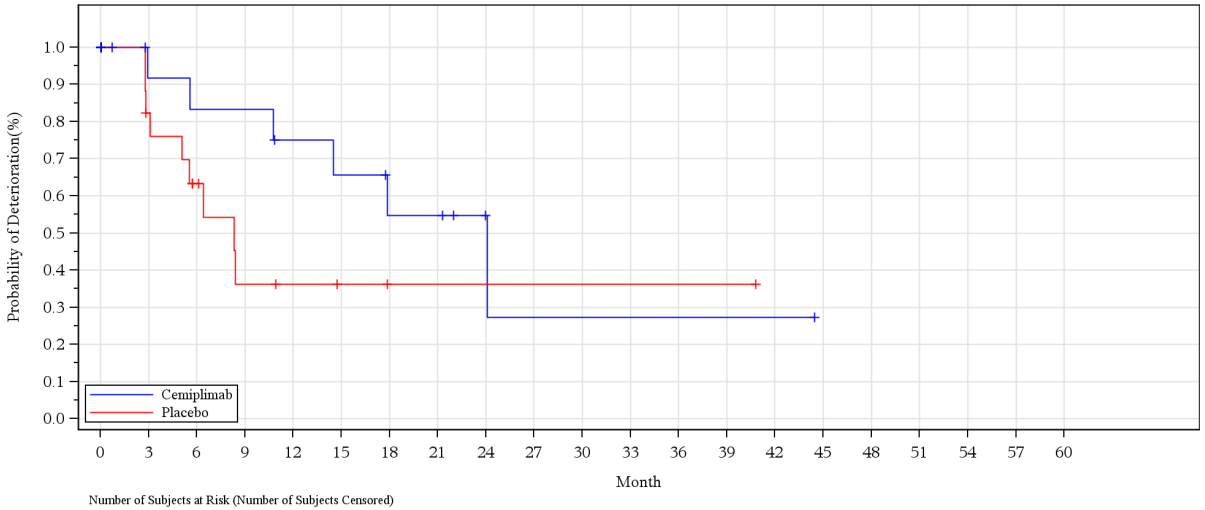
Cemiplimab	189 (0)	133 (39)	105 (48)	87 (58)	66 (69)	58 (75)	48 (84)	45 (86)	38 (92)	31 (98)	24 (102)	19 (107)	15 (110)	12 (112)	11 (113)	9 (115)	3 (121)	3 (121)	1 (123)	0 (124)	0 (124)
Placebo	189 (0)	119 (50)	91 (69)	71 (82)	55 (95)	49 (98)	44 (102)	41 (104)	30 (113)	24 (119)	23 (120)	20 (122)	13 (129)	12 (129)	12 (129)	9 (132)	5 (136)	4 (137)	2 (139)	1 (140)	0 (141)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

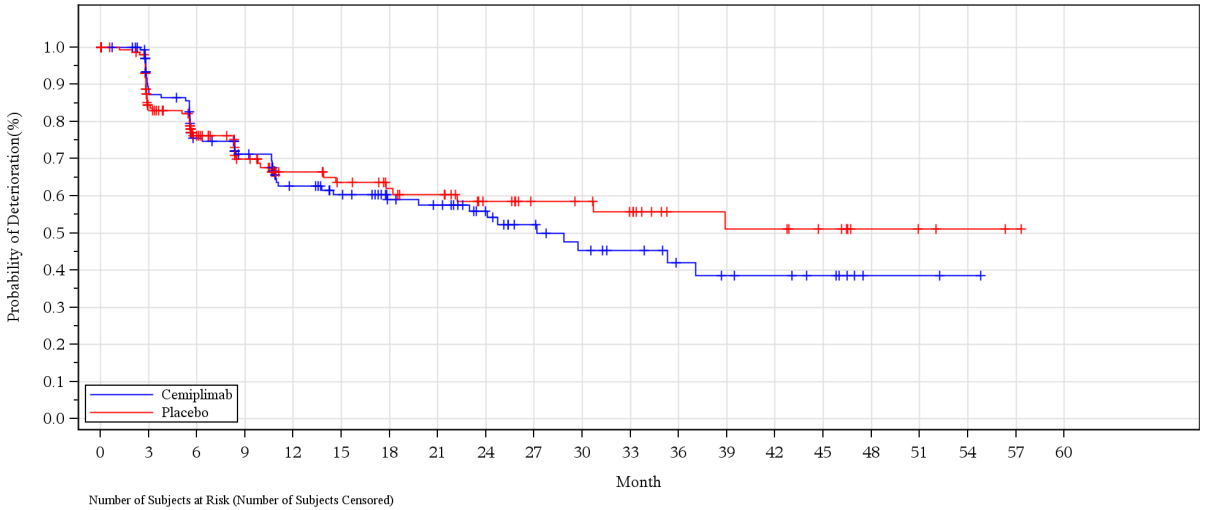
Cemiplimab	20 (0)	11 (8)	10 (8)	10 (8)	8 (9)	7 (9)	5 (10)	5 (10)	2 (13)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	1 (13)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)	0 (14)
Placebo	17 (0)	13 (1)	8 (3)	4 (4)	3 (5)	2 (6)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	1 (7)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

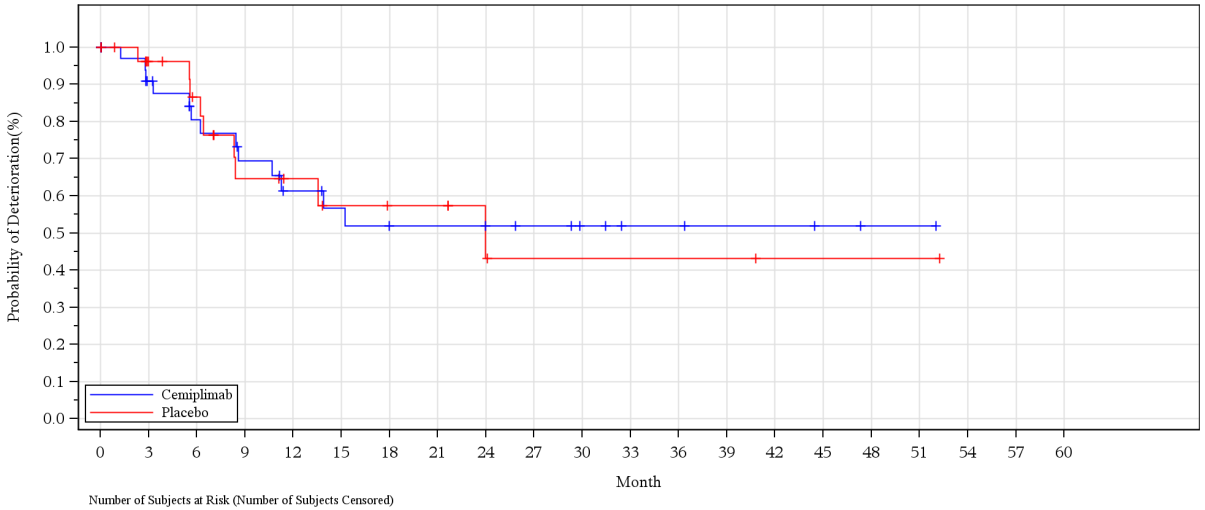
Cemiplimab	166 (0)	116 (35)	93 (41)	79 (50)	60 (60)	53 (65)	43 (74)	40 (76)	31 (84)	24 (89)	19 (91)	16 (94)	12 (97)	10 (98)	9 (99)	7 (101)	2 (106)	2 (106)	1 (107)	0 (108)	0 (108)
Placebo	177 (0)	111 (44)	82 (63)	64 (75)	49 (87)	44 (90)	39 (94)	36 (96)	28 (103)	23 (108)	22 (109)	19 (111)	12 (118)	11 (118)	11 (118)	8 (121)	4 (125)	3 (126)	2 (127)	1 (128)	0 (129)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

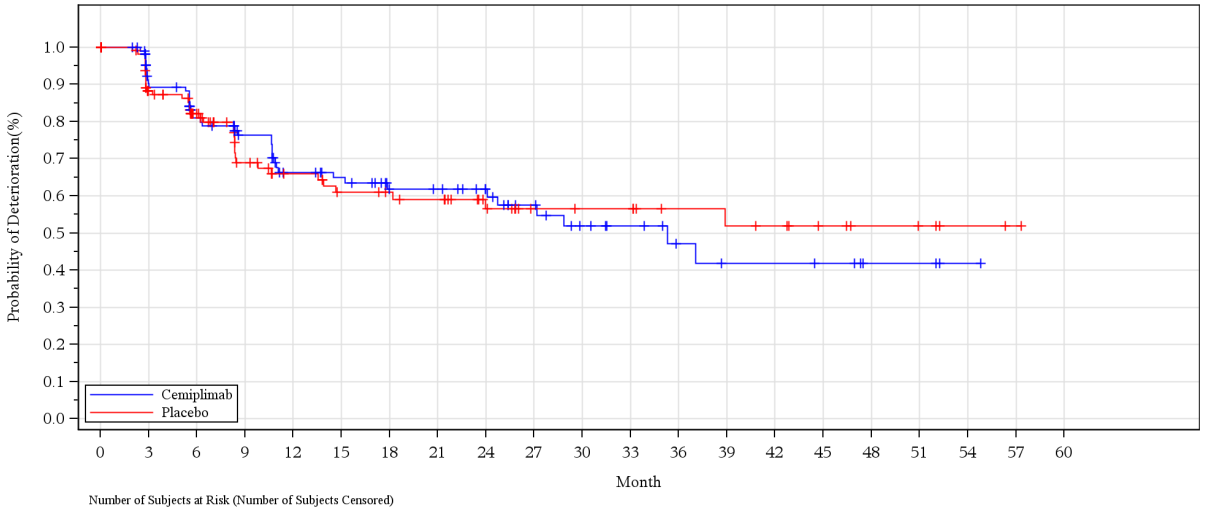
Cemiplimab	43 (0)	28 (12)	22 (15)	18 (16)	14 (18)	12 (19)	10 (20)	10 (20)	9 (21)	8 (22)	6 (24)	4 (26)	4 (26)	3 (27)	3 (27)	2 (28)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)
Placebo	29 (0)	21 (7)	17 (9)	11 (11)	9 (13)	7 (14)	6 (15)	6 (15)	3 (17)	2 (18)	2 (18)	2 (18)	2 (18)	2 (18)	1 (19)	1 (19)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

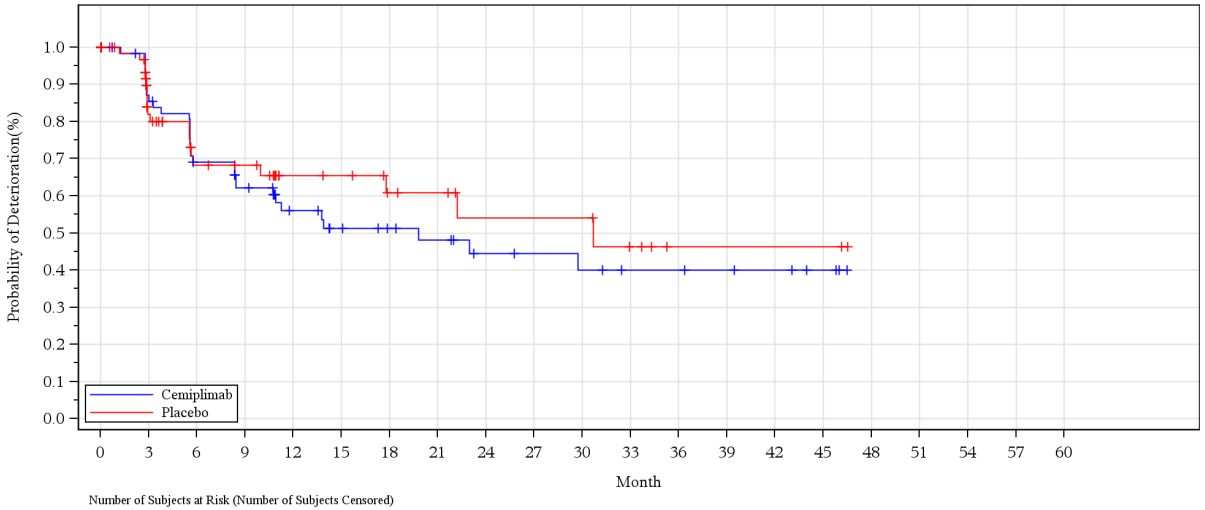
Cemiplimab	133 (0)	90 (33)	74 (40)	62 (48)	49 (53)	45 (56)	36 (63)	35 (64)	29 (70)	22 (75)	16 (79)	13 (82)	9 (85)	7 (86)	7 (86)	6 (87)	3 (90)	3 (90)	1 (92)	0 (93)	0 (93)
Placebo	131 (0)	91 (27)	71 (41)	49 (53)	41 (59)	35 (62)	33 (64)	31 (65)	23 (72)	17 (78)	16 (79)	16 (79)	12 (83)	11 (83)	10 (84)	7 (87)	5 (89)	4 (90)	2 (92)	1 (93)	0 (94)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

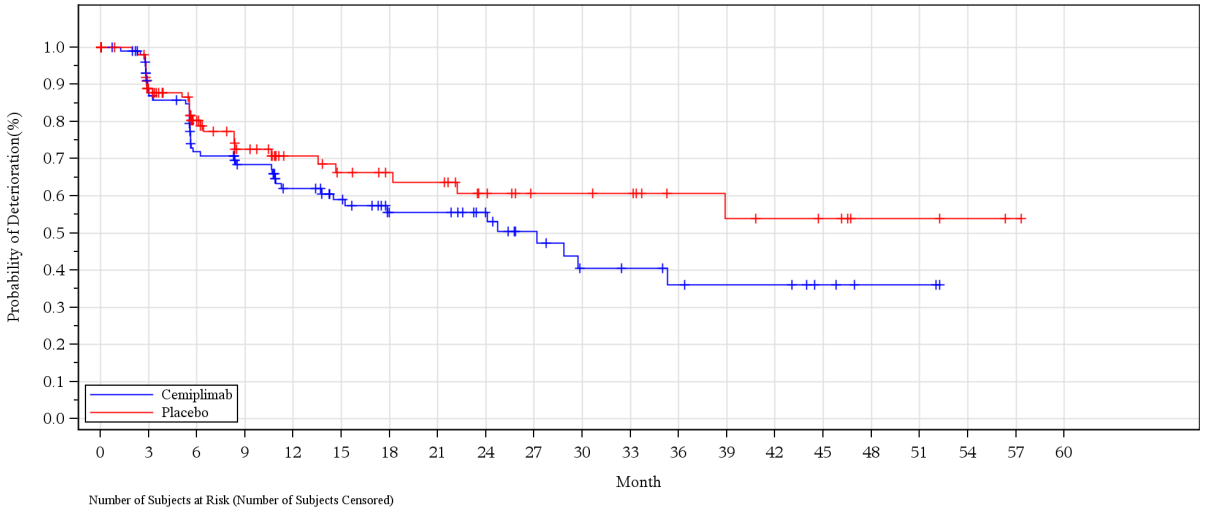
Cemiplimab	76 (0)	54 (14)	41 (16)	35 (18)	25 (25)	20 (28)	17 (31)	15 (32)	11 (35)	10 (36)	9 (36)	7 (38)	7 (38)	6 (39)	5 (40)	3 (42)	0 (45)	0 (45)	0 (45)	0 (45)	0 (45)
Placebo	75 (0)	41 (24)	28 (31)	26 (33)	17 (41)	16 (42)	12 (45)	11 (46)	8 (48)	8 (48)	8 (48)	5 (50)	2 (53)	2 (53)	2 (53)	2 (53)	0 (55)	0 (55)	0 (55)	0 (55)	0 (55)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

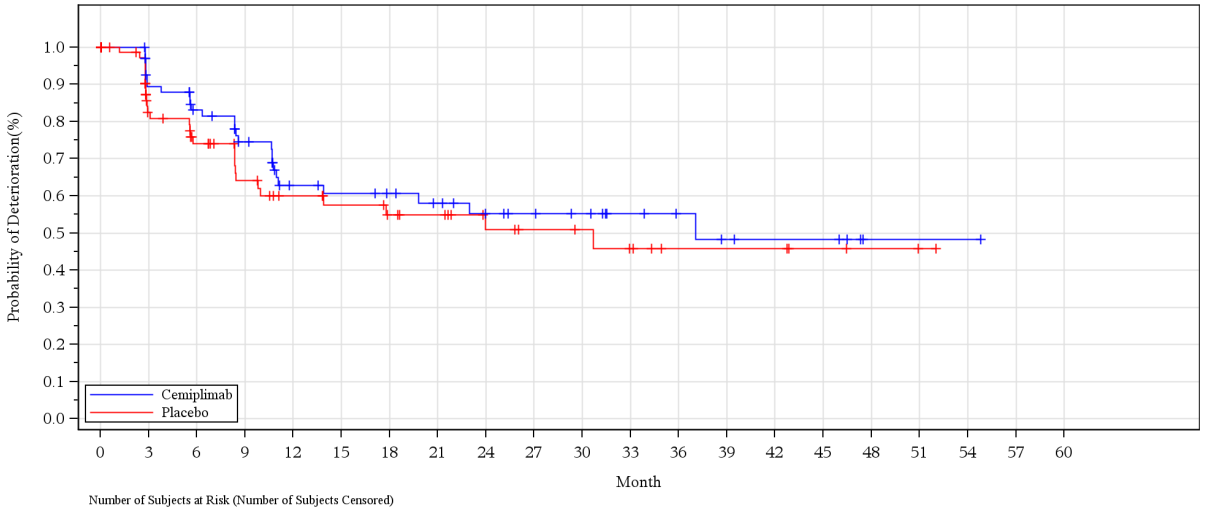
Cemiplimab	125 (0)	86 (28)	65 (33)	56 (39)	45 (45)	38 (50)	28 (58)	28 (58)	22 (64)	16 (68)	11 (70)	10 (71)	8 (72)	7 (73)	7 (73)	4 (76)	2 (78)	2 (78)	0 (80)	0 (80)	0 (80)
Placebo	117 (0)	81 (25)	57 (42)	43 (51)	32 (61)	28 (63)	25 (66)	24 (66)	18 (71)	14 (75)	14 (75)	13 (76)	9 (80)	8 (80)	7 (81)	6 (82)	3 (85)	3 (85)	2 (86)	1 (87)	0 (88)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	58 (19)	50 (23)	41 (27)	29 (33)	27 (34)	25 (36)	22 (38)	18 (41)	16 (43)	14 (45)	10 (49)	8 (51)	6 (52)	5 (53)	5 (53)	1 (57)	1 (57)	1 (57)	0 (58)	0 (58)
Placebo	89 (0)	51 (26)	42 (30)	32 (35)	26 (39)	23 (41)	20 (43)	18 (45)	13 (49)	11 (51)	10 (52)	8 (53)	5 (56)	5 (56)	5 (56)	3 (58)	2 (59)	1 (60)	0 (61)	0 (61)	0 (61)

Data cut-off as of October 4, 2024.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Oct2024/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

2.8.2 2. Datenschnitt

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: <65
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	31 (47.7%)
Number of censored cases	n (%)	27 (48.2%)	34 (52.3%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	1 (1.8%)	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (30.4%)	29 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.79, 5.62]	5.55 [2.79, 5.82]
	Median [95% CI]	10.64 [5.59, 25.59]	9.95 [5.82, NC]
	Q3 [95% CI]	NYR [21.68, NC]	NYR [38.90, NC]
	p-value[b][d]		0.301
	HR [95 % CI][c][d]		1.31 [0.78, 2.23]
	Heterogeneity p-value[e][d]		0.7235

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	85 (55.6%)	60 (42.6%)
Number of censored cases	n (%)	68 (44.4%)	81 (57.4%)
No baseline score	n (%)	15 (9.8%)	16 (11.3%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	50 (32.7%)	60 (42.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.92, 5.62]	3.88 [2.86, 5.65]
	Median [95% CI]	11.27 [8.34, 19.58]	14.52 [10.87, 22.47]
	Q3 [95% CI]	34.96 [28.85, NC]	NYR [33.35, NC]
	p-value[b][d]		0.277
	HR [95 % CI][c][d]		1.20 [0.86, 1.69]
	Heterogeneity p-value[e][d]		0.7235

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	29 (51.8%)	31 (47.7%)
Number of censored cases	n (%)	27 (48.2%)	34 (52.3%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	1 (1.8%)	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (30.4%)	29 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.89 [2.79, 5.62]	5.55 [2.79, 5.82]
	Median [95% CI]	10.64 [5.59, 25.59]	9.95 [5.82, NC]
	Q3 [95% CI]	NYR [21.68, NC]	NYR [38.90, NC]
	p-value[b][d]		0.301
	HR [95 % CI][c][d]		1.31 [0.78, 2.23]
	Heterogeneity p-value[e][d]		0.6034

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	42 (52.5%)	31 (44.9%)
Number of censored cases	n (%)	38 (47.5%)	38 (55.1%)
No baseline score	n (%)	8 (10.0%)	9 (13.0%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	29 (36.3%)	29 (42.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.89, 8.28]	3.84 [2.86, 8.44]
	Median [95% CI]	13.90 [8.34, 30.62]	14.36 [8.44, 23.95]
	Q3 [95% CI]	34.96 [30.16, NC]	NYR [18.20, NC]
	p-value[b][d]		0.982
	HR [95 % CI][c][d]		0.99 [0.61, 1.63]
	Heterogeneity p-value[e][d]		0.6034

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	43 (58.9%)	29 (40.3%)
Number of censored cases	n (%)	30 (41.1%)	43 (59.7%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	21 (28.8%)	31 (43.1%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.86, 5.65]	3.88 [2.83, 8.34]
	Median [95% CI]	8.44 [5.98, 13.80]	21.65 [8.34, NC]
	Q3 [95% CI]	28.85 [13.80, NC]	NYR [33.35, NC]
	p-value[b][d]		0.242
	HR [95 % CI][c][d]		1.33 [0.81, 2.18]
	Heterogeneity p-value[e][d]		0.6034

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	95 (54.6%)	75 (43.1%)
Number of censored cases	n (%)	79 (45.4%)	99 (56.9%)
No baseline score	n (%)	20 (11.5%)	16 (9.2%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	57 (32.8%)	77 (44.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.25 [2.89, 5.59]	3.84 [2.86, 5.62]
	Median [95% CI]	10.97 [8.34, 16.59]	14.36 [9.82, 33.35]
	Q3 [95% CI]	37.06 [28.81, NC]	NYR [NC, NC]
	p-value[b][d]		0.146
	HR [95 % CI][c][d]		1.25 [0.92, 1.69]
	Heterogeneity p-value[e][d]		0.9875

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	19 (54.3%)	16 (50.0%)
Number of censored cases	n (%)	16 (45.7%)	16 (50.0%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	2 (5.7%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	10 (28.6%)	12 (37.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.55 [2.83, 5.65]	5.55 [2.79, 8.31]
	Median [95% CI]	13.90 [5.55, 30.16]	8.44 [5.65, 30.69]
	Q3 [95% CI]	30.16 [25.59, NC]	30.69 [17.77, NC]
	p-value[b][d]		0.377
	HR [95 % CI][c][d]		1.39 [0.67, 2.87]
	Heterogeneity p-value[e][d]		0.9875

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	15 (40.5%)	13 (41.9%)
Number of censored cases	n (%)	22 (59.5%)	18 (58.1%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	17 (45.9%)	13 (41.9%)
Time to first deterioration (months)	Q1 [95% CI]	6.97 [2.86, 27.07]	2.79 [1.18, 5.82]
	Median [95% CI]	30.16 [11.27, NC]	8.21 [3.09, NC]
	Q3 [95% CI]	37.06 [37.06, NC]	NYR [11.27, NC]
	p-value[b][d]		0.167
	HR [95 % CI][c][d]		0.58 [0.26, 1.26]
	Heterogeneity p-value[e][d]		0.0655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	53 (58.9%)	37 (41.1%)
Number of censored cases	n (%)	37 (41.1%)	53 (58.9%)
No baseline score	n (%)	7 (7.8%)	5 (5.6%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	29 (32.2%)	45 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.86, 5.65]	5.59 [2.89, 9.95]
	Median [95% CI]	10.91 [8.34, 19.58]	17.74 [11.40, NC]
	Q3 [95% CI]	30.62 [21.68, NC]	NYR [NC, NC]
	p-value[b][d]		0.115
	HR [95 % CI][c][d]		1.40 [0.92, 2.14]
	Heterogeneity p-value[e][d]		0.0655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	46 (56.1%)	41 (48.2%)
Number of censored cases	n (%)	36 (43.9%)	44 (51.8%)
No baseline score	n (%)	13 (15.9%)	11 (12.9%)
No post-baseline score	n (%)	2 (2.4%)	1 (1.2%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	21 (25.6%)	31 (36.5%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.83, 5.59]	3.48 [2.79, 5.65]
	Median [95% CI]	8.31 [5.59, 13.80]	10.87 [5.65, 30.69]
	Q3 [95% CI]	28.85 [13.80, NC]	NYR [30.69, NC]
	p-value[b][d]		0.140
	HR [95 % CI][c][d]		1.37 [0.89, 2.09]
	Heterogeneity p-value[e][d]		0.0655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: White
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	103 (54.5%)	77 (40.7%)
Number of censored cases	n (%)	86 (45.5%)	112 (59.3%)
No baseline score	n (%)	20 (10.6%)	20 (10.6%)
No post-baseline score	n (%)	3 (1.6%)	5 (2.6%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	63 (33.3%)	86 (45.5%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.89, 5.59]	5.55 [2.89, 5.82]
	Median [95% CI]	11.27 [8.34, 19.58]	17.77 [11.27, 33.35]
	Q3 [95% CI]	37.06 [28.81, NC]	NYR [NC, NC]
	p-value[b][d]		0.075
	HR [95 % CI][c][d]		1.31 [0.97, 1.77]
	Heterogeneity p-value[e][d]		0.3474

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	11 (55.0%)	14 (82.4%)
Number of censored cases	n (%)	9 (45.0%)	3 (17.6%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	4 (20.0%)	3 (17.6%)
Time to first deterioration (months)	Q1 [95% CI]	2.92 [2.79, 5.68]	3.09 [2.79, 5.65]
	Median [95% CI]	10.97 [2.83, NC]	5.65 [2.83, 13.63]
	Q3 [95% CI]	30.16 [10.97, NC]	13.63 [5.65, NC]
	p-value[b][d]		0.725
	HR [95 % CI][c][d]		0.83 [0.31, 2.27]
	Heterogeneity p-value[e][d]		0.3474

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	90 (54.2%)	73 (41.2%)
Number of censored cases	n (%)	76 (45.8%)	104 (58.8%)
No baseline score	n (%)	20 (12.0%)	20 (11.3%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	54 (32.5%)	79 (44.6%)
Time to first deterioration (months)	Q1 [95% CI]	3.78 [2.89, 5.59]	5.09 [2.86, 5.65]
	Median [95% CI]	10.97 [8.34, 21.68]	17.74 [10.87, 38.90]
	Q3 [95% CI]	37.06 [27.73, NC]	NYR [NC, NC]
	p-value[b][d]		0.073
	HR [95 % CI][c][d]		1.32 [0.97, 1.81]
	Heterogeneity p-value[e][d]		0.3715

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	24 (55.8%)	18 (62.1%)
Number of censored cases	n (%)	19 (44.2%)	11 (37.9%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	2 (4.7%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	13 (30.2%)	10 (34.5%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.79, 5.65]	5.55 [2.79, 6.41]
	Median [95% CI]	11.30 [5.62, 30.16]	8.31 [5.55, 21.78]
	Q3 [95% CI]	34.96 [13.83, NC]	21.78 [8.31, NC]
	p-value[b][d]		0.900
	HR [95 % CI][c][d]		0.96 [0.51, 1.80]
	Heterogeneity p-value[e][d]		0.3715

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	70 (52.6%)	58 (44.3%)
Number of censored cases	n (%)	63 (47.4%)	73 (55.7%)
No baseline score	n (%)	16 (12.0%)	12 (9.2%)
No post-baseline score	n (%)	2 (1.5%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	45 (33.8%)	60 (45.8%)
Time to first deterioration (months)	Q1 [95% CI]	5.29 [2.89, 5.65]	5.59 [2.86, 6.51]
	Median [95% CI]	12.52 [8.34, 27.17]	13.90 [9.33, NC]
	Q3 [95% CI]	37.06 [28.85, NC]	NYR [NC, NC]
	p-value[b][d]		0.198
	HR [95 % CI][c][d]		1.26 [0.88, 1.79]
	Heterogeneity p-value[e][d]		0.7158

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	44 (57.9%)	33 (44.0%)
Number of censored cases	n (%)	32 (42.1%)	42 (56.0%)
No baseline score	n (%)	8 (10.5%)	8 (10.7%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	22 (28.9%)	29 (38.7%)
Time to first deterioration (months)	Q1 [95% CI]	3.29 [2.83, 5.59]	2.89 [2.83, 5.55]
	Median [95% CI]	8.44 [5.59, 19.58]	14.36 [5.55, 21.78]
	Q3 [95% CI]	30.62 [19.58, NC]	30.69 [21.65, NC]
	p-value[b][d]		0.587
	HR [95 % CI][c][d]		1.13 [0.70, 1.84]
	Heterogeneity p-value[e][d]		0.7158

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	73 (58.4%)	50 (42.7%)
Number of censored cases	n (%)	52 (41.6%)	67 (57.3%)
No baseline score	n (%)	11 (8.8%)	12 (10.3%)
No post-baseline score	n (%)	3 (2.4%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	38 (30.4%)	53 (45.3%)
Time to first deterioration (months)	Q1 [95% CI]	3.25 [2.86, 5.59]	5.09 [2.86, 5.65]
	Median [95% CI]	10.91 [5.68, 14.23]	13.63 [8.31, NC]
	Q3 [95% CI]	28.85 [21.68, NC]	NYR [NC, NC]
	p-value[b][d]		0.099
	HR [95 % CI][c][d]		1.35 [0.94, 1.96]
	Heterogeneity p-value[e][d]		0.3661

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.1.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 7)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	41 (48.8%)	41 (46.1%)
Number of censored cases	n (%)	43 (51.2%)	48 (53.9%)
No baseline score	n (%)	13 (15.5%)	8 (9.0%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	29 (34.5%)	36 (40.4%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [2.86, 8.31]	3.88 [2.83, 5.82]
	Median [95% CI]	13.90 [8.31, 31.54]	14.36 [8.34, 30.69]
	Q3 [95% CI]	NYR [31.54, NC]	NYR [23.95, NC]
	p-value[b][d]		0.850
	HR [95 % CI][c][d]		1.05 [0.67, 1.64]
	Heterogeneity p-value[e][d]		0.3661

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: <65
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	31 (47.7%)
Number of censored participants, n (%)	27 (48.2%)	34 (52.3%)
Proportionality Test p-value[a][b]	0.7564	
Hazard ratio(interaction)	1.110 (0.573, 2.152)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	85 (55.6%)	60 (42.6%)
Number of censored participants, n (%)	68 (44.4%)	81 (57.4%)
Proportionality Test p-value[a][b]	0.2933	
Hazard ratio(interaction)	0.783 (0.496, 1.236)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	29 (51.8%)	31 (47.7%)
Number of censored participants, n (%)	27 (48.2%)	34 (52.3%)
Proportionality Test p-value[a][b]	0.7564	
Hazard ratio(interaction)	1.110 (0.573, 2.152)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	42 (52.5%)	31 (44.9%)
Number of censored participants, n (%)	38 (47.5%)	38 (55.1%)
Proportionality Test p-value[a][b]	0.9125	
Hazard ratio(interaction)	1.036 (0.550, 1.954)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	43 (58.9%)	29 (40.3%)
Number of censored participants, n (%)	30 (41.1%)	43 (59.7%)
Proportionality Test p-value[a][b]	0.1627	
Hazard ratio(interaction)	0.614 (0.309, 1.218)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	95 (54.6%)	75 (43.1%)
Number of censored participants, n (%)	79 (45.4%)	99 (56.9%)
Proportionality Test p-value[a][b]	0.0850	
Hazard ratio(interaction)	0.706 (0.476, 1.049)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	19 (54.3%)	16 (50.0%)
Number of censored participants, n (%)	16 (45.7%)	16 (50.0%)
Proportionality Test p-value[a][b]	0.8549	
Hazard ratio(interaction)	1.091 (0.429, 2.772)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	15 (40.5%)	13 (41.9%)
Number of censored participants, n (%)	22 (59.5%)	18 (58.1%)
Proportionality Test p-value[a][b]	0.1595	
Hazard ratio(interaction)	0.404 (0.115, 1.428)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	53 (58.9%)	37 (41.1%)
Number of censored participants, n (%)	37 (41.1%)	53 (58.9%)
Proportionality Test p-value[a][b]	0.6862	
Hazard ratio(interaction)	0.889 (0.501, 1.576)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	46 (56.1%)	41 (48.2%)
Number of censored participants, n (%)	36 (43.9%)	44 (51.8%)
Proportionality Test p-value[a][b]	0.4563	
Hazard ratio(interaction)	0.828 (0.503, 1.361)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: White
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	103 (54.5%)	77 (40.7%)
Number of censored participants, n (%)	86 (45.5%)	112 (59.3%)
Proportionality Test p-value[a][b]	0.1329	
Hazard ratio(interaction)	0.751 (0.516, 1.091)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	11 (55.0%)	14 (82.4%)
Number of censored participants, n (%)	9 (45.0%)	3 (17.6%)
Proportionality Test p-value[a][b]	0.8938	
Hazard ratio(interaction)	1.144 (0.158, 8.276)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	90 (54.2%)	73 (41.2%)
Number of censored participants, n (%)	76 (45.8%)	104 (58.8%)
Proportionality Test p-value[a][b]	0.0589	
Hazard ratio(interaction)	0.676 (0.450, 1.015)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	24 (55.8%)	18 (62.1%)
Number of censored participants, n (%)	19 (44.2%)	11 (37.9%)
Proportionality Test p-value[a][b]	0.7251	
Hazard ratio(interaction)	1.143 (0.544, 2.401)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	70 (52.6%)	58 (44.3%)
Number of censored participants, n (%)	63 (47.4%)	73 (55.7%)
Proportionality Test p-value[a][b]	0.2844	
Hazard ratio(interaction)	0.783 (0.501, 1.225)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	44 (57.9%)	33 (44.0%)
Number of censored participants, n (%)	32 (42.1%)	42 (56.0%)
Proportionality Test p-value[a][b]	0.2403	
Hazard ratio(interaction)	0.654 (0.322, 1.328)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	73 (58.4%)	50 (42.7%)
Number of censored participants, n (%)	52 (41.6%)	67 (57.3%)
Proportionality Test p-value[a][b]	0.0714	
Hazard ratio(interaction)	0.631 (0.383, 1.041)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.1.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (7 points) by Subgroup
(Full Analysis Set)

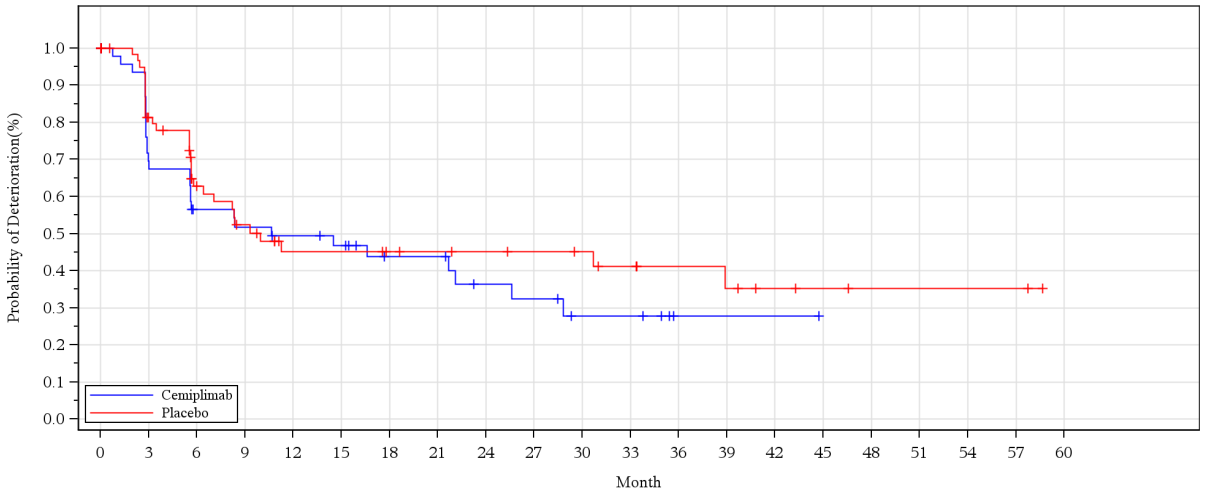
High risk feature: Non-Nodal
EQ5D01-EQ VAS Score (Deterioration threshold = 7)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	41 (48.8%)	41 (46.1%)
Number of censored participants, n (%)	43 (51.2%)	48 (53.9%)
Proportionality Test p-value[a][b]	0.8662	
Hazard ratio(interaction)	0.955 (0.555, 1.640)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 1: <65



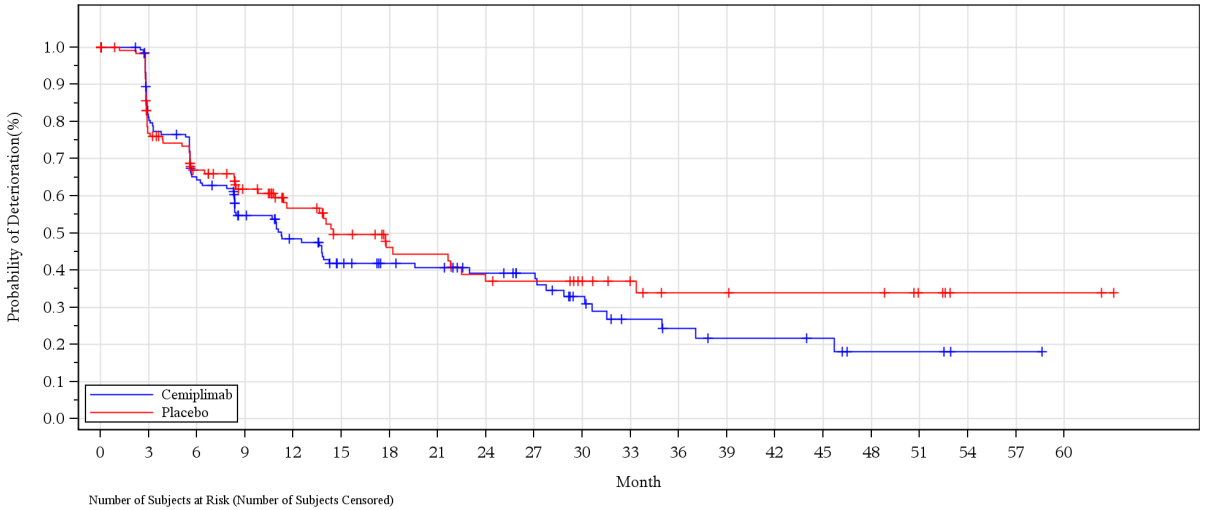
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	32 (10)	24 (12)	22 (12)	20 (13)	18 (14)	13 (18)	13 (18)	9 (20)	8 (20)	5 (22)	5 (22)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	46 (8)	31 (13)	24 (15)	17 (19)	17 (19)	15 (21)	14 (22)	13 (23)	12 (24)	11 (25)	9 (26)	7 (28)	6 (28)	4 (30)	3 (31)	2 (32)	2 (32)	2 (32)	2 (32)	0 (34)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 1: >=65



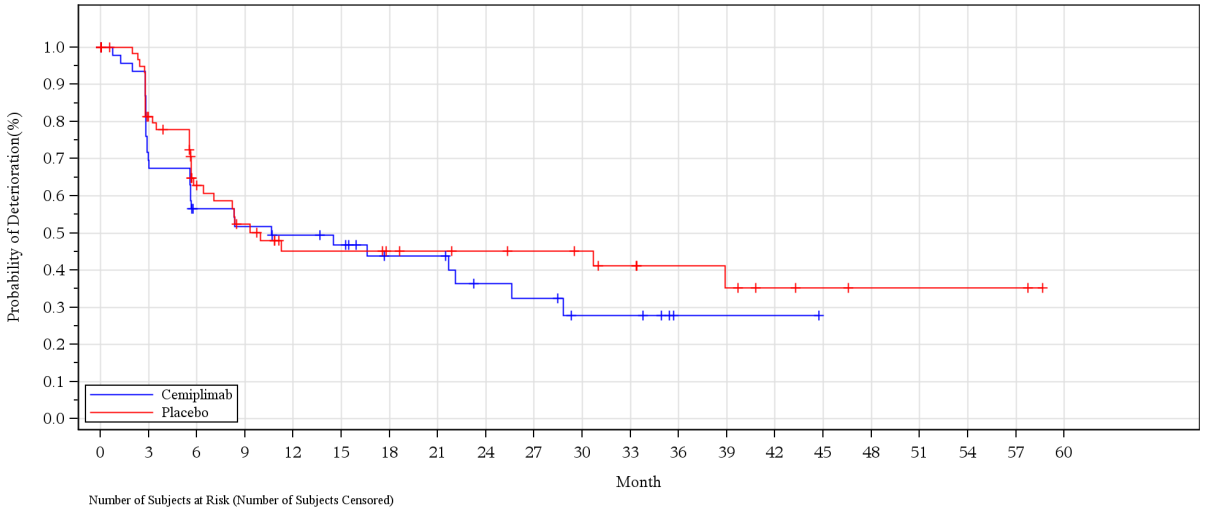
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	153 (0)	107 (21)	83 (23)	64 (30)	53 (34)	41 (39)	36 (44)	34 (45)	29 (49)	25 (53)	17 (57)	11 (60)	9 (61)	7 (62)	7 (62)	6 (63)	3 (65)	3 (65)	1 (67)	1 (67)	0 (68)
Placebo	141 (0)	88 (26)	70 (33)	56 (42)	42 (52)	33 (56)	26 (61)	25 (61)	20 (62)	19 (63)	15 (67)	12 (70)	9 (72)	9 (72)	8 (73)	8 (73)	8 (73)	5 (76)	2 (79)	2 (79)	2 (79)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 2: <65



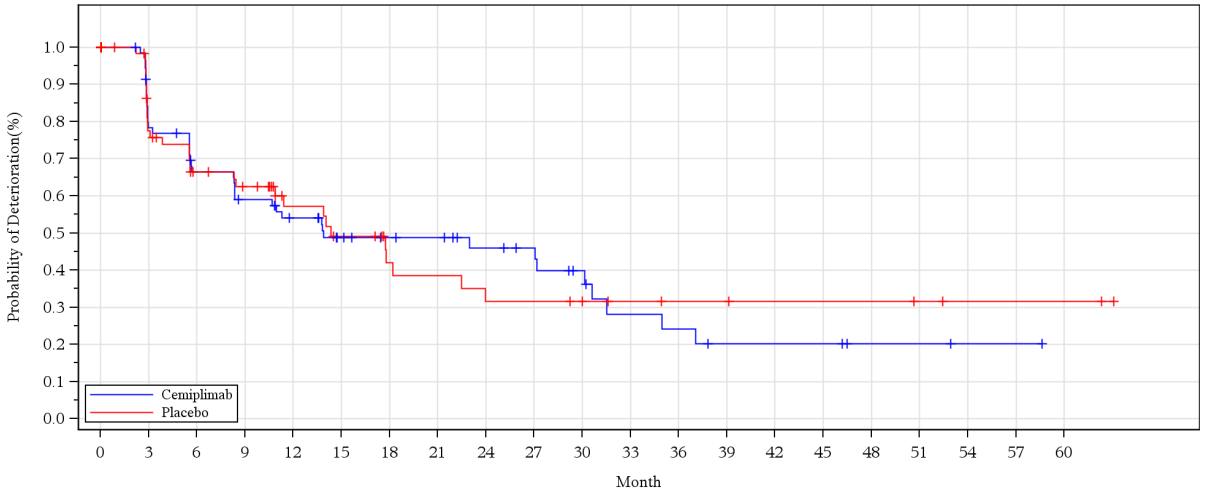
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	32 (10)	24 (12)	22 (12)	20 (13)	18 (14)	13 (18)	13 (18)	9 (20)	8 (20)	5 (22)	5 (22)	1 (26)	1 (26)	1 (26)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)	0 (27)
Placebo	65 (0)	46 (8)	31 (13)	24 (15)	17 (19)	17 (19)	15 (21)	14 (22)	13 (23)	12 (24)	11 (25)	9 (26)	7 (28)	6 (28)	4 (30)	3 (31)	2 (32)	2 (32)	2 (32)	2 (32)	0 (34)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



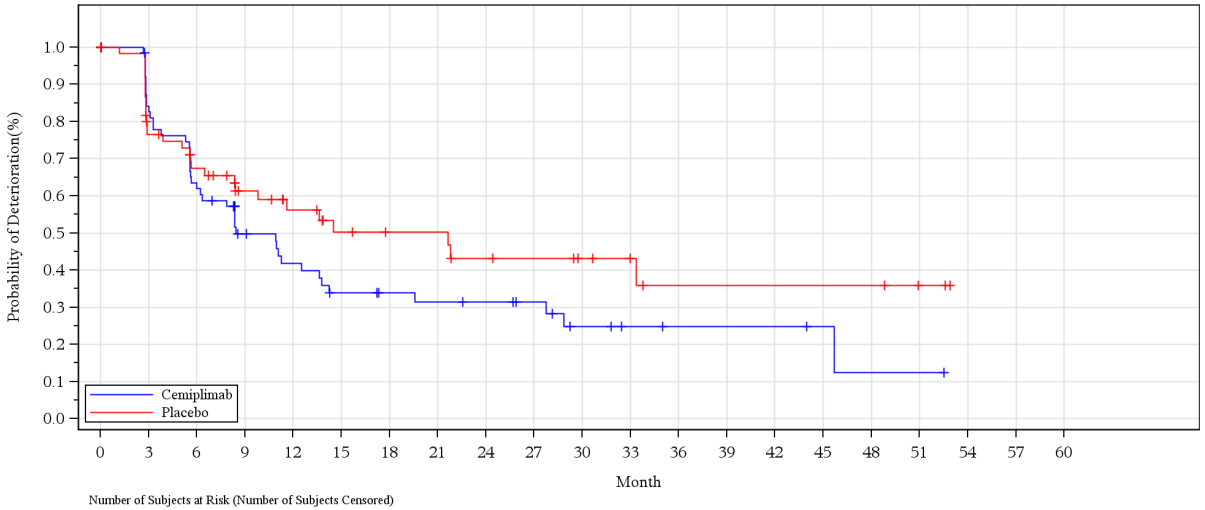
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	80 (0)	54 (11)	44 (13)	38 (14)	32 (17)	25 (21)	22 (24)	21 (25)	17 (28)	15 (30)	11 (32)	7 (33)	6 (33)	4 (34)	4 (34)	4 (34)	2 (36)	2 (36)	1 (37)	1 (37)	0 (38)
Placebo	69 (0)	44 (12)	34 (16)	30 (18)	21 (25)	17 (26)	12 (29)	11 (29)	9 (29)	9 (29)	7 (31)	6 (32)	5 (33)	5 (33)	4 (34)	4 (34)	4 (34)	3 (35)	2 (36)	2 (36)	2 (36)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Age group 2: >=75



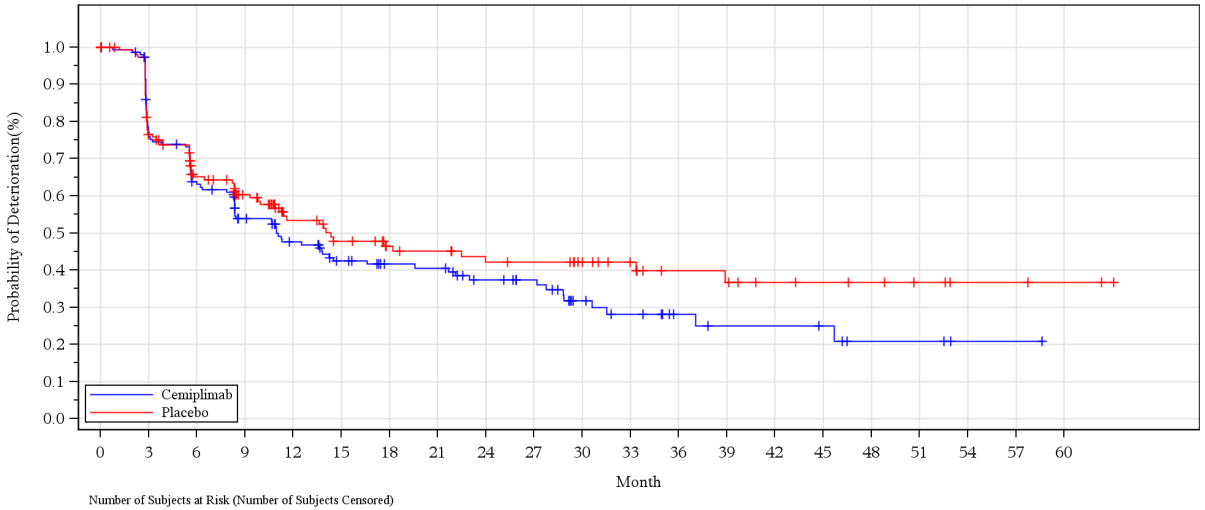
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	73 (0)	53 (10)	39 (10)	26 (16)	21 (17)	16 (18)	14 (20)	13 (20)	12 (21)	10 (23)	6 (25)	4 (27)	3 (28)	3 (28)	3 (28)	2 (29)	1 (29)	1 (29)	0 (30)	0 (30)	0 (30)
Placebo	72 (0)	44 (14)	36 (17)	26 (24)	21 (27)	16 (30)	14 (32)	14 (32)	11 (33)	10 (34)	8 (36)	6 (38)	4 (39)	4 (39)	4 (39)	4 (39)	4 (39)	2 (41)	0 (43)	0 (43)	0 (43)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Gender group: Male



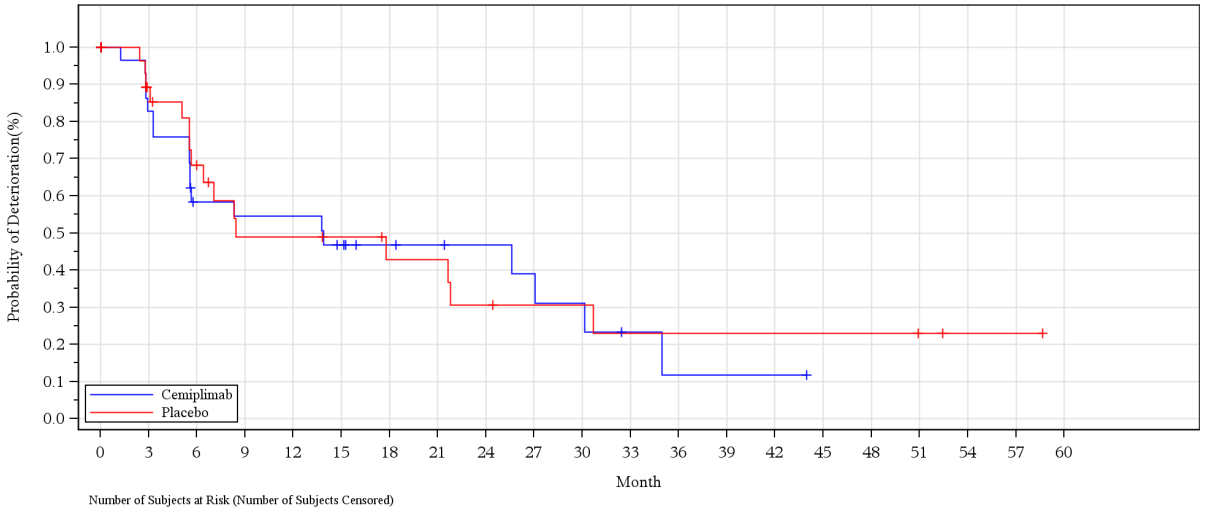
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	174 (0)	115 (25)	92 (27)	72 (34)	59 (39)	48 (44)	41 (50)	40 (50)	32 (55)	28 (59)	18 (65)	14 (67)	9 (72)	7 (73)	7 (73)	6 (74)	3 (76)	3 (76)	1 (78)	1 (78)	0 (79)
Placebo	174 (0)	112 (27)	85 (38)	70 (47)	49 (61)	41 (64)	34 (70)	32 (71)	28 (73)	27 (74)	22 (79)	18 (83)	13 (87)	12 (87)	9 (90)	8 (91)	7 (92)	5 (94)	3 (96)	3 (96)	2 (97)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Gender group: Female



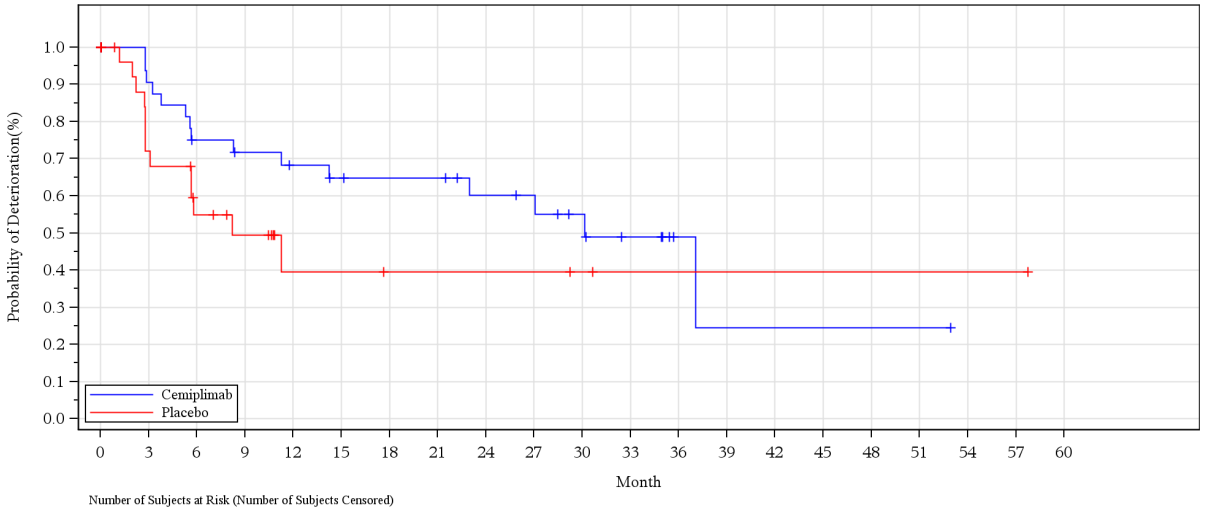
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	35 (0)	24 (6)	15 (8)	14 (8)	14 (8)	11 (9)	8 (12)	7 (13)	6 (14)	5 (14)	4 (14)	2 (15)	1 (15)	1 (15)	1 (15)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)	0 (16)
Placebo	32 (0)	22 (7)	16 (8)	10 (10)	10 (10)	9 (11)	7 (12)	7 (12)	5 (12)	4 (13)	4 (13)	3 (13)	3 (13)	3 (13)	3 (13)	3 (13)	3 (13)	2 (14)	1 (15)	1 (15)	0 (16)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



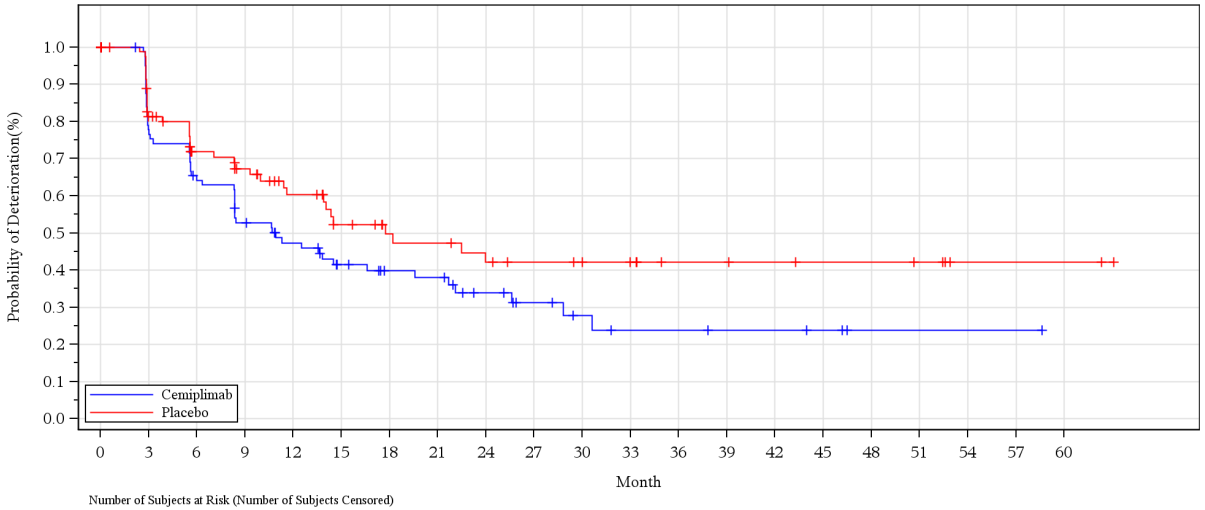
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	37 (0)	29 (5)	23 (6)	21 (7)	19 (8)	17 (9)	16 (10)	16 (10)	13 (12)	12 (13)	9 (15)	6 (17)	2 (21)	1 (21)	1 (21)	1 (21)	1 (21)	1 (21)	0 (22)	0 (22)	0 (22)
Placebo	31 (0)	18 (6)	12 (8)	9 (10)	4 (14)	4 (14)	3 (15)	3 (15)	3 (15)	3 (15)	2 (16)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	1 (17)	0 (18)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



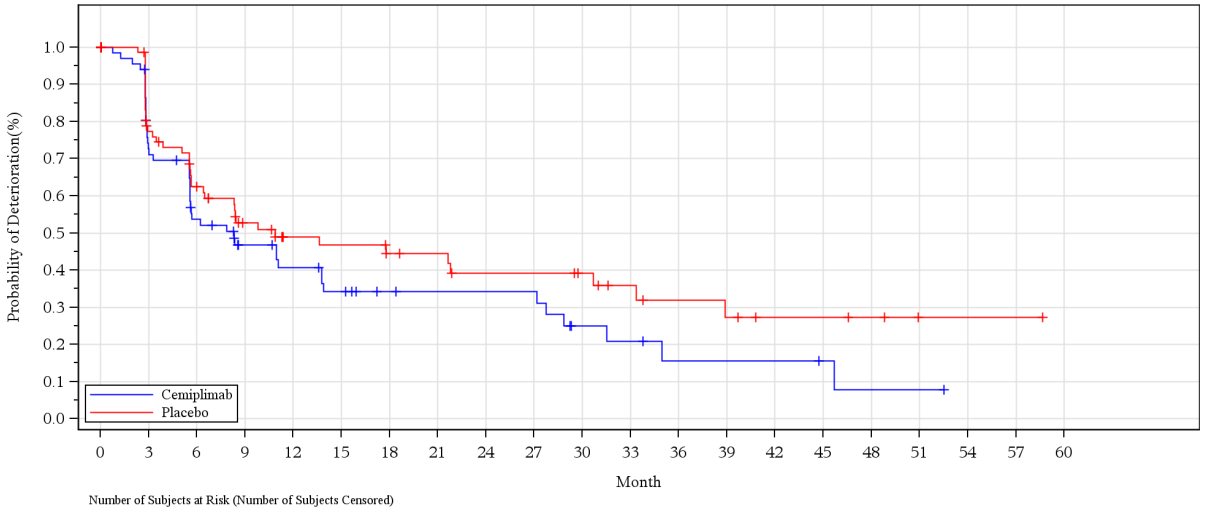
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	90 (0)	63 (9)	51 (10)	41 (11)	34 (14)	26 (18)	21 (22)	20 (22)	14 (26)	10 (29)	7 (31)	5 (32)	5 (32)	4 (33)	4 (33)	3 (34)	1 (36)	1 (36)	1 (36)	1 (36)	0 (37)
Placebo	90 (0)	63 (12)	48 (20)	42 (23)	33 (28)	25 (32)	20 (36)	19 (36)	16 (37)	14 (39)	12 (41)	11 (42)	8 (45)	8 (45)	7 (46)	6 (47)	6 (47)	5 (48)	2 (51)	2 (51)	2 (51)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	82 (0)	47 (17)	33 (19)	24 (24)	20 (25)	16 (26)	12 (30)	11 (31)	11 (31)	11 (31)	6 (33)	5 (33)	3 (34)	3 (34)	3 (34)	2 (35)	1 (35)	1 (35)	0 (36)	0 (36)	0 (36)
Placebo	85 (0)	53 (16)	41 (18)	29 (24)	22 (29)	21 (29)	18 (31)	17 (32)	14 (33)	14 (33)	12 (35)	9 (37)	7 (38)	6 (38)	4 (40)	4 (40)	3 (41)	1 (43)	1 (43)	1 (43)	0 (44)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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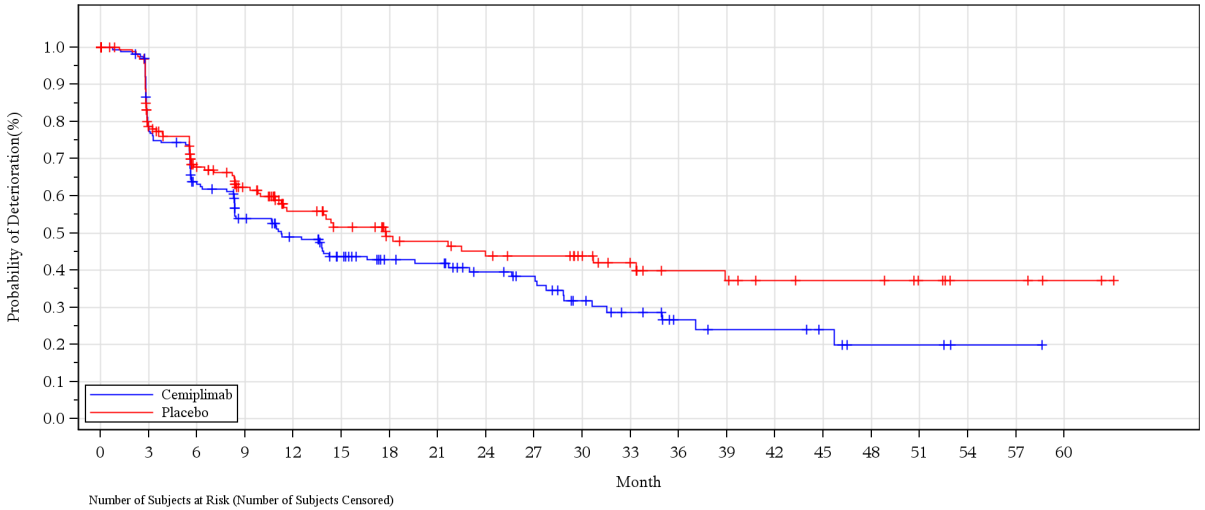
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Race: White



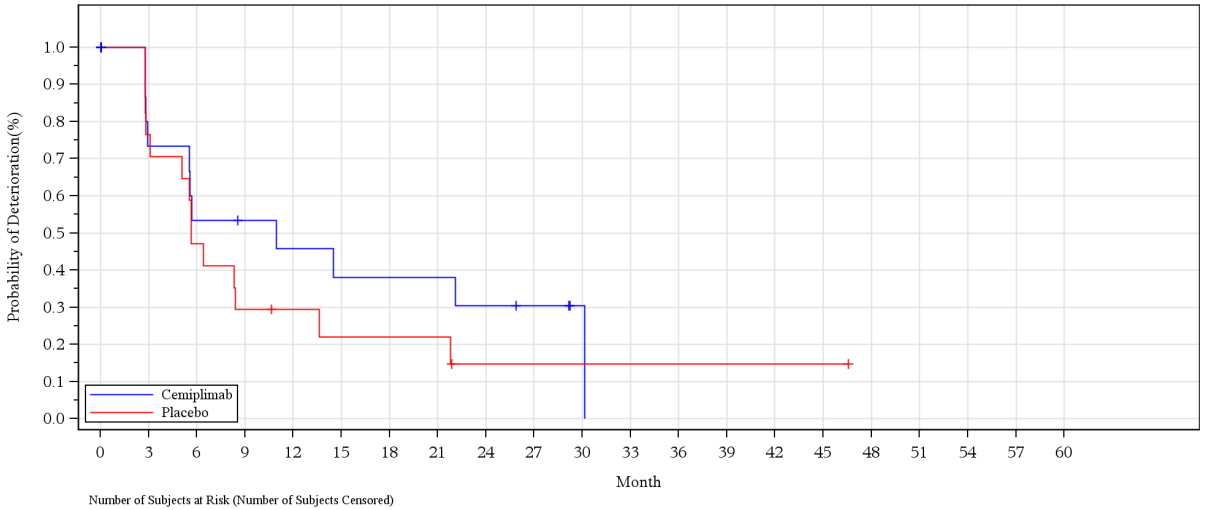
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	189 (0)	128 (26)	99 (30)	79 (36)	67 (41)	54 (47)	44 (56)	42 (57)	34 (63)	30 (66)	21 (70)	16 (73)	10 (78)	8 (79)	8 (79)	6 (81)	3 (83)	3 (83)	1 (85)	1 (85)	0 (86)
Placebo	189 (0)	121 (34)	93 (46)	75 (57)	55 (70)	47 (74)	38 (81)	36 (82)	32 (83)	30 (85)	25 (90)	20 (94)	15 (98)	14 (98)	11 (101)	10 (102)	10 (102)	7 (105)	4 (108)	4 (108)	2 (110)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	20 (0)	11 (5)	8 (5)	7 (6)	6 (6)	5 (6)	5 (6)	5 (6)	4 (6)	3 (7)	1 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)	0 (9)
Placebo	17 (0)	13 (0)	8 (0)	5 (0)	4 (1)	3 (1)	3 (1)	3 (1)	1 (2)	1 (2)	1 (2)	1 (2)	1 (2)	1 (2)	1 (2)	1 (2)	0 (3)	0 (3)	0 (3)	0 (3)	0 (3)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
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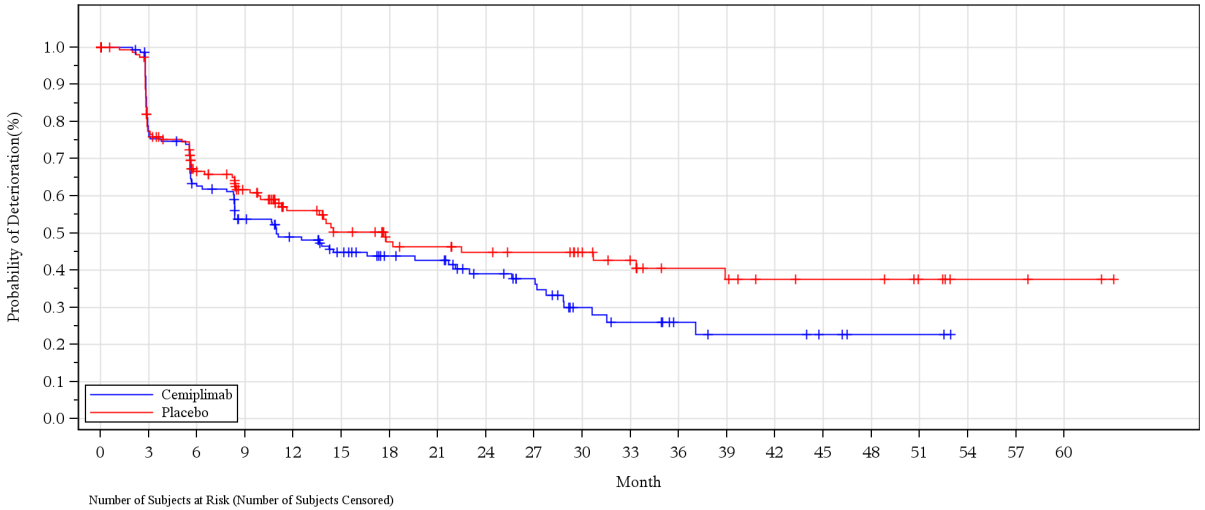
Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



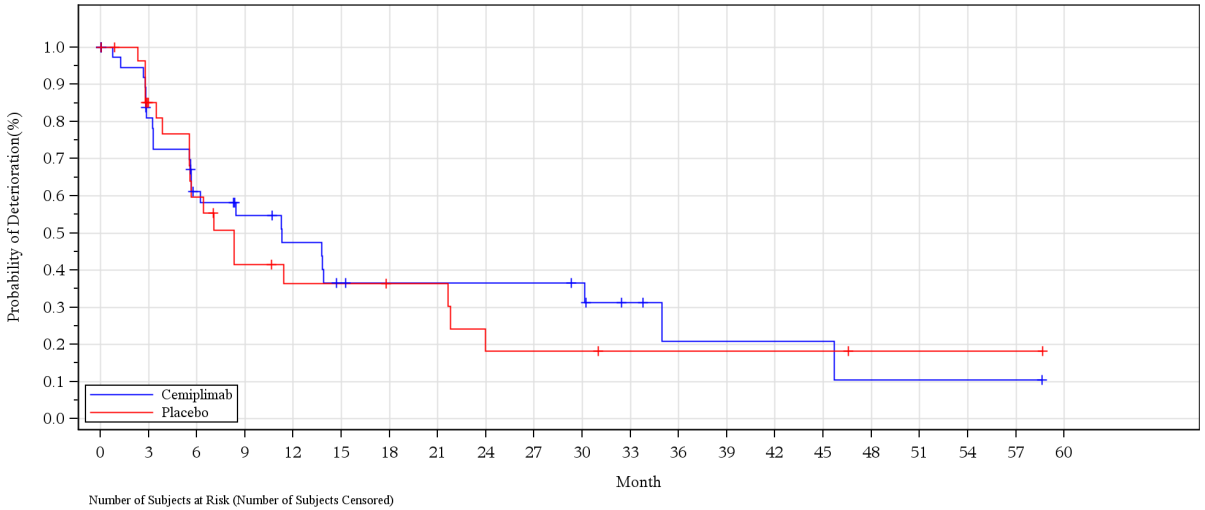
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	166 (0)	110 (24)	87 (26)	70 (31)	60 (35)	50 (40)	41 (48)	39 (49)	30 (55)	25 (59)	15 (64)	12 (65)	8 (69)	6 (70)	6 (70)	4 (72)	2 (74)	2 (74)	0 (76)	0 (76)	0 (76)
Placebo	177 (0)	114 (29)	87 (41)	71 (51)	52 (64)	43 (68)	35 (74)	33 (75)	30 (77)	28 (79)	23 (84)	19 (87)	14 (91)	13 (91)	10 (94)	9 (95)	9 (95)	6 (98)	3 (101)	3 (101)	2 (102)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



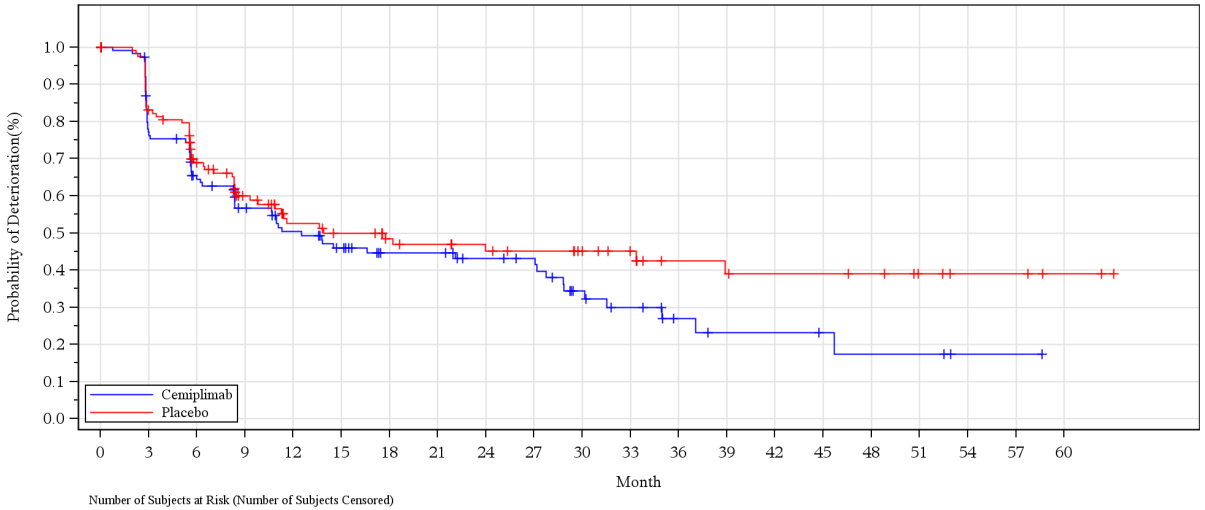
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	29 (7)	20 (9)	16 (11)	13 (12)	9 (13)	8 (14)	8 (14)	8 (14)	8 (14)	7 (15)	4 (17)	2 (18)	2 (18)	2 (18)	2 (18)	1 (18)	1 (18)	1 (18)	1 (18)	0 (19)
Placebo	29 (0)	20 (5)	14 (5)	9 (6)	7 (7)	7 (7)	6 (8)	6 (8)	3 (8)	3 (8)	3 (8)	2 (9)	2 (9)	2 (9)	2 (9)	2 (9)	1 (10)	1 (10)	1 (10)	1 (10)	0 (11)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 0



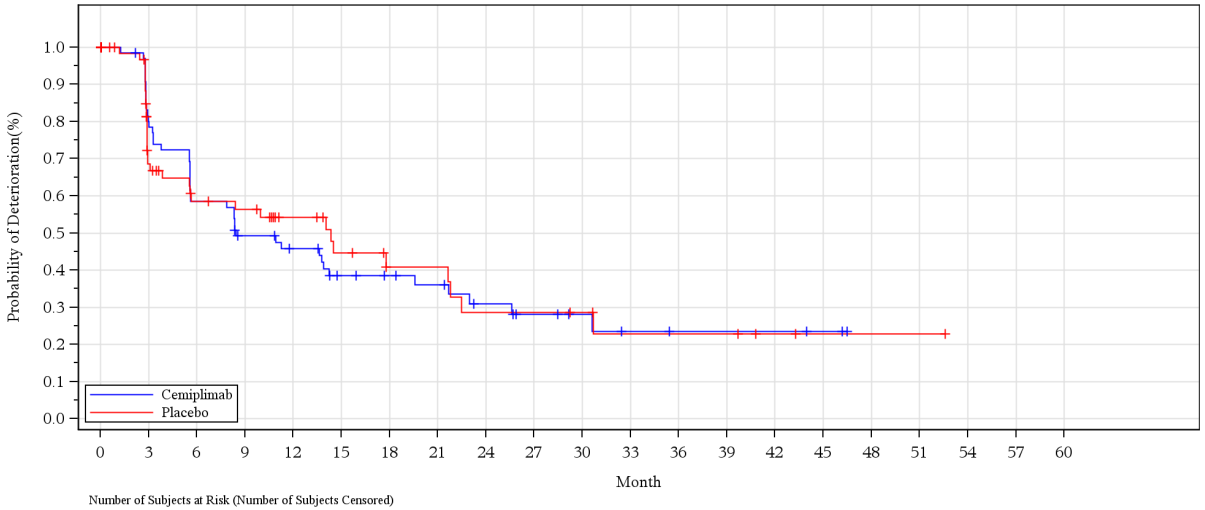
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	87 (20)	69 (24)	56 (29)	47 (32)	40 (35)	32 (42)	32 (42)	27 (46)	25 (48)	16 (52)	12 (54)	7 (58)	5 (59)	5 (59)	4 (60)	3 (60)	3 (60)	1 (62)	1 (62)	0 (63)
Placebo	131 (0)	97 (14)	73 (22)	54 (32)	40 (40)	36 (42)	31 (46)	29 (47)	26 (49)	24 (51)	20 (55)	17 (58)	12 (62)	11 (62)	10 (63)	10 (63)	9 (64)	6 (67)	4 (69)	4 (69)	2 (71)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

ECOG status: 1



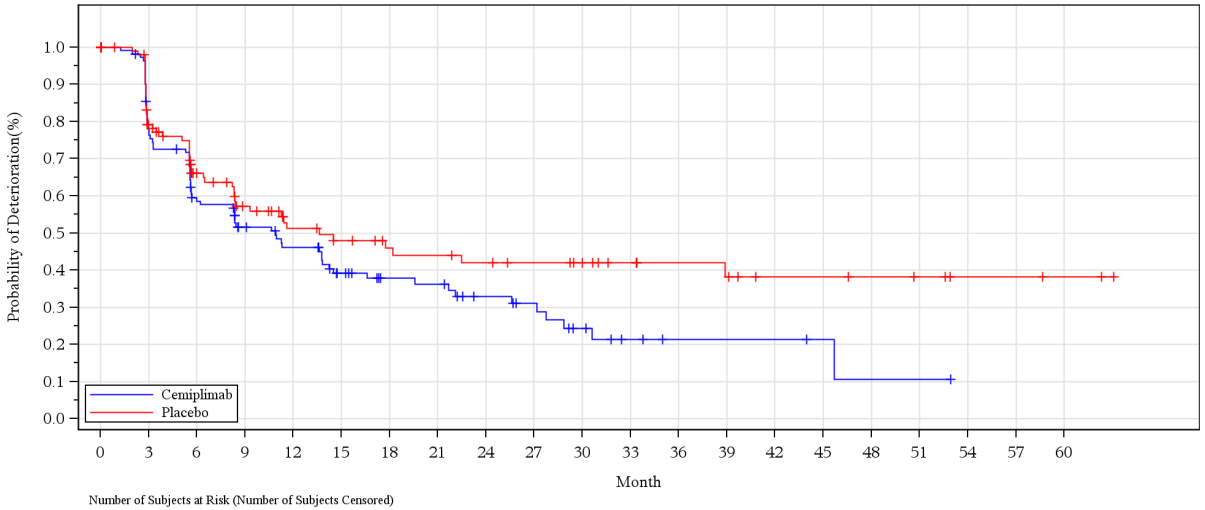
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	76 (0)	52 (11)	38 (11)	30 (13)	26 (15)	19 (18)	17 (20)	15 (21)	11 (23)	8 (25)	6 (27)	4 (28)	3 (29)	3 (29)	3 (29)	2 (30)	0 (32)	0 (32)	0 (32)	0 (32)	0 (32)
Placebo	75 (0)	37 (20)	28 (24)	26 (25)	19 (31)	14 (33)	10 (36)	10 (36)	7 (36)	7 (36)	6 (37)	4 (38)	4 (38)	4 (38)	2 (40)	1 (41)	1 (41)	1 (41)	0 (42)	0 (42)	0 (42)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Nodal



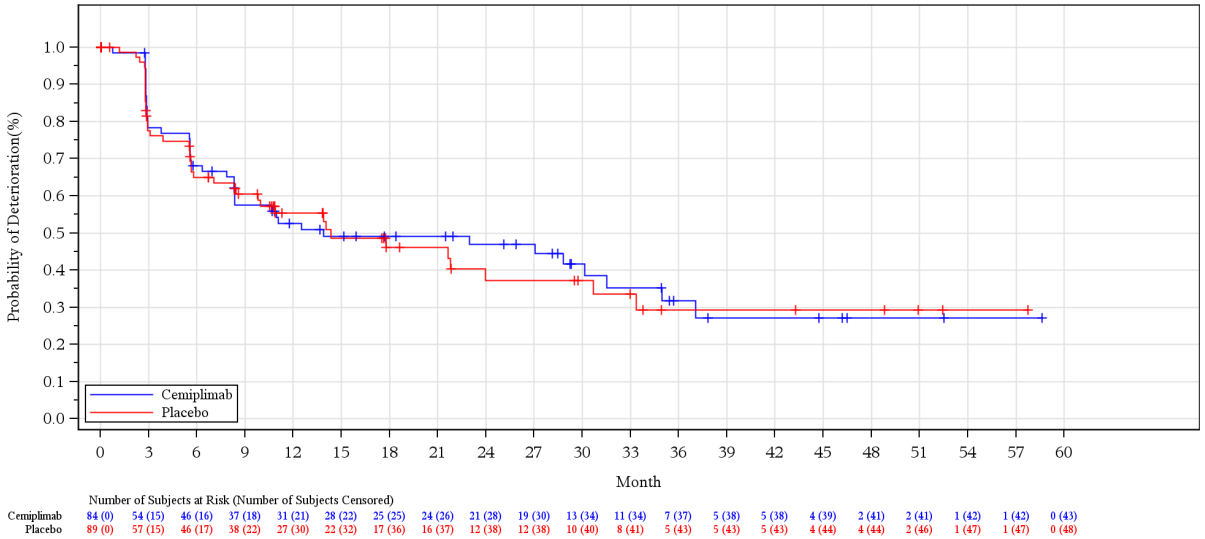
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	85 (16)	61 (19)	49 (24)	42 (26)	31 (31)	24 (37)	23 (37)	17 (41)	14 (43)	9 (45)	5 (48)	3 (50)	3 (50)	3 (50)	2 (51)	1 (51)	1 (51)	0 (52)	0 (52)	0 (52)
Placebo	117 (0)	77 (19)	55 (29)	42 (35)	32 (41)	28 (43)	24 (46)	23 (46)	21 (47)	19 (49)	16 (52)	13 (55)	11 (57)	10 (57)	7 (60)	7 (60)	6 (61)	5 (62)	3 (64)	3 (64)	2 (65)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Figure 14.2.10.1.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale by (7 points) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	54 (15)	46 (16)	37 (18)	31 (21)	28 (22)	25 (25)	24 (26)	21 (28)	19 (30)	13 (34)	11 (34)	7 (37)	5 (38)	5 (38)	4 (39)	2 (41)	2 (41)	1 (42)	1 (42)	0 (43)
Placebo	89 (0)	57 (15)	46 (17)	38 (22)	27 (30)	22 (32)	17 (36)	16 (37)	12 (38)	12 (38)	10 (40)	8 (41)	5 (43)	5 (43)	5 (43)	4 (44)	4 (44)	2 (46)	1 (47)	1 (47)	0 (48)

Data cut-off as of April 07, 2025.
Note(s): Thresholds used are based on literature
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Non Countable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:19 SAS Linux 9.4)

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup (Full Analysis Set)

Age group 1: <65
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	21 (37.5%)	23 (35.4%)
Number of censored cases	n (%)	35 (62.5%)	42 (64.6%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	1 (1.8%)	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	25 (44.6%)	37 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.89, 14.49]	8.31 [5.55, 9.95]
	Median [95% CI]	29.73 [10.87, NC]	38.90 [9.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.720
	HR [95 % CI][c][d]		1.12 [0.60, 2.09]
	Heterogeneity p-value[e][d]		0.5655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=153)	Placebo (N=141)
Total number of patients[a]	n	153	141
Number of patients with events	n (%)	63 (41.2%)	39 (27.7%)
Number of censored cases	n (%)	90 (58.8%)	102 (72.3%)
No baseline score	n (%)	15 (9.8%)	16 (11.3%)
No post-baseline score	n (%)	3 (2.0%)	4 (2.8%)
No deterioration possible	n (%)	0	1 (0.7%)
No first deterioration	n (%)	72 (47.1%)	81 (57.4%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 10.78]	8.48 [5.55, 18.20]
	Median [95% CI]	27.17 [13.90, 37.06]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.155
	HR [95 % CI][c][d]		1.34 [0.89, 2.02]
	Heterogeneity p-value[e][d]		0.5655

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=56)	Placebo (N=65)
Total number of patients[a]	n	56	65
Number of patients with events	n (%)	21 (37.5%)	23 (35.4%)
Number of censored cases	n (%)	35 (62.5%)	42 (64.6%)
No baseline score	n (%)	9 (16.1%)	4 (6.2%)
No post-baseline score	n (%)	1 (1.8%)	1 (1.5%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	25 (44.6%)	37 (56.9%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.89, 14.49]	8.31 [5.55, 9.95]
	Median [95% CI]	29.73 [10.87, NC]	38.90 [9.95, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.720
	HR [95 % CI][c][d]		1.12 [0.60, 2.09]
	Heterogeneity p-value[e][d]		0.7403

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=80)	Placebo (N=69)
Total number of patients[a]	n	80	69
Number of patients with events	n (%)	30 (37.5%)	19 (27.5%)
Number of censored cases	n (%)	50 (62.5%)	50 (72.5%)
No baseline score	n (%)	8 (10.0%)	9 (13.0%)
No post-baseline score	n (%)	1 (1.3%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	41 (51.3%)	41 (59.4%)
Time to first deterioration (months)	Q1 [95% CI]	10.68 [5.59, 19.81]	8.34 [2.92, 18.20]
	Median [95% CI]	27.17 [19.81, NC]	NYR [17.77, NC]
	Q3 [95% CI]	NYR [34.96, NC]	NYR [NC, NC]
	p-value[b][d]		0.617
	HR [95 % CI][c][d]		1.16 [0.63, 2.13]
	Heterogeneity p-value[e][d]		0.7403

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=73)	Placebo (N=72)
Total number of patients[a]	n	73	72
Number of patients with events	n (%)	33 (45.2%)	20 (27.8%)
Number of censored cases	n (%)	40 (54.8%)	52 (72.2%)
No baseline score	n (%)	7 (9.6%)	7 (9.7%)
No post-baseline score	n (%)	2 (2.7%)	4 (5.6%)
No deterioration possible	n (%)	0	1 (1.4%)
No first deterioration	n (%)	31 (42.5%)	40 (55.6%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [3.78, 8.44]	9.82 [2.86, 22.21]
	Median [95% CI]	13.80 [10.64, NC]	33.35 [21.78, NC]
	Q3 [95% CI]	NYR [35.29, NC]	NYR [33.35, NC]
	p-value[b][d]		0.159
	HR [95 % CI][c][d]		1.50 [0.84, 2.67]
	Heterogeneity p-value[e][d]		0.7403

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=174)	Placebo (N=174)
Total number of patients[a]	n	174	174
Number of patients with events	n (%)	69 (39.7%)	50 (28.7%)
Number of censored cases	n (%)	105 (60.3%)	124 (71.3%)
No baseline score	n (%)	20 (11.5%)	16 (9.2%)
No post-baseline score	n (%)	2 (1.1%)	5 (2.9%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	83 (47.7%)	102 (58.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 10.68]	8.38 [5.55, 13.90]
	Median [95% CI]	28.81 [15.21, NC]	NYR [33.35, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.124
	HR [95 % CI][c][d]		1.33 [0.92, 1.92]
	Heterogeneity p-value[e][d]		0.8145

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=35)	Placebo (N=32)
Total number of patients[a]	n	35	32
Number of patients with events	n (%)	15 (42.9%)	12 (37.5%)
Number of censored cases	n (%)	20 (57.1%)	20 (62.5%)
No baseline score	n (%)	4 (11.4%)	4 (12.5%)
No post-baseline score	n (%)	2 (5.7%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	14 (40.0%)	16 (50.0%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [3.29, 19.81]	8.31 [3.09, 21.65]
	Median [95% CI]	29.73 [10.87, NC]	21.78 [8.31, NC]
	Q3 [95% CI]	34.96 [29.73, NC]	NYR [21.78, NC]
	p-value[b][d]		0.411
	HR [95 % CI][c][d]		1.43 [0.61, 3.34]
	Heterogeneity p-value[e][d]		0.8145

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
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[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=37)	Placebo (N=31)
Total number of patients[a]	n	37	31
Number of patients with events	n (%)	9 (24.3%)	6 (19.4%)
Number of censored cases	n (%)	28 (75.7%)	25 (80.6%)
No baseline score	n (%)	4 (10.8%)	4 (12.9%)
No post-baseline score	n (%)	1 (2.7%)	1 (3.2%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	23 (62.2%)	20 (64.5%)
Time to first deterioration (months)	Q1 [95% CI]	22.97 [5.55, 37.06]	8.44 [1.18, NC]
	Median [95% CI]	37.06 [30.16, NC]	NYR [8.44, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.695
	HR [95 % CI][c][d]		0.80 [0.27, 2.41]
	Heterogeneity p-value[e][d]		0.5328

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=90)	Placebo (N=90)
Total number of patients[a]	n	90	90
Number of patients with events	n (%)	40 (44.4%)	25 (27.8%)
Number of censored cases	n (%)	50 (55.6%)	65 (72.2%)
No baseline score	n (%)	7 (7.8%)	5 (5.6%)
No post-baseline score	n (%)	1 (1.1%)	3 (3.3%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	42 (46.7%)	57 (63.3%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.55, 10.68]	13.54 [5.59, 22.21]
	Median [95% CI]	28.81 [10.97, NC]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.100
	HR [95 % CI][c][d]		1.52 [0.92, 2.50]
	Heterogeneity p-value[e][d]		0.5328

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=82)	Placebo (N=85)
Total number of patients[a]	n	82	85
Number of patients with events	n (%)	35 (42.7%)	31 (36.5%)
Number of censored cases	n (%)	47 (57.3%)	54 (63.5%)
No baseline score	n (%)	13 (15.9%)	11 (12.9%)
No post-baseline score	n (%)	2 (2.4%)	1 (1.2%)
No deterioration possible	n (%)	0	1 (1.2%)
No first deterioration	n (%)	32 (39.0%)	41 (48.2%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [2.92, 10.64]	5.65 [5.09, 8.41]
	Median [95% CI]	17.87 [10.64, 28.85]	30.69 [9.82, NC]
	Q3 [95% CI]	NYR [27.17, NC]	NYR [38.90, NC]
	p-value[b][d]		0.393
	HR [95 % CI][c][d]		1.23 [0.76, 2.00]
	Heterogeneity p-value[e][d]		0.5328

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: White
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=189)	Placebo (N=189)
Total number of patients[a]	n	189	189
Number of patients with events	n (%)	75 (39.7%)	52 (27.5%)
Number of censored cases	n (%)	114 (60.3%)	137 (72.5%)
No baseline score	n (%)	20 (10.6%)	20 (10.6%)
No post-baseline score	n (%)	3 (1.6%)	5 (2.6%)
No deterioration possible	n (%)	0	1 (0.5%)
No first deterioration	n (%)	91 (48.1%)	111 (58.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 10.64]	8.48 [5.65, 17.77]
	Median [95% CI]	29.73 [15.21, NC]	NYR [25.53, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.064
	HR [95 % CI][c][d]		1.40 [0.98, 2.01]
	Heterogeneity p-value[e][d]		0.2202

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=20)	Placebo (N=17)
Total number of patients[a]	n	20	17
Number of patients with events	n (%)	9 (45.0%)	10 (58.8%)
Number of censored cases	n (%)	11 (55.0%)	7 (41.2%)
No baseline score	n (%)	4 (20.0%)	0
No post-baseline score	n (%)	1 (5.0%)	0
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	6 (30.0%)	7 (41.2%)
Time to first deterioration (months)	Q1 [95% CI]	10.78 [2.92, 22.11]	5.09 [2.79, 8.31]
	Median [95% CI]	22.11 [5.59, NC]	8.41 [3.09, NC]
	Q3 [95% CI]	30.16 [22.11, NC]	NYR [8.31, NC]
	p-value[b][d]		0.176
	HR [95 % CI][c][d]		0.45 [0.14, 1.44]
	Heterogeneity p-value[e][d]		0.2202

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=166)	Placebo (N=177)
Total number of patients[a]	n	166	177
Number of patients with events	n (%)	68 (41.0%)	50 (28.2%)
Number of censored cases	n (%)	98 (59.0%)	127 (71.8%)
No baseline score	n (%)	20 (12.0%)	20 (11.3%)
No post-baseline score	n (%)	2 (1.2%)	4 (2.3%)
No deterioration possible	n (%)	0	1 (0.6%)
No first deterioration	n (%)	76 (45.8%)	102 (57.6%)
Time to first deterioration (months)	Q1 [95% CI]	8.34 [5.59, 10.68]	8.38 [5.55, 14.65]
	Median [95% CI]	28.81 [14.59, 37.06]	NYR [30.69, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [NC, NC]
	p-value[b][d]		0.075
	HR [95 % CI][c][d]		1.39 [0.96, 2.01]
	Heterogeneity p-value[e][d]		0.4116

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=43)	Placebo (N=29)
Total number of patients[a]	n	43	29
Number of patients with events	n (%)	16 (37.2%)	12 (41.4%)
Number of censored cases	n (%)	27 (62.8%)	17 (58.6%)
No baseline score	n (%)	4 (9.3%)	0
No post-baseline score	n (%)	2 (4.7%)	1 (3.4%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	21 (48.8%)	16 (55.2%)
Time to first deterioration (months)	Q1 [95% CI]	8.44 [3.29, 13.90]	8.31 [5.55, 21.65]
	Median [95% CI]	30.16 [10.68, NC]	21.78 [8.31, NC]
	Q3 [95% CI]	NYR [34.96, NC]	NYR [21.78, NC]
	p-value[b][d]		0.931
	HR [95 % CI][c][d]		0.97 [0.45, 2.09]
	Heterogeneity p-value[e][d]		0.4116

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=133)	Placebo (N=131)
Total number of patients[a]	n	133	131
Number of patients with events	n (%)	50 (37.6%)	39 (29.8%)
Number of censored cases	n (%)	83 (62.4%)	92 (70.2%)
No baseline score	n (%)	16 (12.0%)	12 (9.2%)
No post-baseline score	n (%)	2 (1.5%)	1 (0.8%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	65 (48.9%)	79 (60.3%)
Time to first deterioration (months)	Q1 [95% CI]	10.64 [5.65, 11.10]	8.41 [6.24, 14.65]
	Median [95% CI]	30.16 [22.11, NC]	NYR [23.95, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.226
	HR [95 % CI][c][d]		1.29 [0.85, 1.98]
	Heterogeneity p-value[e][d]		0.9593

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=76)	Placebo (N=75)
Total number of patients[a]	n	76	75
Number of patients with events	n (%)	34 (44.7%)	23 (30.7%)
Number of censored cases	n (%)	42 (55.3%)	52 (69.3%)
No baseline score	n (%)	8 (10.5%)	8 (10.7%)
No post-baseline score	n (%)	2 (2.6%)	4 (5.3%)
No deterioration possible	n (%)	0	1 (1.3%)
No first deterioration	n (%)	32 (42.1%)	39 (52.0%)
Time to first deterioration (months)	Q1 [95% CI]	5.59 [3.29, 8.34]	5.59 [2.89, 17.77]
	Median [95% CI]	19.81 [8.44, NC]	25.53 [17.77, NC]
	Q3 [95% CI]	NYR [NC, NC]	NYR [30.69, NC]
	p-value[b][d]		0.147
	HR [95 % CI][c][d]		1.52 [0.86, 2.70]
	Heterogeneity p-value[e][d]		0.9593

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=125)	Placebo (N=117)
Total number of patients[a]	n	125	117
Number of patients with events	n (%)	51 (40.8%)	31 (26.5%)
Number of censored cases	n (%)	74 (59.2%)	86 (73.5%)
No baseline score	n (%)	11 (8.8%)	12 (10.3%)
No post-baseline score	n (%)	3 (2.4%)	2 (1.7%)
No deterioration possible	n (%)	0	0
No first deterioration	n (%)	60 (48.0%)	72 (61.5%)
Time to first deterioration (months)	Q1 [95% CI]	5.65 [5.55, 10.87]	8.38 [5.55, 21.65]
	Median [95% CI]	27.17 [14.49, NC]	NYR [22.21, NC]
	Q3 [95% CI]	NYR [35.29, NC]	NYR [NC, NC]
	p-value[b][d]		0.043
	HR [95 % CI][c][d]		1.59 [1.01, 2.50]
	Heterogeneity p-value[e][d]		0.3025

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.11.3.1 Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal
EQ-5D-3L VAS Score (Deterioration threshold = 15)

	Statistic	Cemiplimab (N=84)	Placebo (N=89)
Total number of patients[a]	n	84	89
Number of patients with events	n (%)	33 (39.3%)	31 (34.8%)
Number of censored cases	n (%)	51 (60.7%)	58 (65.2%)
No baseline score	n (%)	13 (15.5%)	8 (9.0%)
No post-baseline score	n (%)	1 (1.2%)	3 (3.4%)
No deterioration possible	n (%)	0	1 (1.1%)
No first deterioration	n (%)	37 (44.0%)	46 (51.7%)
Time to first deterioration (months)	Q1 [95% CI]	8.38 [5.59, 10.97]	8.34 [2.89, 13.90]
	Median [95% CI]	30.16 [11.07, NC]	30.69 [13.90, NC]
	Q3 [95% CI]	NYR [37.06, NC]	NYR [NC, NC]
	p-value[b][d]		0.987
	HR [95 % CI][c][d]		1.00 [0.60, 1.66]
	Heterogeneity p-value[e][d]		0.3025

Data cut-off as of April 07, 2025.
Note(s): [a] The thresholds for clinically meaningful deterioration are based on literature. CI: Confidence Interval; EQ-5D-3L: EuroQoL 5 Dimensions 3 Levels; FAS: Full analysis set; HR: Hazard Ration; VAS: Visual Analogue Scale.
[b] Stratified log-rank test. [c]Hazard ratio (HR) is based on a stratified Cox regression model.
[d] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
The analysis will be performed on the FAS population, with all PRO assessments (including EOT and FU assessments). Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.
[e] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: <65
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	21 (37.5%)	23 (35.4%)
Number of censored participants, n (%)	35 (62.5%)	42 (64.6%)
Proportionality Test p-value[a][b]	0.8491	
Hazard ratio(interaction)	0.929 (0.435, 1.985)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: >=65
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=153)	Placebo (N=141)
Number of events, n (%)	63 (41.2%)	39 (27.7%)
Number of censored participants, n (%)	90 (58.8%)	102 (72.3%)
Proportionality Test p-value[a][b]	0.1607	
Hazard ratio(interaction)	0.675 (0.389, 1.169)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: <65
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=56)	Placebo (N=65)
Number of events, n (%)	21 (37.5%)	23 (35.4%)
Number of censored participants, n (%)	35 (62.5%)	42 (64.6%)
Proportionality Test p-value[a][b]	0.8491	
Hazard ratio(interaction)	0.929 (0.435, 1.985)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=80)	Placebo (N=69)
Number of events, n (%)	30 (37.5%)	19 (27.5%)
Number of censored participants, n (%)	50 (62.5%)	50 (72.5%)
Proportionality Test p-value[a][b]	0.1915	
Hazard ratio(interaction)	0.562 (0.237, 1.334)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=75
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=73)	Placebo (N=72)
Number of events, n (%)	33 (45.2%)	20 (27.8%)
Number of censored participants, n (%)	40 (54.8%)	52 (72.2%)
Proportionality Test p-value[a][b]	0.4907	
Hazard ratio(interaction)	0.771 (0.368, 1.616)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Male
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=174)	Placebo (N=174)
Number of events, n (%)	69 (39.7%)	50 (28.7%)
Number of censored participants, n (%)	105 (60.3%)	124 (71.3%)
Proportionality Test p-value[a][b]	0.0338	
Hazard ratio(interaction)	0.587 (0.358, 0.960)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Female
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=35)	Placebo (N=32)
Number of events, n (%)	15 (42.9%)	12 (37.5%)
Number of censored participants, n (%)	20 (57.1%)	20 (62.5%)
Proportionality Test p-value[a][b]	0.7194	
Hazard ratio(interaction)	0.833 (0.308, 2.255)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=37)	Placebo (N=31)
Number of events, n (%)	9 (24.3%)	6 (19.4%)
Number of censored participants, n (%)	28 (75.7%)	25 (80.6%)
Proportionality Test p-value[a][b]	0.1267	
Hazard ratio(interaction)	0.193 (0.023, 1.593)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=90)	Placebo (N=90)
Number of events, n (%)	40 (44.4%)	25 (27.8%)
Number of censored participants, n (%)	50 (55.6%)	65 (72.2%)
Proportionality Test p-value[a][b]	0.4173	
Hazard ratio(interaction)	0.761 (0.394, 1.471)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): Rest of World
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=82)	Placebo (N=85)
Number of events, n (%)	35 (42.7%)	31 (36.5%)
Number of censored participants, n (%)	47 (57.3%)	54 (63.5%)
Proportionality Test p-value[a][b]	0.5808	
Hazard ratio(interaction)	0.844 (0.463, 1.540)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: White
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=189)	Placebo (N=189)
Number of events, n (%)	75 (39.7%)	52 (27.5%)
Number of censored participants, n (%)	114 (60.3%)	137 (72.5%)
Proportionality Test p-value[a][b]	0.2390	
Hazard ratio(interaction)	0.766 (0.491, 1.194)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: Non-white
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=20)	Placebo (N=17)
Number of events, n (%)	9 (45.0%)	10 (58.8%)
Number of censored participants, n (%)	11 (55.0%)	7 (41.2%)
Proportionality Test p-value[a][b]	0.2558	
Hazard ratio(interaction)	0.358 (0.061, 2.107)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=166)	Placebo (N=177)
Number of events, n (%)	68 (41.0%)	50 (28.2%)
Number of censored participants, n (%)	98 (59.0%)	127 (71.8%)
Proportionality Test p-value[a][b]	0.0143	
Hazard ratio(interaction)	0.548 (0.339, 0.887)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=43)	Placebo (N=29)
Number of events, n (%)	16 (37.2%)	12 (41.4%)
Number of censored participants, n (%)	27 (62.8%)	17 (58.6%)
Proportionality Test p-value[a][b]	0.1848	
Hazard ratio(interaction)	2.050 (0.710, 5.921)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 0
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=133)	Placebo (N=131)
Number of events, n (%)	50 (37.6%)	39 (29.8%)
Number of censored participants, n (%)	83 (62.4%)	92 (70.2%)
Proportionality Test p-value[a][b]	0.0741	
Hazard ratio(interaction)	0.612 (0.357, 1.049)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 1
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=76)	Placebo (N=75)
Number of events, n (%)	34 (44.7%)	23 (30.7%)
Number of censored participants, n (%)	42 (55.3%)	52 (69.3%)
Proportionality Test p-value[a][b]	0.1447	
Hazard ratio(interaction)	0.525 (0.221, 1.248)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Nodal
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=125)	Placebo (N=117)
Number of events, n (%)	51 (40.8%)	31 (26.5%)
Number of censored participants, n (%)	74 (59.2%)	86 (73.5%)
Proportionality Test p-value[a][b]	0.1540	
Hazard ratio(interaction)	0.644 (0.351, 1.180)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Table 14.2.9.3.1 Test of Proportional Hazards Assumption for Time to first deterioration in EQ-5D-3L VAS scale (excluding death) (15% of the scale range) by Subgroup
(Full Analysis Set)

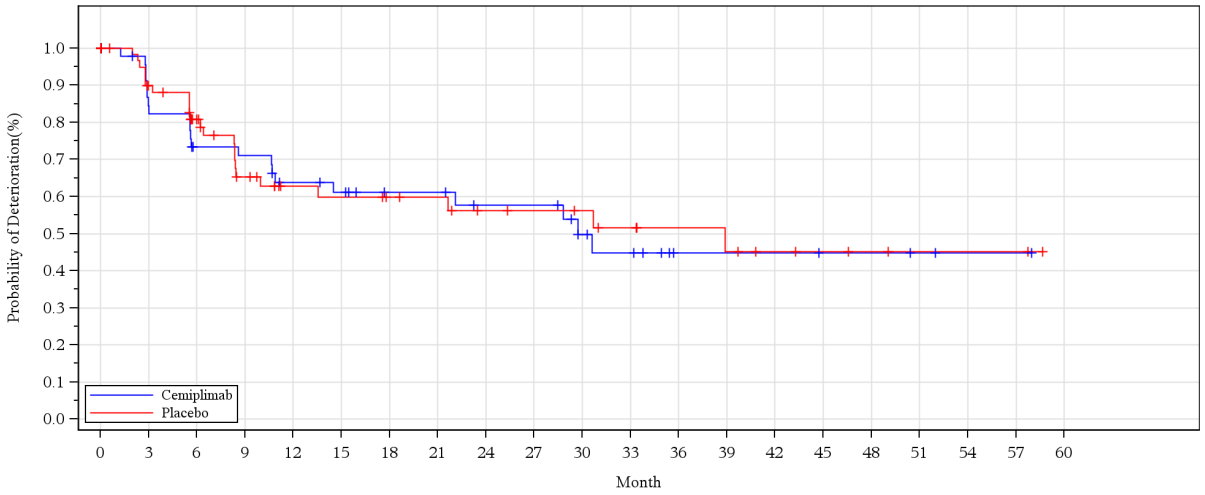
High risk feature: Non-Nodal
EQ5D01-EQ VAS Score (15% of the scale range)

	Cemiplimab (N=84)	Placebo (N=89)
Number of events, n (%)	33 (39.3%)	31 (34.8%)
Number of censored participants, n (%)	51 (60.7%)	58 (65.2%)
Proportionality Test p-value[a][b]	0.3280	
Hazard ratio(interaction)	0.726 (0.382, 1.379)	

Data cut-off as of April 07, 2025.
[a] Stratified by high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region) per EDC.
[b] proportional hazards assumption was tested by including time dependent covariate in the model for treatment arm*log(time)
Non-white includes not reported and unknown values.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: <65



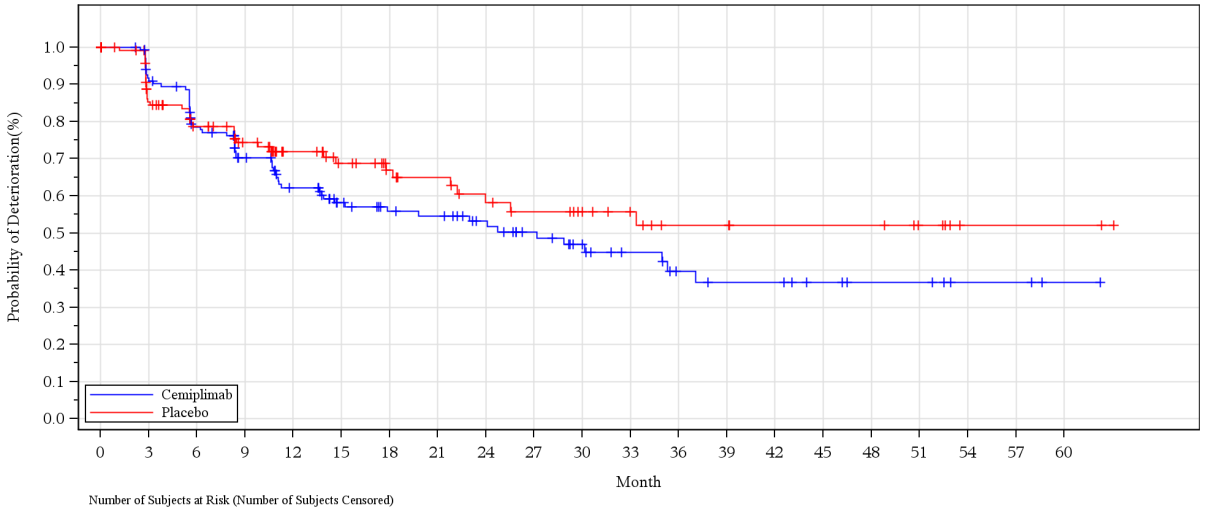
Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	56 (0)	38 (11)	31 (13)	30 (13)	25 (15)	23 (16)	19 (20)	19 (20)	16 (22)	16 (22)	11 (25)	9 (26)	4 (31)	4 (31)	4 (31)	3 (32)	3 (32)	2 (33)	1 (34)	1 (34)	0 (35)
Placebo	65 (0)	51 (8)	40 (14)	28 (19)	21 (25)	20 (25)	18 (27)	17 (28)	14 (30)	13 (31)	12 (32)	10 (33)	8 (35)	7 (35)	5 (37)	4 (38)	3 (39)	2 (40)	2 (40)	2 (40)	0 (42)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 1: >=65



Number of Subjects at Risk (Number of Subjects Censored)

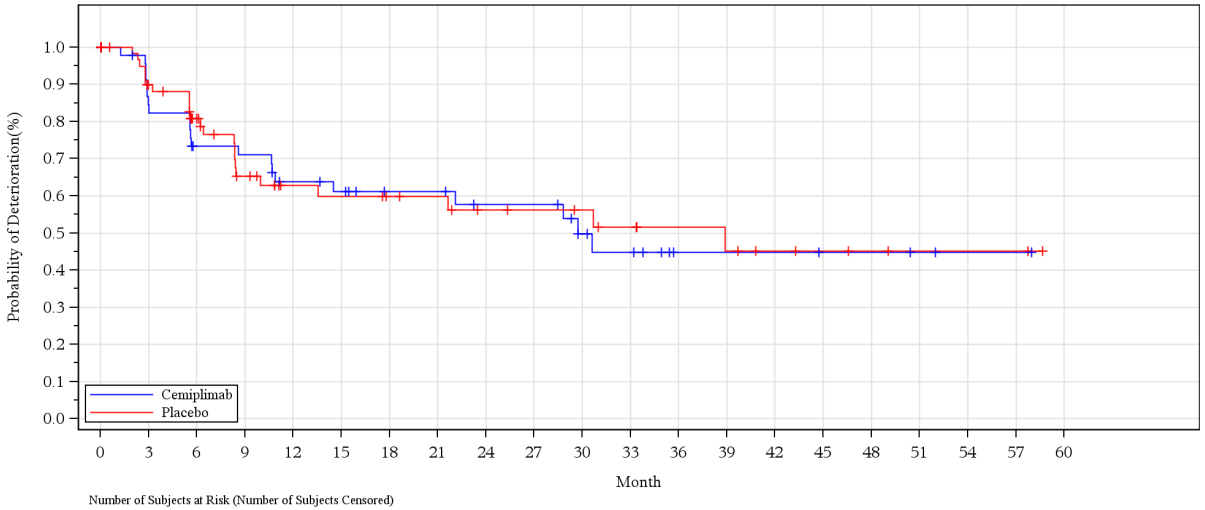
Cemiplimab	153 (0)	121 (21)	99 (26)	81 (34)	66 (40)	53 (49)	46 (54)	44 (55)	37 (61)	30 (66)	23 (71)	18 (75)	13 (78)	11 (79)	11 (79)	8 (82)	6 (84)	6 (84)	3 (87)	3 (87)	1 (89)
Placebo	141 (0)	96 (28)	78 (39)	65 (48)	50 (61)	42 (67)	34 (74)	30 (77)	25 (79)	22 (81)	18 (85)	15 (88)	11 (91)	11 (91)	9 (93)	9 (93)	9 (93)	6 (96)	2 (100)	2 (100)	2 (100)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: <65



Number of Subjects at Risk (Number of Subjects Censored)

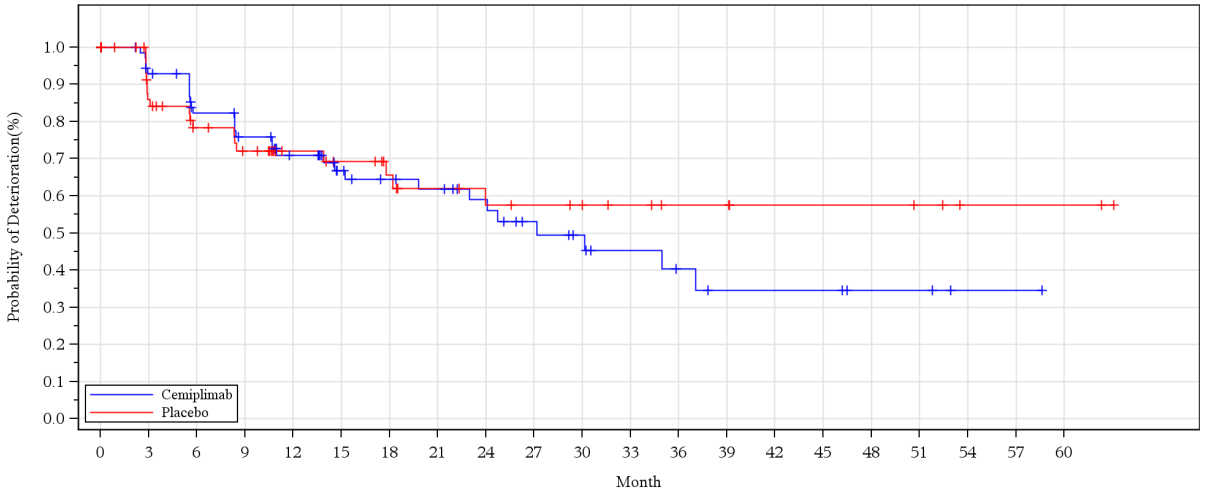
Cemiplimab	56 (0)	38 (11)	31 (13)	30 (13)	25 (15)	23 (16)	19 (20)	19 (20)	16 (22)	16 (22)	11 (25)	9 (26)	4 (31)	4 (31)	4 (31)	3 (32)	3 (32)	2 (33)	1 (34)	1 (34)	0 (35)
Placebo	65 (0)	51 (8)	40 (14)	28 (19)	21 (25)	20 (25)	18 (27)	17 (28)	14 (30)	13 (31)	12 (32)	10 (33)	8 (35)	7 (35)	5 (37)	4 (38)	3 (39)	2 (40)	2 (40)	2 (40)	0 (42)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=65 and <75



Number of Subjects at Risk (Number of Subjects Censored)

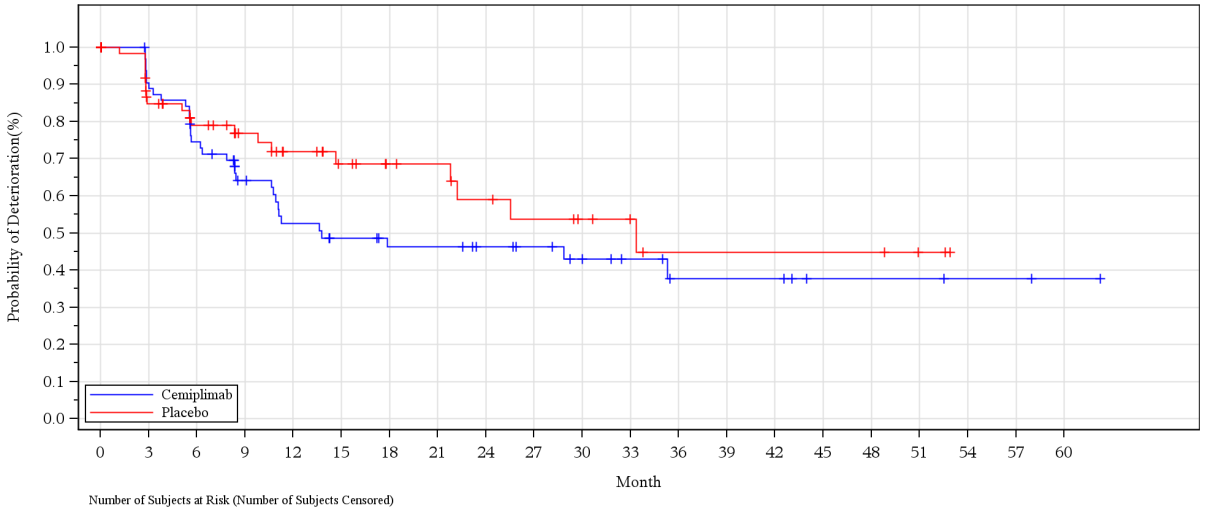
Cemiplimab	80 (0)	64 (11)	53 (15)	47 (17)	39 (22)	30 (29)	26 (32)	24 (33)	20 (36)	15 (39)	12 (41)	9 (43)	7 (44)	5 (45)	5 (45)	5 (45)	3 (47)	3 (47)	1 (49)	1 (49)	0 (50)
Placebo	69 (0)	48 (13)	39 (18)	34 (20)	25 (29)	22 (31)	18 (34)	15 (36)	13 (37)	12 (38)	10 (40)	9 (41)	7 (43)	7 (43)	5 (45)	5 (45)	5 (45)	4 (46)	2 (48)	2 (48)	2 (48)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Age group 2: >=75



Number of Subjects at Risk (Number of Subjects Censored)

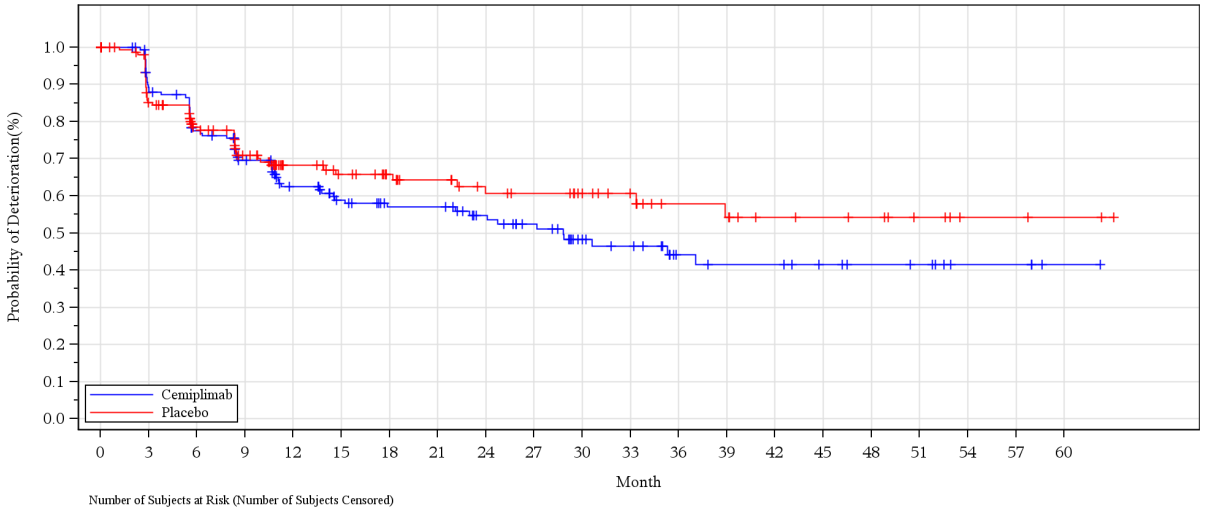
Cemiplimab	73 (0)	57 (10)	46 (11)	34 (17)	27 (18)	23 (20)	20 (22)	20 (22)	17 (25)	15 (27)	11 (30)	9 (32)	6 (34)	6 (34)	6 (34)	3 (37)	3 (37)	3 (37)	2 (38)	2 (38)	1 (39)
Placebo	72 (0)	48 (15)	39 (21)	31 (28)	25 (32)	20 (36)	16 (40)	15 (41)	12 (42)	10 (43)	8 (45)	6 (47)	4 (48)	4 (48)	4 (48)	4 (48)	4 (48)	2 (50)	0 (52)	0 (52)	0 (52)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Male



Number of Subjects at Risk (Number of Subjects Censored)

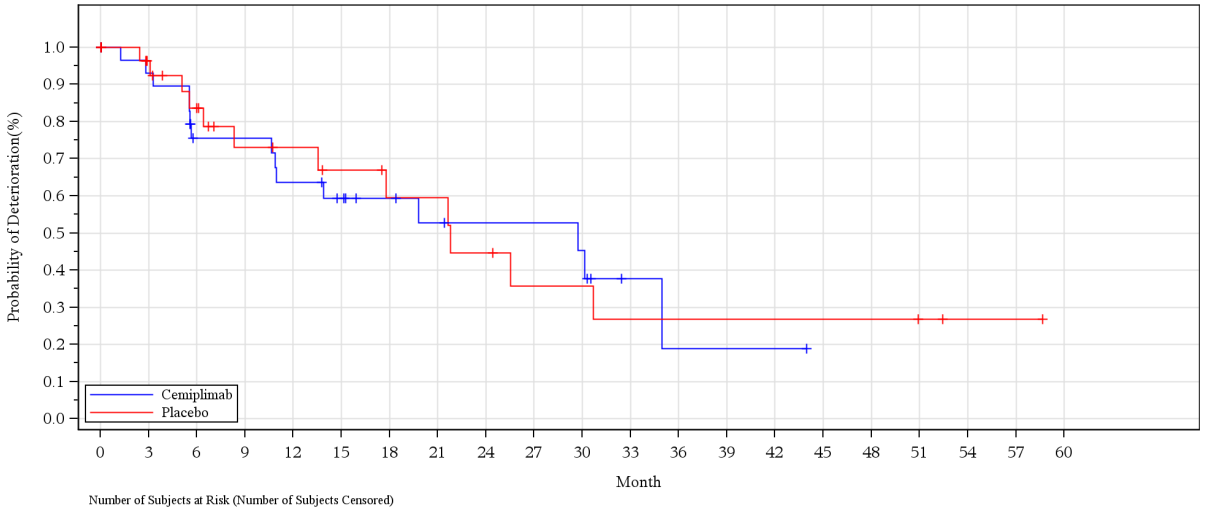
Cemiplimab	174 (0)	132 (26)	111 (30)	92 (38)	75 (46)	63 (54)	55 (60)	55 (60)	46 (67)	39 (72)	28 (80)	25 (82)	16 (90)	14 (91)	14 (91)	11 (94)	9 (96)	8 (97)	4 (101)	4 (101)	1 (104)
Placebo	174 (0)	123 (29)	99 (44)	80 (54)	59 (72)	52 (77)	44 (85)	39 (89)	33 (93)	31 (95)	26 (100)	22 (104)	16 (109)	15 (109)	11 (113)	10 (114)	9 (115)	6 (118)	3 (121)	3 (121)	2 (122)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Gender group: Female



Number of Subjects at Risk (Number of Subjects Censored)

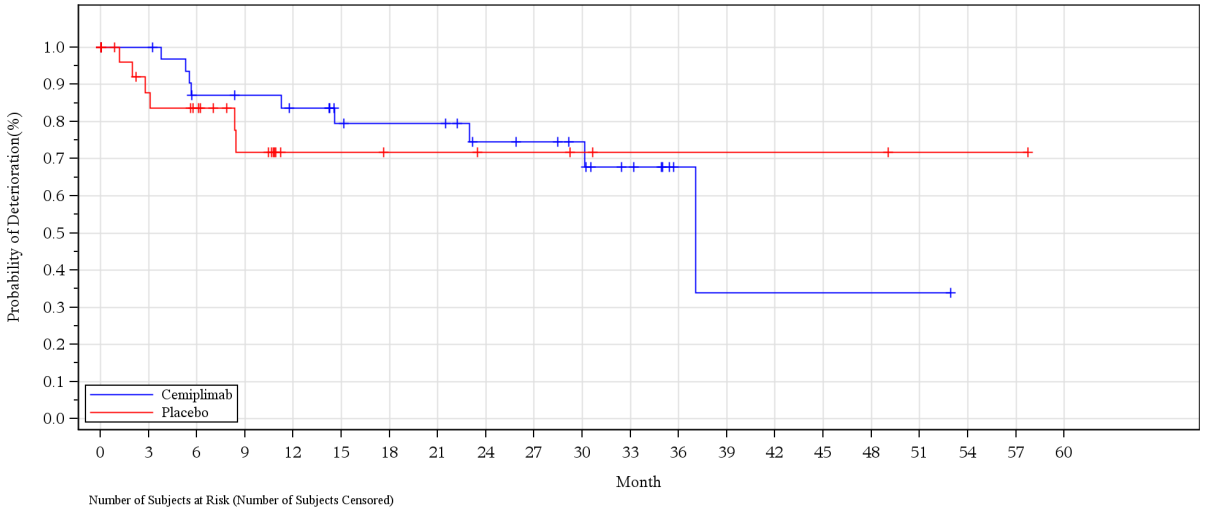
Cemiplimab	35 (0)	27 (6)	19 (9)	19 (9)	16 (9)	13 (11)	10 (14)	8 (15)	7 (16)	7 (16)	6 (16)	2 (19)	1 (19)	1 (19)	1 (19)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)	0 (20)
Placebo	32 (0)	24 (7)	19 (9)	13 (13)	12 (14)	10 (15)	8 (16)	8 (16)	6 (16)	4 (17)	4 (17)	3 (17)	3 (17)	3 (17)	3 (17)	3 (17)	3 (17)	2 (18)	1 (19)	1 (19)	0 (20)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Geographic region group (EDC): North America



Number of Subjects at Risk (Number of Subjects Censored)

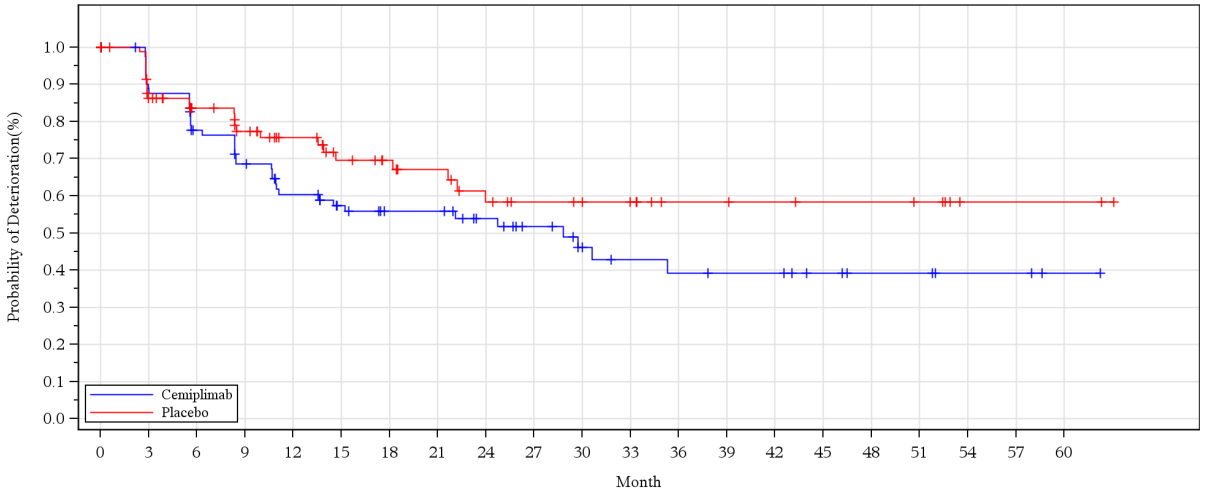
Cemiplimab	37 (0)	32 (5)	26 (7)	25 (8)	23 (9)	19 (12)	18 (13)	18 (13)	14 (16)	13 (17)	11 (19)	7 (22)	2 (27)	1 (27)	1 (27)	1 (27)	1 (27)	1 (27)	0 (28)	0 (28)	0 (28)
Placebo	31 (0)	21 (7)	18 (9)	12 (13)	6 (19)	6 (19)	5 (20)	5 (20)	4 (21)	4 (21)	3 (22)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	2 (23)	1 (24)	1 (24)	1 (24)	0 (25)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Geographic region group (EDC): Australia/New Zealand



Number of Subjects at Risk (Number of Subjects Censored)

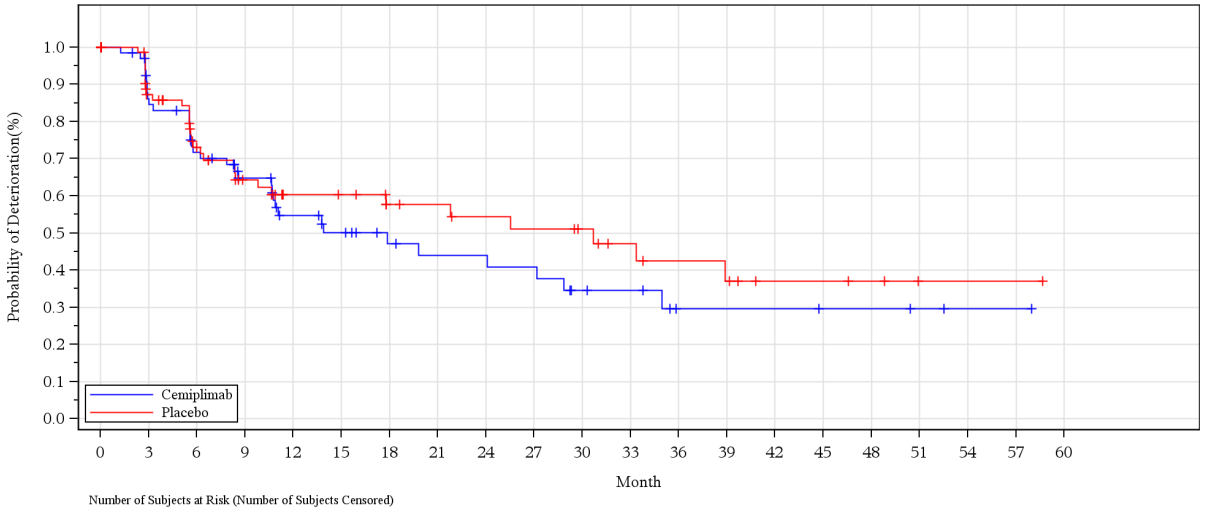
Cemiplimab	90 (0)	72 (9)	60 (12)	52 (13)	43 (16)	36 (21)	31 (25)	31 (25)	25 (30)	20 (34)	14 (38)	12 (39)	11 (39)	10 (40)	10 (40)	7 (43)	5 (45)	5 (45)	3 (47)	3 (47)	1 (49)
Placebo	90 (0)	67 (12)	56 (21)	48 (25)	40 (32)	32 (37)	28 (41)	24 (44)	19 (46)	16 (49)	14 (51)	13 (52)	9 (56)	9 (56)	8 (57)	7 (58)	7 (58)	6 (59)	2 (63)	2 (63)	2 (63)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Geographic region group (EDC): Rest of World



Number of Subjects at Risk (Number of Subjects Censored)

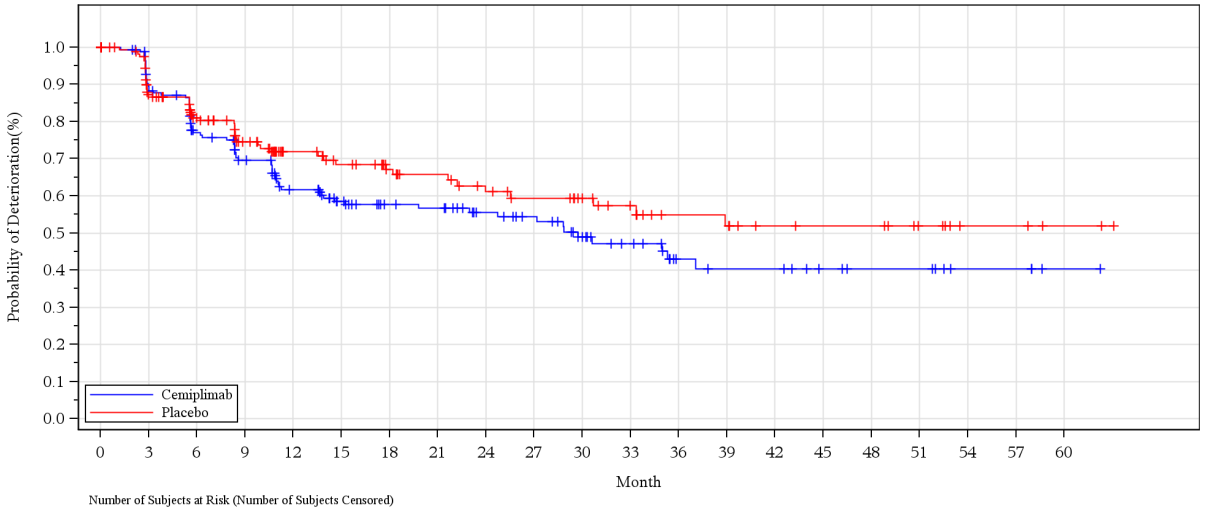
Cemiplimab	82 (0)	55 (18)	44 (20)	34 (26)	25 (30)	21 (32)	16 (36)	14 (37)	14 (37)	13 (37)	9 (39)	8 (40)	4 (43)	4 (43)	4 (43)	3 (44)	3 (44)	2 (45)	1 (46)	1 (46)	0 (47)
Placebo	85 (0)	59 (17)	44 (23)	33 (29)	25 (35)	24 (36)	19 (40)	18 (41)	16 (42)	15 (42)	13 (44)	10 (46)	8 (47)	7 (47)	4 (50)	4 (50)	3 (51)	1 (53)	1 (53)	1 (53)	0 (54)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: White



Number of Subjects at Risk (Number of Subjects Censored)

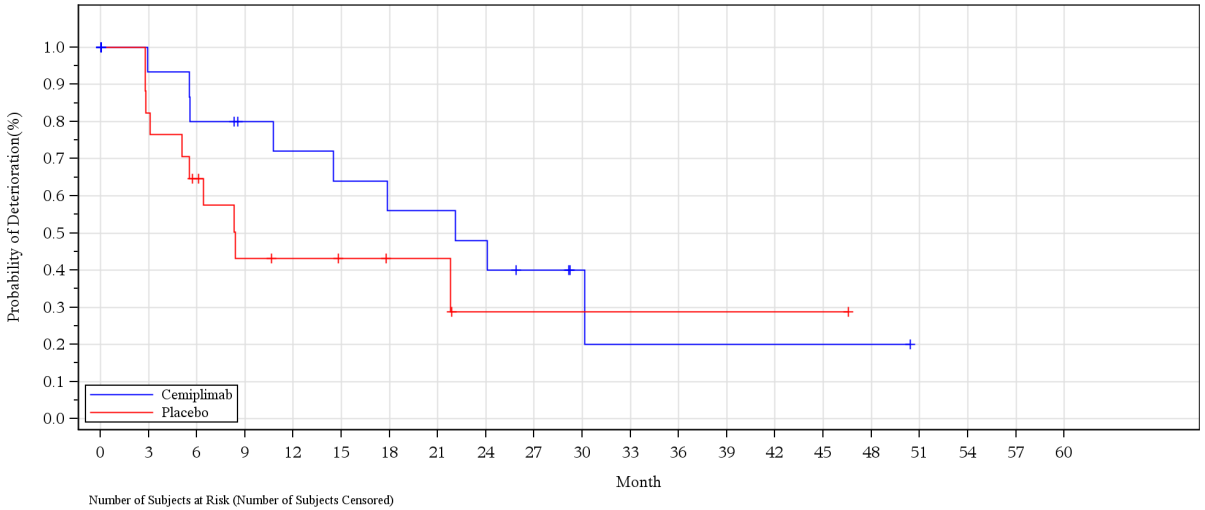
Cemiplimab	189 (0)	145 (27)	118 (34)	101 (40)	82 (48)	68 (58)	58 (67)	56 (68)	47 (76)	42 (80)	32 (86)	26 (91)	16 (99)	14 (100)	14 (100)	10 (104)	8 (106)	8 (106)	4 (110)	4 (110)	1 (113)
Placebo	189 (0)	133 (36)	108 (52)	87 (65)	66 (83)	58 (88)	49 (96)	44 (100)	38 (103)	34 (106)	29 (111)	24 (115)	18 (120)	17 (120)	13 (124)	12 (125)	12 (125)	8 (129)	4 (133)	4 (133)	2 (135)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

Race: Non-white



Number of Subjects at Risk (Number of Subjects Censored)

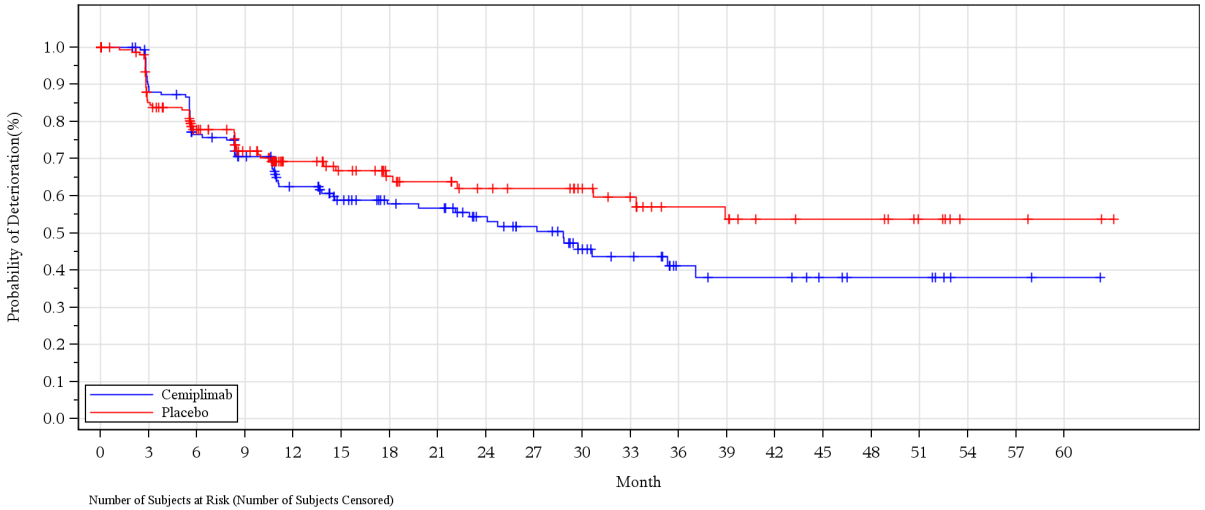
Cemiplimab	20 (0)	14 (5)	12 (5)	10 (7)	9 (7)	8 (7)	7 (7)	7 (7)	6 (7)	4 (8)	2 (10)	1 (10)	1 (10)	1 (10)	1 (10)	1 (10)	1 (10)	0 (11)	0 (11)	0 (11)	0 (11)
Placebo	17 (0)	14 (0)	10 (1)	6 (2)	5 (3)	4 (4)	3 (5)	3 (5)	1 (6)	1 (6)	1 (6)	1 (6)	1 (6)	1 (6)	1 (6)	1 (6)	0 (7)	0 (7)	0 (7)	0 (7)	0 (7)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

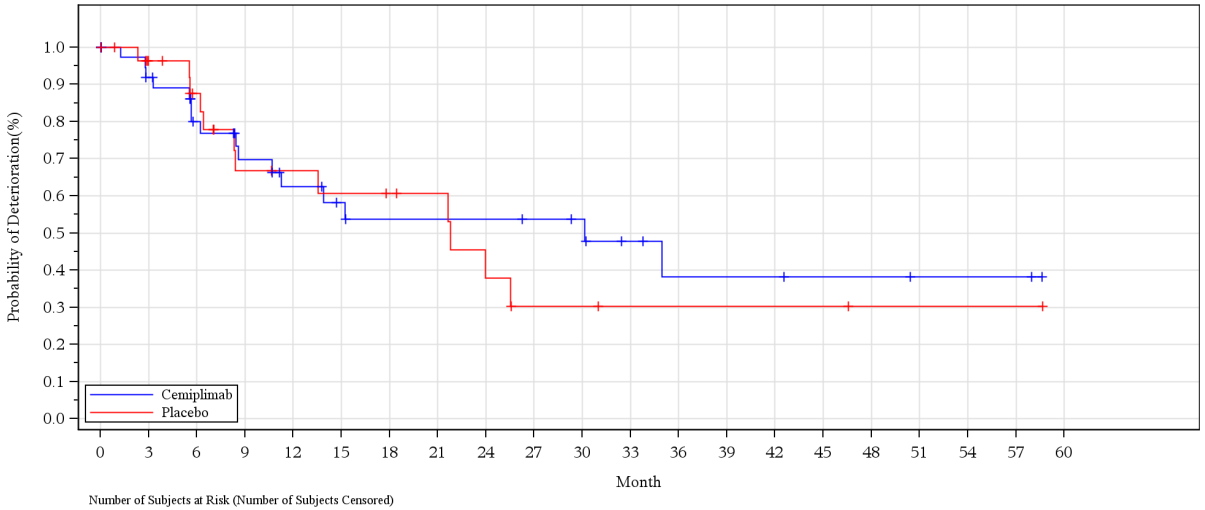
Cemiplimab	166 (0)	126 (25)	105 (28)	91 (34)	75 (40)	63 (48)	54 (56)	52 (57)	42 (65)	36 (69)	25 (76)	21 (79)	13 (86)	11 (87)	11 (87)	8 (90)	6 (92)	6 (92)	2 (96)	2 (96)	1 (97)
Placebo	177 (0)	124 (31)	100 (45)	81 (57)	60 (75)	52 (81)	43 (89)	39 (92)	34 (96)	32 (98)	27 (103)	23 (106)	17 (111)	16 (111)	12 (115)	11 (116)	11 (116)	7 (120)	3 (124)	3 (124)	2 (125)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	43 (0)	33 (7)	25 (11)	20 (13)	16 (15)	13 (17)	11 (18)	11 (18)	11 (18)	10 (19)	9 (20)	6 (22)	4 (23)	4 (23)	4 (23)	3 (24)	3 (24)	2 (25)	2 (25)	2 (25)	0 (27)
Placebo	29 (0)	23 (5)	18 (8)	12 (10)	11 (11)	10 (11)	9 (12)	8 (13)	5 (13)	3 (14)	3 (14)	2 (15)	2 (15)	2 (15)	2 (15)	2 (15)	1 (16)	1 (16)	1 (16)	1 (16)	0 (17)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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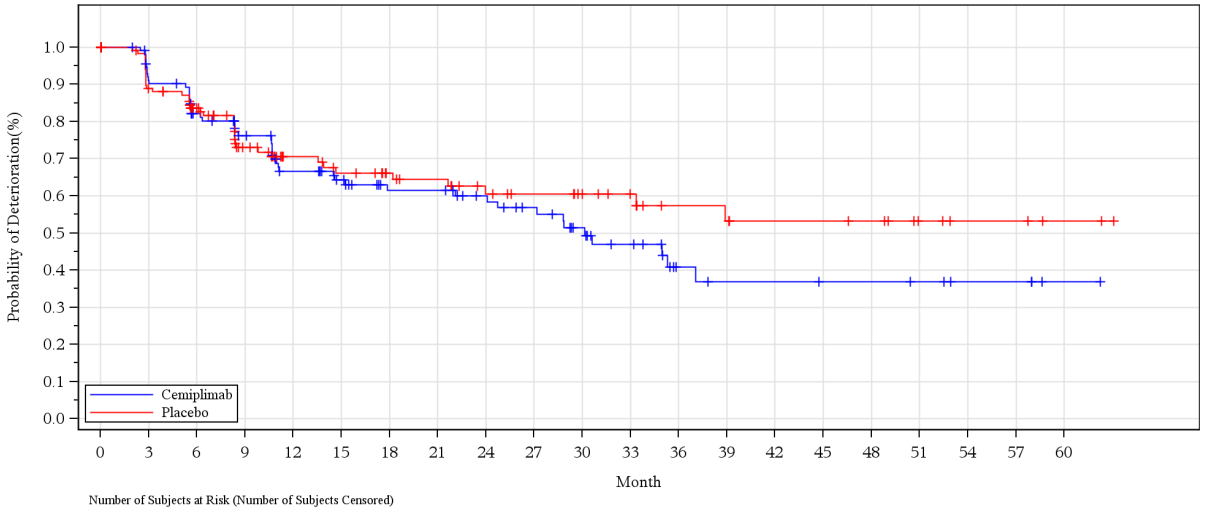
Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

ECOG status: 0



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	133 (0)	102 (21)	87 (26)	75 (32)	60 (38)	52 (44)	43 (51)	43 (51)	37 (56)	32 (59)	25 (63)	19 (67)	10 (74)	8 (75)	8 (75)	7 (76)	7 (76)	6 (77)	4 (79)	4 (79)	1 (82)
Placebo	131 (0)	103 (15)	86 (26)	63 (39)	49 (51)	44 (53)	38 (59)	35 (61)	29 (65)	26 (68)	22 (72)	19 (75)	14 (79)	13 (79)	11 (81)	11 (81)	10 (82)	6 (86)	4 (88)	4 (88)	2 (90)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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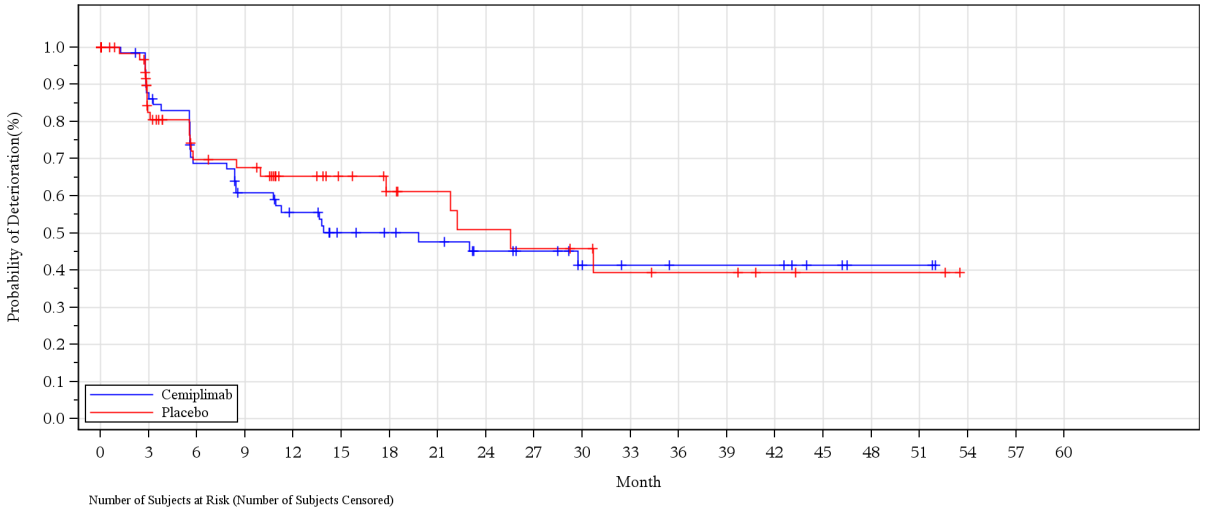
Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup (Full Analysis Set)

ECOG status: 1



Number of Subjects at Risk (Number of Subjects Censored)

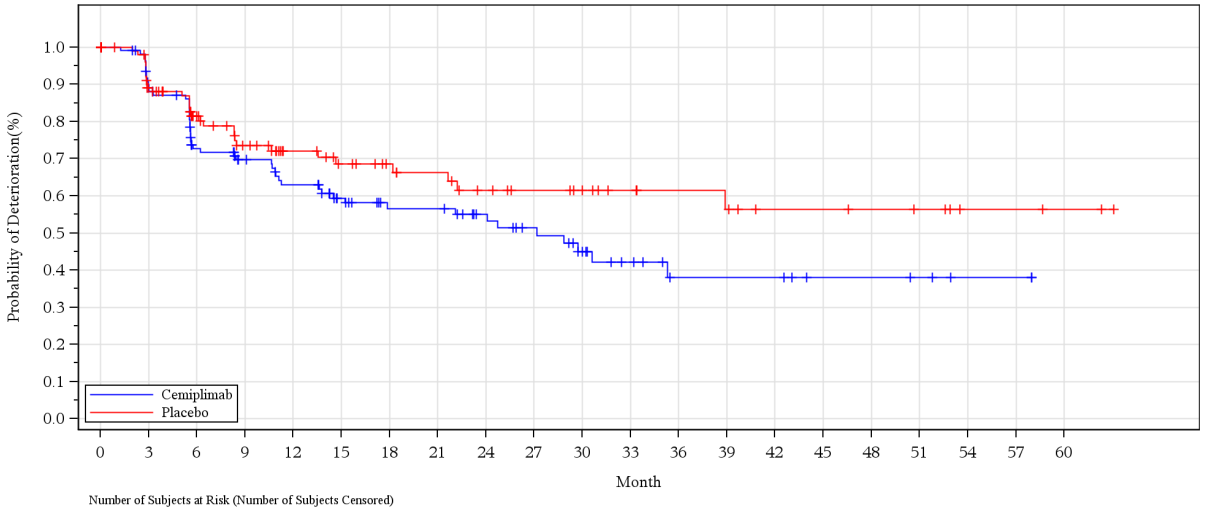
Cemiplimab	76 (0)	57 (11)	43 (13)	36 (15)	31 (17)	24 (21)	22 (23)	20 (24)	16 (27)	14 (29)	9 (33)	8 (34)	7 (35)	7 (35)	7 (35)	4 (38)	2 (40)	2 (40)	0 (42)	0 (42)	0 (42)
Placebo	75 (0)	44 (21)	32 (27)	30 (28)	22 (35)	18 (39)	14 (42)	12 (44)	10 (44)	9 (44)	8 (45)	6 (46)	5 (47)	5 (47)	3 (49)	2 (50)	2 (50)	2 (50)	0 (52)	0 (52)	0 (52)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	125 (0)	97 (17)	73 (23)	64 (29)	56 (31)	45 (39)	37 (45)	37 (45)	30 (51)	25 (54)	18 (58)	13 (62)	8 (66)	8 (66)	8 (66)	5 (69)	5 (69)	4 (70)	2 (72)	2 (72)	0 (74)
Placebo	117 (0)	87 (19)	67 (32)	53 (40)	42 (50)	36 (54)	31 (59)	28 (61)	23 (64)	20 (67)	17 (70)	14 (73)	12 (75)	11 (75)	8 (78)	8 (78)	7 (79)	6 (80)	3 (83)	3 (83)	2 (84)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

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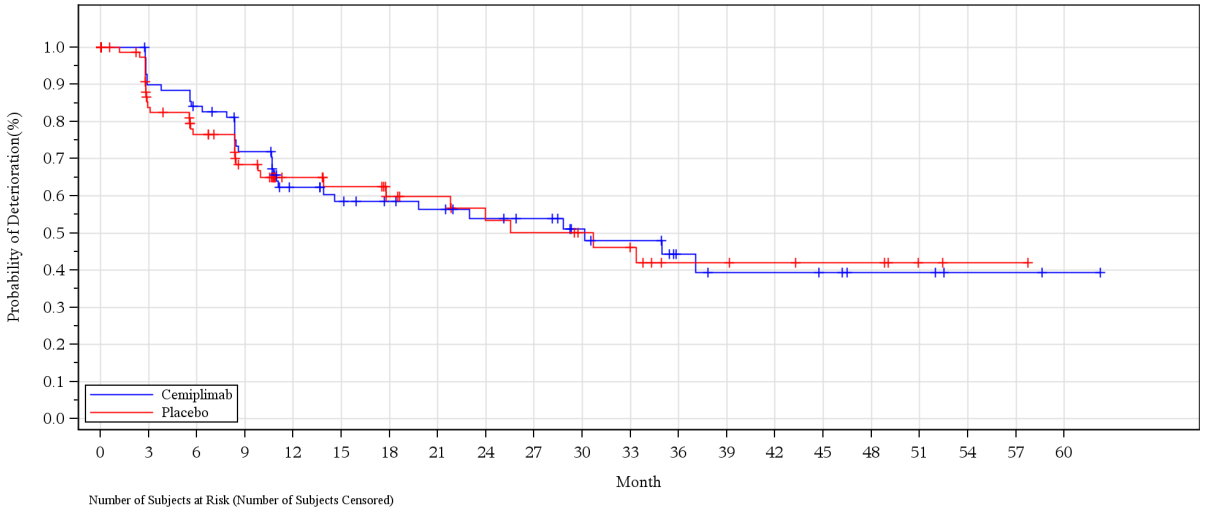
Figure 14.2.10.3.1 Time to First Deterioration (Excluding Death) - EQ-5D-3L VAS scale (15% of the scale range) by Subgroup
(Full Analysis Set)

High risk feature: Non-Nodal



Number of Subjects at Risk (Number of Subjects Censored)

Cemiplimab	84 (0)	62 (15)	57 (16)	47 (18)	35 (24)	31 (26)	28 (29)	26 (30)	23 (32)	21 (34)	16 (38)	14 (39)	9 (43)	7 (44)	7 (44)	6 (45)	4 (47)	4 (47)	2 (49)	2 (49)	1 (50)
Placebo	89 (0)	60 (17)	51 (21)	40 (27)	29 (36)	26 (38)	21 (42)	19 (44)	16 (45)	15 (45)	13 (47)	11 (48)	7 (51)	7 (51)	6 (52)	5 (53)	5 (53)	2 (56)	1 (57)	1 (57)	0 (58)

Data cut-off as of April 07, 2025.
Death was not considered a deterioration event
CI: Confidence Interval; EQ-5D-3L: EuroQol-5 Dimensions-3 Levels; HR: Hazard Ration; NYR: Not Yet Reached; NC: Not Calculable.
Subgroup analyses were performed only if all subgroups had >=10 patients per treatment arm and at least one subgroup in any treatment arm had >=10 events.

/sasdata/Data/Production/BDM/MA/R2810/R2810-ONC/R2810-ONC-1788/HTA/Germany/Apr2025/Analysis_MA/Programs/TFL/f-ttd-km-bysub1.sas (pingping.xu 24NOV2025 7:21 SAS Linux 9.4)

2.9 Verträglichkeit

2.9.1 1. Datenschnitt

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE	53 (98.1%)	58 (89.2%)
Odds ratio (95% CI)	7.545 (0.844, 67.411)	
P-value for Odds Ratio	0.0702	
Relative Risk (95% CI)	1.12 (0.87, 1.45)	
P-value for Relative Risk	0.3676	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	13.53 (-9.04, 36.11)	
P-value for Risk Difference	0.2374	
TEAE with any NCI grade 3/4/5	11 (20.4%)	7 (10.8%)
Odds ratio (95% CI)	2.134 (0.751, 6.066)	
P-value for Odds Ratio	0.1534	
Relative Risk (95% CI)	1.85 (0.76, 4.47)	
P-value for Relative Risk	0.1729	
Heterogeneity p-value of RR	0.6560	
Risk difference (95% CI)	12.12 (-2.66, 26.90)	
P-value for Risk Difference	0.1071	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	6 (11.1%)	2 (3.1%)
Odds ratio (95% CI)	5.491 (0.885, 34.057)	
P-value for Odds Ratio	0.0671	
Relative Risk (95% CI)	3.92 (0.84, 18.36)	
P-value for Relative Risk	0.0819	
Heterogeneity p-value of RR	0.2765	
Risk difference (95% CI)	10.74 (-8.49, 29.96)	
P-value for Risk Difference	0.2710	
TEAE leading to study treatment discontinuation	3 (5.6%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.32 (0.55, 19.95)	
P-value for Relative Risk	0.1675	
Heterogeneity p-value of RR	0.2837	
Risk difference (95% CI)	9.37 (-186.02, 204.75)	
P-value for Risk Difference	0.9245	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE leading to study treatment interruption/delay	11 (20.4%)	7 (10.8%)
Odds ratio (95% CI)	2.156 (0.760, 6.120)	
P-value for Odds Ratio	0.1473	
Relative Risk (95% CI)	1.89 (0.78, 4.59)	
P-value for Relative Risk	0.1580	
Heterogeneity p-value of RR	0.7829	
Risk difference (95% CI)	10.88 (-2.28, 24.03)	
P-value for Risk Difference	0.1042	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TEAE	134 (88.7%)	124 (89.2%)
Odds ratio (95% CI)	0.930 (0.431, 2.006)	
P-value for Odds Ratio	0.8520	
Relative Risk (95% CI)	1.01 (0.94, 1.08)	
P-value for Relative Risk	0.8157	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	0.23 (-5.62, 6.09)	
P-value for Risk Difference	0.9383	
TEAE with any NCI grade 3/4/5	38 (25.2%)	22 (15.8%)
Odds ratio (95% CI)	1.690 (0.929, 3.075)	
P-value for Odds Ratio	0.0854	
Relative Risk (95% CI)	1.49 (0.92, 2.41)	
P-value for Relative Risk	0.1041	
Heterogeneity p-value of RR	0.6560	
Risk difference (95% CI)	8.94 (-0.10, 17.98)	
P-value for Risk Difference	0.0525	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TE-SAE	30 (19.9%)	17 (12.2%)
Odds ratio (95% CI)	1.710 (0.886, 3.298)	
P-value for Odds Ratio	0.1093	
Relative Risk (95% CI)	1.56 (0.89, 2.73)	
P-value for Relative Risk	0.1196	
Heterogeneity p-value of RR	0.2765	
Risk difference (95% CI)	7.25 (-1.15, 15.66)	
P-value for Risk Difference	0.0906	
TEAE leading to study treatment discontinuation	17 (11.3%)	3 (2.2%)
Odds ratio (95% CI)	5.868 (1.660, 20.743)	
P-value for Odds Ratio	0.0062	
Relative Risk (95% CI)	5.32 (1.58, 17.96)	
P-value for Relative Risk	0.0072	
Heterogeneity p-value of RR	0.2837	
Risk difference (95% CI)	9.86 (1.62, 18.09)	
P-value for Risk Difference	0.0192	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TEAE leading to study treatment interruption/delay	35 (23.2%)	19 (13.7%)
Odds ratio (95% CI)	1.770 (0.945, 3.317)	
P-value for Odds Ratio	0.0744	
Relative Risk (95% CI)	1.60 (0.96, 2.67)	
P-value for Relative Risk	0.0741	
Heterogeneity p-value of RR	0.7829	
Risk difference (95% CI)	7.76 (-1.05, 16.57)	
P-value for Risk Difference	0.0842	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE	53 (98.1%)	58 (89.2%)
Odds ratio (95% CI)	7.545 (0.844, 67.411)	
P-value for Odds Ratio	0.0702	
Relative Risk (95% CI)	1.12 (0.87, 1.45)	
P-value for Relative Risk	0.3676	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	13.53 (-9.04, 36.11)	
P-value for Risk Difference	0.2374	
TEAE with any NCI grade 3/4/5	11 (20.4%)	7 (10.8%)
Odds ratio (95% CI)	2.134 (0.751, 6.066)	
P-value for Odds Ratio	0.1534	
Relative Risk (95% CI)	1.85 (0.76, 4.47)	
P-value for Relative Risk	0.1729	
Heterogeneity p-value of RR	0.4678	
Risk difference (95% CI)	12.12 (-2.66, 26.90)	
P-value for Risk Difference	0.1071	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	6 (11.1%)	2 (3.1%)
Odds ratio (95% CI)	5.491 (0.885, 34.057)	
P-value for Odds Ratio	0.0671	
Relative Risk (95% CI)	3.92 (0.84, 18.36)	
P-value for Relative Risk	0.0819	
Heterogeneity p-value of RR	0.4529	
Risk difference (95% CI)	10.74 (-8.49, 29.96)	
P-value for Risk Difference	0.2710	
TEAE leading to study treatment discontinuation	3 (5.6%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.32 (0.55, 19.95)	
P-value for Relative Risk	0.1675	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	9.37 (-186.02, 204.75)	
P-value for Risk Difference	0.9245	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE leading to study treatment interruption/delay	11 (20.4%)	7 (10.8%)
Odds ratio (95% CI)	2.156 (0.760, 6.120)	
P-value for Odds Ratio	0.1473	
Relative Risk (95% CI)	1.89 (0.78, 4.59)	
P-value for Relative Risk	0.1580	
Heterogeneity p-value of RR	0.6391	
Risk difference (95% CI)	10.88 (-2.28, 24.03)	
P-value for Risk Difference	0.1042	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TEAE	70 (87.5%)	61 (89.7%)
Odds ratio (95% CI)	0.963 (0.320, 2.901)	
P-value for Odds Ratio	0.9460	
Relative Risk (95% CI)	0.98 (0.90, 1.08)	
P-value for Relative Risk	0.7005	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	-1.11 (-9.45, 7.24)	
P-value for Risk Difference	0.7933	
TEAE with any NCI grade 3/4/5	16 (20.0%)	12 (17.6%)
Odds ratio (95% CI)	1.099 (0.459, 2.633)	
P-value for Odds Ratio	0.8313	
Relative Risk (95% CI)	1.06 (0.54, 2.08)	
P-value for Relative Risk	0.8631	
Heterogeneity p-value of RR	0.4678	
Risk difference (95% CI)	1.47 (-10.93, 13.87)	
P-value for Risk Difference	0.8153	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TE-SAE	12 (15.0%)	8 (11.8%)
Odds ratio (95% CI)	1.359 (0.495, 3.729)	
P-value for Odds Ratio	0.5494	
Relative Risk (95% CI)	1.19 (0.52, 2.76)	
P-value for Relative Risk	0.6774	
Heterogeneity p-value of RR	0.4529	
Risk difference (95% CI)	6.60 (-8.09, 21.29)	
P-value for Risk Difference	0.3761	
TEAE leading to study treatment discontinuation	6 (7.5%)	1 (1.5%)
Odds ratio (95% CI)	5.167 (0.584, 45.742)	
P-value for Odds Ratio	0.1388	
Relative Risk (95% CI)	4.92 (0.58, 41.46)	
P-value for Relative Risk	0.1421	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	7.35 (-34.74, 49.45)	
P-value for Risk Difference	0.7304	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TEAE leading to study treatment interruption/delay	16 (20.0%)	10 (14.7%)
Odds ratio (95% CI)	1.281 (0.521, 3.147)	
P-value for Odds Ratio	0.5870	
Relative Risk (95% CI)	1.25 (0.60, 2.58)	
P-value for Relative Risk	0.5474	
Heterogeneity p-value of RR	0.6391	
Risk difference (95% CI)	2.59 (-10.07, 15.25)	
P-value for Risk Difference	0.6865	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TEAE	64 (90.1%)	63 (88.7%)
Odds ratio (95% CI)	1.006 (0.330, 3.071)	
P-value for Odds Ratio	0.9909	
Relative Risk (95% CI)	1.05 (0.88, 1.27)	
P-value for Relative Risk	0.5680	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	4.61 (-10.91, 20.13)	
P-value for Risk Difference	0.5577	
TEAE with any NCI grade 3/4/5	22 (31.0%)	10 (14.1%)
Odds ratio (95% CI)	2.592 (1.094, 6.139)	
P-value for Odds Ratio	0.0307	
Relative Risk (95% CI)	2.10 (1.06, 4.16)	
P-value for Relative Risk	0.0330	
Heterogeneity p-value of RR	0.4678	
Risk difference (95% CI)	15.04 (1.30, 28.77)	
P-value for Risk Difference	0.0322	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TE-SAE	18 (25.4%)	9 (12.7%)
Odds ratio (95% CI)	2.427 (0.981, 6.003)	
P-value for Odds Ratio	0.0549	
Relative Risk (95% CI)	2.03 (0.97, 4.24)	
P-value for Relative Risk	0.0604	
Heterogeneity p-value of RR	0.4529	
Risk difference (95% CI)	14.74 (0.62, 28.87)	
P-value for Risk Difference	0.0409	
TEAE leading to study treatment discontinuation	11 (15.5%)	2 (2.8%)
Odds ratio (95% CI)	6.466 (1.340, 31.195)	
P-value for Odds Ratio	0.0204	
Relative Risk (95% CI)	5.55 (1.26, 24.53)	
P-value for Relative Risk	0.0240	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	14.52 (-4.88, 33.91)	
P-value for Risk Difference	0.1411	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TEAE leading to study treatment interruption/delay	19 (26.8%)	9 (12.7%)
Odds ratio (95% CI)	2.564 (1.034, 6.361)	
P-value for Odds Ratio	0.0423	
Relative Risk (95% CI)	2.14 (1.03, 4.44)	
P-value for Relative Risk	0.0425	
Heterogeneity p-value of RR	0.6391	
Risk difference (95% CI)	14.48 (1.22, 27.73)	
P-value for Risk Difference	0.0325	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TEAE	157 (91.8%)	154 (89.5%)
Odds ratio (95% CI)	1.289 (0.605, 2.748)	
P-value for Odds Ratio	0.5101	
Relative Risk (95% CI)	1.03 (0.97, 1.09)	
P-value for Relative Risk	0.3397	
Heterogeneity p-value of RR	0.4910	
Risk difference (95% CI)	2.45 (-2.82, 7.72)	
P-value for Risk Difference	0.3616	
TEAE with any NCI grade 3/4/5	41 (24.0%)	23 (13.4%)
Odds ratio (95% CI)	2.010 (1.136, 3.556)	
P-value for Odds Ratio	0.0166	
Relative Risk (95% CI)	1.71 (1.07, 2.73)	
P-value for Relative Risk	0.0246	
Heterogeneity p-value of RR	0.4967	
Risk difference (95% CI)	10.99 (3.02, 18.96)	
P-value for Risk Difference	0.0070	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TE-SAE	31 (18.1%)	17 (9.9%)
Odds ratio (95% CI)	1.925 (1.010, 3.667)	
P-value for Odds Ratio	0.0465	
Relative Risk (95% CI)	1.70 (0.97, 2.96)	
P-value for Relative Risk	0.0621	
Heterogeneity p-value of RR	0.8036	
Risk difference (95% CI)	7.19 (-0.07, 14.44)	
P-value for Risk Difference	0.0522	
TEAE leading to study treatment discontinuation	20 (11.7%)	2 (1.2%)
Odds ratio (95% CI)	11.034 (2.520, 48.314)	
P-value for Odds Ratio	0.0015	
Relative Risk (95% CI)	9.82 (2.31, 41.66)	
P-value for Relative Risk	0.0020	
Heterogeneity p-value of RR	0.0318	
Risk difference (95% CI)	10.70 (2.96, 18.43)	
P-value for Risk Difference	0.0069	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TEAE leading to study treatment interruption/delay	34 (19.9%)	20 (11.6%)
Odds ratio (95% CI)	1.829 (1.000, 3.348)	
P-value for Odds Ratio	0.0502	
Relative Risk (95% CI)	1.65 (0.99, 2.75)	
P-value for Relative Risk	0.0555	
Heterogeneity p-value of RR	0.8972	
Risk difference (95% CI)	8.00 (0.39, 15.61)	
P-value for Risk Difference	0.0393	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TEAE	30 (88.2%)	28 (87.5%)
Odds ratio (95% CI)	1.403 (0.264, 7.446)	
P-value for Odds Ratio	0.6864	
Relative Risk (95% CI)	1.00 (0.66, 1.52)	
P-value for Relative Risk	0.9993	
Heterogeneity p-value of RR	0.4910	
Risk difference (95% CI)	2.51 (-28.74, 33.77)	
P-value for Risk Difference	0.8728	
TEAE with any NCI grade 3/4/5	8 (23.5%)	6 (18.8%)
Odds ratio (95% CI)	1.387 (0.404, 4.769)	
P-value for Odds Ratio	0.5979	
Relative Risk (95% CI)	1.33 (0.50, 3.52)	
P-value for Relative Risk	0.5570	
Heterogeneity p-value of RR	0.4967	
Risk difference (95% CI)	3.01 (-18.32, 24.34)	
P-value for Risk Difference	0.7788	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TE-SAE	5 (14.7%)	2 (6.3%)
Odds ratio (95% CI)	4.241 (0.632, 28.463)	
P-value for Odds Ratio	0.1344	
Relative Risk (95% CI)	3.21 (0.69, 15.04)	
P-value for Relative Risk	0.1356	
Heterogeneity p-value of RR	0.8036	
Risk difference (95% CI)	13.39 (-14.44, 41.23)	
P-value for Risk Difference	0.3398	
TEAE leading to study treatment discontinuation	0	1 (3.1%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.54 (0.02, 11.75)	
P-value for Relative Risk	0.6956	
Heterogeneity p-value of RR	0.0318	
Risk difference (95% CI)	-5.46 (-81.79, 70.87)	
P-value for Risk Difference	0.8868	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TEAE leading to study treatment interruption/delay	12 (35.3%)	6 (18.8%)
Odds ratio (95% CI)	2.447 (0.747, 8.015)	
P-value for Odds Ratio	0.1367	
Relative Risk (95% CI)	1.96 (0.81, 4.73)	
P-value for Relative Risk	0.1303	
Heterogeneity p-value of RR	0.8972	
Risk difference (95% CI)	16.90 (-6.13, 39.93)	
P-value for Risk Difference	0.1475	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

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Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Participant with at least one	Cemiplimab (N=37)	Placebo (N=31)
TEAE	35 (94.6%)	29 (93.5%)
Odds ratio (95% CI)	1.111 (0.141, 8.772)	
P-value for Odds Ratio	0.9192	
Relative Risk (95% CI)	1.01 (0.88, 1.15)	
P-value for Relative Risk	0.9212	
Heterogeneity p-value of RR	0.9885	
Risk difference (95% CI)	0.59 (-12.11, 13.29)	
P-value for Risk Difference	0.9261	
TEAE with any NCI grade 3/4/5	9 (24.3%)	3 (9.7%)
Odds ratio (95% CI)	3.097 (0.732, 13.107)	
P-value for Odds Ratio	0.1225	
Relative Risk (95% CI)	2.56 (0.74, 8.86)	
P-value for Relative Risk	0.1346	
Heterogeneity p-value of RR	0.3295	
Risk difference (95% CI)	15.98 (-3.03, 34.98)	
P-value for Risk Difference	0.0980	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Participant with at least one	Cemiplimab (N=37)	Placebo (N=31)
TE-SAE	7 (18.9%)	3 (9.7%)
Odds ratio (95% CI)	2.036 (0.459, 9.038)	
P-value for Odds Ratio	0.3443	
Relative Risk (95% CI)	1.78 (0.48, 6.66)	
P-value for Relative Risk	0.3846	
Heterogeneity p-value of RR	0.9981	
Risk difference (95% CI)	9.80 (-6.27, 25.86)	
P-value for Risk Difference	0.2277	
TEAE leading to study treatment interruption/delay	8 (21.6%)	4 (12.9%)
Odds ratio (95% CI)	1.671 (0.426, 6.557)	
P-value for Odds Ratio	0.4560	
Relative Risk (95% CI)	1.63 (0.55, 4.86)	
P-value for Relative Risk	0.3724	
Heterogeneity p-value of RR	0.9887	
Risk difference (95% CI)	4.54 (-13.27, 22.34)	
P-value for Risk Difference	0.6127	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Participant with at least one	Cemiplimab (N=87)	Placebo (N=89)
TEAE	85 (97.7%)	85 (95.5%)
Odds ratio (95% CI)	1.921 (0.337, 10.941)	
P-value for Odds Ratio	0.4599	
Relative Risk (95% CI)	1.02 (0.96, 1.09)	
P-value for Relative Risk	0.4502	
Heterogeneity p-value of RR	0.9885	
Risk difference (95% CI)	2.11 (-3.89, 8.11)	
P-value for Risk Difference	0.4883	
TEAE with any NCI grade 3/4/5	22 (25.3%)	18 (20.2%)
Odds ratio (95% CI)	1.294 (0.630, 2.658)	
P-value for Odds Ratio	0.4808	
Relative Risk (95% CI)	1.19 (0.68, 2.06)	
P-value for Relative Risk	0.5363	
Heterogeneity p-value of RR	0.3295	
Risk difference (95% CI)	5.00 (-7.25, 17.26)	
P-value for Risk Difference	0.4217	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Participant with at least one	Cemiplimab (N=87)	Placebo (N=89)
TE-SAE	18 (20.7%)	10 (11.2%)
Odds ratio (95% CI)	1.993 (0.848, 4.688)	
P-value for Odds Ratio	0.1132	
Relative Risk (95% CI)	1.71 (0.84, 3.51)	
P-value for Relative Risk	0.1395	
Heterogeneity p-value of RR	0.9981	
Risk difference (95% CI)	9.26 (-1.17, 19.68)	
P-value for Risk Difference	0.0816	
TEAE leading to study treatment interruption/delay	18 (20.7%)	10 (11.2%)
Odds ratio (95% CI)	2.005 (0.857, 4.690)	
P-value for Odds Ratio	0.1080	
Relative Risk (95% CI)	1.74 (0.85, 3.59)	
P-value for Relative Risk	0.1311	
Heterogeneity p-value of RR	0.9887	
Risk difference (95% CI)	9.80 (-0.73, 20.33)	
P-value for Risk Difference	0.0678	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Participant with at least one	Cemiplimab (N=81)	Placebo (N=84)
TEAE	67 (82.7%)	68 (81.0%)
Odds ratio (95% CI)	1.155 (0.517, 2.581)	
P-value for Odds Ratio	0.7230	
Relative Risk (95% CI)	1.01 (0.88, 1.17)	
P-value for Relative Risk	0.8497	
Heterogeneity p-value of RR	0.9885	
Risk difference (95% CI)	1.36 (-10.51, 13.23)	
P-value for Risk Difference	0.8211	
TEAE with any NCI grade 3/4/5	18 (22.2%)	8 (9.5%)
Odds ratio (95% CI)	2.667 (1.076, 6.608)	
P-value for Odds Ratio	0.0343	
Relative Risk (95% CI)	2.30 (1.05, 5.03)	
P-value for Relative Risk	0.0376	
Heterogeneity p-value of RR	0.3295	
Risk difference (95% CI)	12.42 (1.24, 23.60)	
P-value for Risk Difference	0.0296	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Participant with at least one	Cemiplimab (N=81)	Placebo (N=84)
TE-SAE	11 (13.6%)	6 (7.1%)
Odds ratio (95% CI)	2.214 (0.764, 6.414)	
P-value for Odds Ratio	0.1421	
Relative Risk (95% CI)	2.00 (0.77, 5.17)	
P-value for Relative Risk	0.1507	
Heterogeneity p-value of RR	0.9981	
Risk difference (95% CI)	7.52 (-4.38, 19.42)	
P-value for Risk Difference	0.2136	
TEAE leading to study treatment interruption/delay	20 (24.7%)	12 (14.3%)
Odds ratio (95% CI)	1.921 (0.861, 4.287)	
P-value for Odds Ratio	0.1100	
Relative Risk (95% CI)	1.69 (0.88, 3.26)	
P-value for Relative Risk	0.1133	
Heterogeneity p-value of RR	0.9887	
Risk difference (95% CI)	9.93 (-2.24, 22.10)	
P-value for Risk Difference	0.1090	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TEAE	172 (92.5%)	169 (90.4%)
Odds ratio (95% CI)	1.286 (0.602, 2.747)	
P-value for Odds Ratio	0.5146	
Relative Risk (95% CI)	1.02 (0.97, 1.08)	
P-value for Relative Risk	0.4455	
Heterogeneity p-value of RR	0.7173	
Risk difference (95% CI)	1.91 (-2.97, 6.78)	
P-value for Risk Difference	0.4422	
TEAE with any NCI grade 3/4/5	46 (24.7%)	28 (15.0%)
Odds ratio (95% CI)	1.808 (1.064, 3.072)	
P-value for Odds Ratio	0.0288	
Relative Risk (95% CI)	1.57 (1.03, 2.42)	
P-value for Relative Risk	0.0382	
Heterogeneity p-value of RR	0.5811	
Risk difference (95% CI)	9.94 (1.95, 17.93)	
P-value for Risk Difference	0.0149	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TE-SAE	34 (18.3%)	19 (10.2%)
Odds ratio (95% CI)	1.915 (1.040, 3.529)	
P-value for Odds Ratio	0.0372	
Relative Risk (95% CI)	1.74 (1.02, 2.95)	
P-value for Relative Risk	0.0410	
Heterogeneity p-value of RR	0.2001	
Risk difference (95% CI)	7.53 (0.44, 14.62)	
P-value for Risk Difference	0.0374	
TEAE leading to study treatment discontinuation	18 (9.7%)	3 (1.6%)
Odds ratio (95% CI)	6.491 (1.861, 22.642)	
P-value for Odds Ratio	0.0034	
Relative Risk (95% CI)	5.96 (1.77, 20.05)	
P-value for Relative Risk	0.0041	
Heterogeneity p-value of RR	0.4750	
Risk difference (95% CI)	8.58 (1.52, 15.64)	
P-value for Risk Difference	0.0174	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TEAE leading to study treatment interruption/delay	42 (22.6%)	25 (13.4%)
Odds ratio (95% CI)	1.757 (1.009, 3.057)	
P-value for Odds Ratio	0.0463	
Relative Risk (95% CI)	1.56 (0.99, 2.47)	
P-value for Relative Risk	0.0566	
Heterogeneity p-value of RR	0.2990	
Risk difference (95% CI)	8.33 (0.74, 15.93)	
P-value for Risk Difference	0.0315	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TEAE	15 (78.9%)	13 (76.5%)
Odds ratio (95% CI)	0.499 (0.067, 3.720)	
P-value for Odds Ratio	0.4856	
Relative Risk (95% CI)	0.75 (0.45, 1.25)	
P-value for Relative Risk	0.2559	
Heterogeneity p-value of RR	0.7173	
Risk difference (95% CI)	-23.94 (-75.86, 27.99)	
P-value for Risk Difference	0.3544	
TEAE with any NCI grade 3/4/5	3 (15.8%)	1 (5.9%)
Odds ratio (95% CI)	3.310 (0.247, 44.303)	
P-value for Odds Ratio	0.3540	
Relative Risk (95% CI)	3.03 (0.25, 36.42)	
P-value for Relative Risk	0.3701	
Heterogeneity p-value of RR	0.5811	
Risk difference (95% CI)	16.70 (-28.52, 61.92)	
P-value for Risk Difference	0.4570	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TE-SAE	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.2001	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	
TEAE leading to study treatment discontinuation	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.4750	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TEAE leading to study treatment interruption/delay	4 (21.1%)	1 (5.9%)
Odds ratio (95% CI)	3.310 (0.247, 44.303)	
P-value for Odds Ratio	0.3540	
Relative Risk (95% CI)	3.10 (0.28, 34.40)	
P-value for Relative Risk	0.3450	
Heterogeneity p-value of RR	0.2990	
Risk difference (95% CI)	11.55 (-14.32, 37.43)	
P-value for Risk Difference	0.3695	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TEAE	149 (90.9%)	159 (90.9%)
Odds ratio (95% CI)	0.961 (0.450, 2.054)	
P-value for Odds Ratio	0.9180	
Relative Risk (95% CI)	1.01 (0.96, 1.07)	
P-value for Relative Risk	0.6227	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	1.15 (-3.89, 6.19)	
P-value for Risk Difference	0.6536	
TEAE with any NCI grade 3/4/5	38 (23.2%)	23 (13.1%)
Odds ratio (95% CI)	1.988 (1.121, 3.526)	
P-value for Odds Ratio	0.0189	
Relative Risk (95% CI)	1.74 (1.09, 2.80)	
P-value for Relative Risk	0.0215	
Heterogeneity p-value of RR	0.5256	
Risk difference (95% CI)	10.29 (2.16, 18.41)	
P-value for Risk Difference	0.0132	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TE-SAE	29 (17.7%)	15 (8.6%)
Odds ratio (95% CI)	2.290 (1.175, 4.461)	
P-value for Odds Ratio	0.0151	
Relative Risk (95% CI)	2.06 (1.14, 3.71)	
P-value for Relative Risk	0.0161	
Heterogeneity p-value of RR	0.4238	
Risk difference (95% CI)	9.12 (1.90, 16.34)	
P-value for Risk Difference	0.0134	
TEAE leading to study treatment discontinuation	17 (10.4%)	2 (1.1%)
Odds ratio (95% CI)	9.995 (2.258, 44.241)	
P-value for Odds Ratio	0.0025	
Relative Risk (95% CI)	9.04 (2.11, 38.75)	
P-value for Relative Risk	0.0031	
Heterogeneity p-value of RR	0.3103	
Risk difference (95% CI)	9.80 (0.08, 19.53)	
P-value for Risk Difference	0.0482	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TEAE leading to study treatment interruption/delay	33 (20.1%)	20 (11.4%)
Odds ratio (95% CI)	1.972 (1.076, 3.615)	
P-value for Odds Ratio	0.0281	
Relative Risk (95% CI)	1.77 (1.06, 2.96)	
P-value for Relative Risk	0.0296	
Heterogeneity p-value of RR	0.7948	
Risk difference (95% CI)	8.85 (1.12, 16.58)	
P-value for Risk Difference	0.0249	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TEAE	38 (92.7%)	23 (79.3%)
Odds ratio (95% CI)	3.500 (0.717, 17.093)	
P-value for Odds Ratio	0.1195	
Relative Risk (95% CI)	1.14 (0.85, 1.52)	
P-value for Relative Risk	0.3834	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	13.59 (-12.46, 39.64)	
P-value for Risk Difference	0.3015	
TEAE with any NCI grade 3/4/5	11 (26.8%)	6 (20.7%)
Odds ratio (95% CI)	1.481 (0.452, 4.847)	
P-value for Odds Ratio	0.5110	
Relative Risk (95% CI)	1.24 (0.52, 2.96)	
P-value for Relative Risk	0.6283	
Heterogeneity p-value of RR	0.5256	
Risk difference (95% CI)	10.27 (-9.94, 30.48)	
P-value for Risk Difference	0.3141	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TE-SAE	7 (17.1%)	4 (13.8%)
Odds ratio (95% CI)	1.256 (0.290, 5.450)	
P-value for Odds Ratio	0.7571	
Relative Risk (95% CI)	1.09 (0.37, 3.21)	
P-value for Relative Risk	0.8739	
Heterogeneity p-value of RR	0.4238	
Risk difference (95% CI)	6.28 (-28.19, 40.75)	
P-value for Risk Difference	0.7172	
TEAE leading to study treatment discontinuation	3 (7.3%)	1 (3.4%)
Odds ratio (95% CI)	2.044 (0.189, 22.053)	
P-value for Odds Ratio	0.5505	
Relative Risk (95% CI)	1.83 (0.18, 18.32)	
P-value for Relative Risk	0.6016	
Heterogeneity p-value of RR	0.3103	
Risk difference (95% CI)	6.31 (-34.30, 46.92)	
P-value for Risk Difference	0.7574	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TEAE leading to study treatment interruption/delay	13 (31.7%)	6 (20.7%)
Odds ratio (95% CI)	1.717 (0.547, 5.390)	
P-value for Odds Ratio	0.3489	
Relative Risk (95% CI)	1.52 (0.65, 3.57)	
P-value for Relative Risk	0.3265	
Heterogeneity p-value of RR	0.7948	
Risk difference (95% CI)	9.84 (-11.18, 30.86)	
P-value for Risk Difference	0.3534	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TEAE	118 (90.8%)	117 (89.3%)
Odds ratio (95% CI)	1.246 (0.530, 2.926)	
P-value for Odds Ratio	0.6129	
Relative Risk (95% CI)	1.01 (0.94, 1.07)	
P-value for Relative Risk	0.8664	
Heterogeneity p-value of RR	0.5699	
Risk difference (95% CI)	0.58 (-5.23, 6.39)	
P-value for Risk Difference	0.8451	
TEAE with any NCI grade 3/4/5	32 (24.6%)	17 (13.0%)
Odds ratio (95% CI)	2.292 (1.180, 4.450)	
P-value for Odds Ratio	0.0145	
Relative Risk (95% CI)	1.83 (1.07, 3.13)	
P-value for Relative Risk	0.0265	
Heterogeneity p-value of RR	0.5141	
Risk difference (95% CI)	14.58 (4.60, 24.56)	
P-value for Risk Difference	0.0044	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TE-SAE	23 (17.7%)	13 (9.9%)
Odds ratio (95% CI)	2.027 (0.965, 4.256)	
P-value for Odds Ratio	0.0620	
Relative Risk (95% CI)	1.80 (0.95, 3.39)	
P-value for Relative Risk	0.0698	
Heterogeneity p-value of RR	0.7855	
Risk difference (95% CI)	8.73 (-0.63, 18.10)	
P-value for Risk Difference	0.0675	
TEAE leading to study treatment discontinuation	14 (10.8%)	1 (0.8%)
Odds ratio (95% CI)	15.935 (2.038, 124.576)	
P-value for Odds Ratio	0.0085	
Relative Risk (95% CI)	14.27 (1.88, 108.16)	
P-value for Relative Risk	0.0103	
Heterogeneity p-value of RR	0.2073	
Risk difference (95% CI)	10.73 (0.53, 20.93)	
P-value for Risk Difference	0.0394	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TEAE leading to study treatment interruption/delay	29 (22.3%)	16 (12.2%)
Odds ratio (95% CI)	1.958 (0.995, 3.854)	
P-value for Odds Ratio	0.0517	
Relative Risk (95% CI)	1.72 (0.98, 3.02)	
P-value for Relative Risk	0.0572	
Heterogeneity p-value of RR	0.8884	
Risk difference (95% CI)	9.35 (0.43, 18.27)	
P-value for Risk Difference	0.0400	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TEAE	69 (92.0%)	65 (89.0%)
Odds ratio (95% CI)	1.331 (0.422, 4.197)	
P-value for Odds Ratio	0.6237	
Relative Risk (95% CI)	1.03 (0.93, 1.13)	
P-value for Relative Risk	0.5633	
Heterogeneity p-value of RR	0.5699	
Risk difference (95% CI)	2.52 (-6.29, 11.32)	
P-value for Risk Difference	0.5730	
TEAE with any NCI grade 3/4/5	17 (22.7%)	12 (16.4%)
Odds ratio (95% CI)	1.378 (0.590, 3.219)	
P-value for Odds Ratio	0.4556	
Relative Risk (95% CI)	1.27 (0.66, 2.47)	
P-value for Relative Risk	0.4713	
Heterogeneity p-value of RR	0.5141	
Risk difference (95% CI)	4.37 (-8.59, 17.33)	
P-value for Risk Difference	0.5060	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TE-SAE	13 (17.3%)	6 (8.2%)
Odds ratio (95% CI)	2.135 (0.739, 6.172)	
P-value for Odds Ratio	0.1600	
Relative Risk (95% CI)	1.76 (0.69, 4.49)	
P-value for Relative Risk	0.2328	
Heterogeneity p-value of RR	0.7855	
Risk difference (95% CI)	8.58 (-1.55, 18.70)	
P-value for Risk Difference	0.0962	
TEAE leading to study treatment discontinuation	6 (8.0%)	2 (2.7%)
Odds ratio (95% CI)	2.996 (0.571, 15.728)	
P-value for Odds Ratio	0.1929	
Relative Risk (95% CI)	2.82 (0.58, 13.79)	
P-value for Relative Risk	0.1994	
Heterogeneity p-value of RR	0.2073	
Risk difference (95% CI)	6.11 (-8.13, 20.35)	
P-value for Risk Difference	0.3978	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TEAE leading to study treatment interruption/delay	17 (22.7%)	10 (13.7%)
Odds ratio (95% CI)	1.839 (0.768, 4.400)	
P-value for Odds Ratio	0.1699	
Relative Risk (95% CI)	1.66 (0.81, 3.40)	
P-value for Relative Risk	0.1634	
Heterogeneity p-value of RR	0.8884	
Risk difference (95% CI)	8.28 (-4.32, 20.87)	
P-value for Risk Difference	0.1961	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TEAE	110 (89.4%)	107 (92.2%)
Odds ratio (95% CI)	0.750 (0.296, 1.902)	
P-value for Odds Ratio	0.5429	
Relative Risk (95% CI)	0.99 (0.91, 1.07)	
P-value for Relative Risk	0.7409	
Heterogeneity p-value of RR	0.7185	
Risk difference (95% CI)	-1.44 (-8.73, 5.84)	
P-value for Risk Difference	0.6968	
TEAE with any NCI grade 3/4/5	34 (27.6%)	17 (14.7%)
Odds ratio (95% CI)	2.212 (1.143, 4.281)	
P-value for Odds Ratio	0.0186	
Relative Risk (95% CI)	1.83 (1.08, 3.11)	
P-value for Relative Risk	0.0254	
Heterogeneity p-value of RR	0.4076	
Risk difference (95% CI)	12.90 (2.68, 23.12)	
P-value for Risk Difference	0.0136	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TE-SAE	21 (17.1%)	11 (9.5%)
Odds ratio (95% CI)	1.906 (0.859, 4.228)	
P-value for Odds Ratio	0.1122	
Relative Risk (95% CI)	1.72 (0.86, 3.42)	
P-value for Relative Risk	0.1240	
Heterogeneity p-value of RR	0.9312	
Risk difference (95% CI)	5.88 (-3.26, 15.02)	
P-value for Risk Difference	0.2062	
TEAE leading to study treatment discontinuation	13 (10.6%)	2 (1.7%)
Odds ratio (95% CI)	6.699 (1.457, 30.804)	
P-value for Odds Ratio	0.0148	
Relative Risk (95% CI)	6.04 (1.38, 26.51)	
P-value for Relative Risk	0.0173	
Heterogeneity p-value of RR	0.8763	
Risk difference (95% CI)	9.27 (0.59, 17.95)	
P-value for Risk Difference	0.0364	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TEAE leading to study treatment interruption/delay	27 (22.0%)	14 (12.1%)
Odds ratio (95% CI)	1.929 (0.940, 3.960)	
P-value for Odds Ratio	0.0732	
Relative Risk (95% CI)	1.71 (0.95, 3.10)	
P-value for Relative Risk	0.0753	
Heterogeneity p-value of RR	0.9160	
Risk difference (95% CI)	8.32 (-1.08, 17.71)	
P-value for Risk Difference	0.0824	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TEAE	77 (93.9%)	75 (85.2%)
Odds ratio (95% CI)	2.524 (0.826, 7.711)	
P-value for Odds Ratio	0.1036	
Relative Risk (95% CI)	1.10 (0.94, 1.30)	
P-value for Relative Risk	0.2347	
Heterogeneity p-value of RR	0.7185	
Risk difference (95% CI)	9.38 (-4.44, 23.19)	
P-value for Risk Difference	0.1822	
TEAE with any NCI grade 3/4/5	15 (18.3%)	12 (13.6%)
Odds ratio (95% CI)	1.395 (0.604, 3.222)	
P-value for Odds Ratio	0.4331	
Relative Risk (95% CI)	1.30 (0.64, 2.63)	
P-value for Relative Risk	0.4690	
Heterogeneity p-value of RR	0.4076	
Risk difference (95% CI)	6.12 (-4.95, 17.18)	
P-value for Risk Difference	0.2767	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TE-SAE	15 (18.3%)	8 (9.1%)
Odds ratio (95% CI)	2.289 (0.903, 5.806)	
P-value for Odds Ratio	0.0808	
Relative Risk (95% CI)	2.02 (0.90, 4.54)	
P-value for Relative Risk	0.0897	
Heterogeneity p-value of RR	0.9312	
Risk difference (95% CI)	10.79 (-0.58, 22.16)	
P-value for Risk Difference	0.0627	
TEAE leading to study treatment discontinuation	7 (8.5%)	1 (1.1%)
Odds ratio (95% CI)	8.279 (0.976, 70.194)	
P-value for Odds Ratio	0.0526	
Relative Risk (95% CI)	7.60 (0.94, 61.43)	
P-value for Relative Risk	0.0570	
Heterogeneity p-value of RR	0.8763	
Risk difference (95% CI)	8.44 (-5.00, 21.87)	
P-value for Risk Difference	0.2169	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TEAE leading to study treatment interruption/delay	19 (23.2%)	12 (13.6%)
Odds ratio (95% CI)	1.874 (0.838, 4.190)	
P-value for Odds Ratio	0.1253	
Relative Risk (95% CI)	1.68 (0.86, 3.26)	
P-value for Relative Risk	0.1253	
Heterogeneity p-value of RR	0.9160	
Risk difference (95% CI)	9.34 (-2.64, 21.32)	
P-value for Risk Difference	0.1258	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TEAE	141 (92.2%)	137 (90.1%)
Odds ratio (95% CI)	1.308 (0.581, 2.948)	
P-value for Odds Ratio	0.5155	
Relative Risk (95% CI)	1.03 (0.97, 1.09)	
P-value for Relative Risk	0.3316	
Heterogeneity p-value of RR	0.6733	
Risk difference (95% CI)	2.76 (-2.82, 8.34)	
P-value for Risk Difference	0.3316	
TEAE with any NCI grade 3/4/5	38 (24.8%)	22 (14.5%)
Odds ratio (95% CI)	1.923 (1.069, 3.461)	
P-value for Odds Ratio	0.0292	
Relative Risk (95% CI)	1.68 (1.04, 2.71)	
P-value for Relative Risk	0.0338	
Heterogeneity p-value of RR	0.9714	
Risk difference (95% CI)	10.63 (1.78, 19.47)	
P-value for Risk Difference	0.0187	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TE-SAE	28 (18.3%)	14 (9.2%)
Odds ratio (95% CI)	2.221 (1.112, 4.436)	
P-value for Odds Ratio	0.0240	
Relative Risk (95% CI)	1.99 (1.09, 3.64)	
P-value for Relative Risk	0.0261	
Heterogeneity p-value of RR	0.7219	
Risk difference (95% CI)	9.23 (1.62, 16.83)	
P-value for Risk Difference	0.0176	
TEAE leading to study treatment discontinuation	16 (10.5%)	2 (1.3%)
Odds ratio (95% CI)	8.773 (1.963, 39.214)	
P-value for Odds Ratio	0.0046	
Relative Risk (95% CI)	7.89 (1.83, 33.98)	
P-value for Relative Risk	0.0057	
Heterogeneity p-value of RR	0.3619	
Risk difference (95% CI)	9.13 (1.78, 16.47)	
P-value for Risk Difference	0.0151	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TEAE leading to study treatment interruption/delay	38 (24.8%)	19 (12.5%)
Odds ratio (95% CI)	2.275 (1.233, 4.197)	
P-value for Odds Ratio	0.0087	
Relative Risk (95% CI)	1.94 (1.17, 3.20)	
P-value for Relative Risk	0.0103	
Heterogeneity p-value of RR	0.1981	
Risk difference (95% CI)	11.68 (3.07, 20.30)	
P-value for Risk Difference	0.0080	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TEAE	35 (87.5%)	37 (86.0%)
Odds ratio (95% CI)	1.146 (0.269, 4.890)	
P-value for Odds Ratio	0.8520	
Relative Risk (95% CI)	1.01 (0.72, 1.43)	
P-value for Relative Risk	0.9460	
Heterogeneity p-value of RR	0.6733	
Risk difference (95% CI)	2.32 (-28.30, 32.94)	
P-value for Risk Difference	0.8805	
TEAE with any NCI grade 3/4/5	9 (22.5%)	6 (14.0%)
Odds ratio (95% CI)	2.193 (0.617, 7.799)	
P-value for Odds Ratio	0.2215	
Relative Risk (95% CI)	1.51 (0.61, 3.70)	
P-value for Relative Risk	0.3684	
Heterogeneity p-value of RR	0.9714	
Risk difference (95% CI)	5.78 (-10.20, 21.76)	
P-value for Risk Difference	0.4737	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TE-SAE	7 (17.5%)	5 (11.6%)
Odds ratio (95% CI)	1.780 (0.467, 6.779)	
P-value for Odds Ratio	0.3932	
Relative Risk (95% CI)	1.54 (0.55, 4.32)	
P-value for Relative Risk	0.4032	
Heterogeneity p-value of RR	0.7219	
Risk difference (95% CI)	-1.08 (-22.21, 20.05)	
P-value for Risk Difference	0.9190	
TEAE leading to study treatment discontinuation	2 (5.0%)	1 (2.3%)
Odds ratio (95% CI)	2.273 (0.186, 27.788)	
P-value for Odds Ratio	0.5156	
Relative Risk (95% CI)	2.18 (0.20, 23.97)	
P-value for Relative Risk	0.5188	
Heterogeneity p-value of RR	0.3619	
Risk difference (95% CI)	4.15 (-40.35, 48.65)	
P-value for Risk Difference	0.8532	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TEAE leading to study treatment interruption/delay	5 (12.5%)	6 (14.0%)
Odds ratio (95% CI)	1.016 (0.256, 4.036)	
P-value for Odds Ratio	0.9814	
Relative Risk (95% CI)	0.88 (0.31, 2.50)	
P-value for Relative Risk	0.8056	
Heterogeneity p-value of RR	0.1981	
Risk difference (95% CI)	-4.25 (-23.49, 14.99)	
P-value for Risk Difference	0.6612	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TEAE	36 (94.7%)	38 (88.4%)
Odds ratio (95% CI)	2.456 (0.416, 14.489)	
P-value for Odds Ratio	0.3165	
Relative Risk (95% CI)	1.09 (0.77, 1.55)	
P-value for Relative Risk	0.6054	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	8.04 (-17.78, 33.87)	
P-value for Risk Difference	0.5369	
TEAE with any NCI grade 3/4/5	11 (28.9%)	6 (14.0%)
Odds ratio (95% CI)	2.481 (0.783, 7.867)	
P-value for Odds Ratio	0.1210	
Relative Risk (95% CI)	1.88 (0.75, 4.70)	
P-value for Relative Risk	0.1719	
Heterogeneity p-value of RR	0.6149	
Risk difference (95% CI)	17.44 (-4.50, 39.39)	
P-value for Risk Difference	0.1175	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TE-SAE	9 (23.7%)	4 (9.3%)
Odds ratio (95% CI)	3.218 (0.851, 12.174)	
P-value for Odds Ratio	0.0843	
Relative Risk (95% CI)	2.38 (0.78, 7.28)	
P-value for Relative Risk	0.1260	
Heterogeneity p-value of RR	0.5332	
Risk difference (95% CI)	20.57 (-1.64, 42.79)	
P-value for Risk Difference	0.0690	
TEAE leading to study treatment discontinuation	6 (15.8%)	1 (2.3%)
Odds ratio (95% CI)	8.443 (0.912, 78.149)	
P-value for Odds Ratio	0.0600	
Relative Risk (95% CI)	6.79 (0.83, 55.82)	
P-value for Relative Risk	0.0741	
Heterogeneity p-value of RR	0.9788	
Risk difference (95% CI)	16.56 (-28.26, 61.38)	
P-value for Risk Difference	0.4641	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TEAE leading to study treatment interruption/delay	9 (23.7%)	6 (14.0%)
Odds ratio (95% CI)	1.794 (0.538, 5.976)	
P-value for Odds Ratio	0.3368	
Relative Risk (95% CI)	1.61 (0.63, 4.09)	
P-value for Relative Risk	0.3117	
Heterogeneity p-value of RR	0.9847	
Risk difference (95% CI)	5.10 (-12.45, 22.66)	
P-value for Risk Difference	0.5644	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TEAE	151 (90.4%)	144 (89.4%)
Odds ratio (95% CI)	1.067 (0.504, 2.259)	
P-value for Odds Ratio	0.8651	
Relative Risk (95% CI)	1.01 (0.95, 1.07)	
P-value for Relative Risk	0.7419	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	0.89 (-4.17, 5.95)	
P-value for Risk Difference	0.7293	
TEAE with any NCI grade 3/4/5	38 (22.8%)	23 (14.3%)
Odds ratio (95% CI)	1.726 (0.968, 3.077)	
P-value for Odds Ratio	0.0643	
Relative Risk (95% CI)	1.54 (0.96, 2.48)	
P-value for Relative Risk	0.0750	
Heterogeneity p-value of RR	0.6149	
Risk difference (95% CI)	8.49 (0.18, 16.81)	
P-value for Risk Difference	0.0452	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TE-SAE	27 (16.2%)	15 (9.3%)
Odds ratio (95% CI)	1.865 (0.945, 3.681)	
P-value for Odds Ratio	0.0722	
Relative Risk (95% CI)	1.72 (0.95, 3.13)	
P-value for Relative Risk	0.0744	
Heterogeneity p-value of RR	0.5332	
Risk difference (95% CI)	6.69 (-0.55, 13.93)	
P-value for Risk Difference	0.0701	
TEAE leading to study treatment discontinuation	14 (8.4%)	2 (1.2%)
Odds ratio (95% CI)	7.490 (1.658, 33.841)	
P-value for Odds Ratio	0.0090	
Relative Risk (95% CI)	6.89 (1.58, 30.07)	
P-value for Relative Risk	0.0104	
Heterogeneity p-value of RR	0.9788	
Risk difference (95% CI)	8.14 (-0.76, 17.03)	
P-value for Risk Difference	0.0728	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TEAE leading to study treatment interruption/delay	37 (22.2%)	20 (12.4%)
Odds ratio (95% CI)	1.957 (1.073, 3.569)	
P-value for Odds Ratio	0.0287	
Relative Risk (95% CI)	1.74 (1.05, 2.88)	
P-value for Relative Risk	0.0323	
Heterogeneity p-value of RR	0.9847	
Risk difference (95% CI)	9.55 (1.48, 17.62)	
P-value for Risk Difference	0.0205	

Data cut-off as of October 4, 2024.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	6 (11.1%)	2 (3.1%)
Odds ratio (95% CI)	5.491 (0.885, 34.057)	
P-value for Odds Ratio	0.0671	
Relative Risk (95% CI)	3.92 (0.84, 18.36)	
P-value for Relative Risk	0.0819	
Heterogeneity p-value of RR	0.2765	
Risk difference (95% CI)	10.74 (-8.49, 29.96)	
P-value for Risk Difference	0.2710	
TE-SAE with any NCI grade 3/4/5	6 (11.1%)	2 (3.1%)
Odds ratio (95% CI)	5.491 (0.885, 34.057)	
P-value for Odds Ratio	0.0671	
Relative Risk (95% CI)	3.92 (0.84, 18.36)	
P-value for Relative Risk	0.0819	
Heterogeneity p-value of RR	0.3855	
Risk difference (95% CI)	10.74 (-8.49, 29.96)	
P-value for Risk Difference	0.2710	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TE-SAE	30 (19.9%)	17 (12.2%)
Odds ratio (95% CI)	1.710 (0.886, 3.298)	
P-value for Odds Ratio	0.1093	
Relative Risk (95% CI)	1.56 (0.89, 2.73)	
P-value for Relative Risk	0.1196	
Heterogeneity p-value of RR	0.2765	
Risk difference (95% CI)	7.25 (-1.15, 15.66)	
P-value for Risk Difference	0.0906	
TE-SAE with any NCI grade 3/4/5	25 (16.6%)	12 (8.6%)
Odds ratio (95% CI)	2.030 (0.964, 4.273)	
P-value for Odds Ratio	0.0622	
Relative Risk (95% CI)	1.84 (0.95, 3.55)	
P-value for Relative Risk	0.0700	
Heterogeneity p-value of RR	0.3855	
Risk difference (95% CI)	7.79 (0.32, 15.26)	
P-value for Risk Difference	0.0410	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	6 (11.1%)	2 (3.1%)
Odds ratio (95% CI)	5.491 (0.885, 34.057)	
P-value for Odds Ratio	0.0671	
Relative Risk (95% CI)	3.92 (0.84, 18.36)	
P-value for Relative Risk	0.0819	
Heterogeneity p-value of RR	0.4529	
Risk difference (95% CI)	10.74 (-8.49, 29.96)	
P-value for Risk Difference	0.2710	
TE-SAE with any NCI grade 3/4/5	6 (11.1%)	2 (3.1%)
Odds ratio (95% CI)	5.491 (0.885, 34.057)	
P-value for Odds Ratio	0.0671	
Relative Risk (95% CI)	3.92 (0.84, 18.36)	
P-value for Relative Risk	0.0819	
Heterogeneity p-value of RR	0.5625	
Risk difference (95% CI)	10.74 (-8.49, 29.96)	
P-value for Risk Difference	0.2710	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TE-SAE	12 (15.0%)	8 (11.8%)
Odds ratio (95% CI)	1.359 (0.495, 3.729)	
P-value for Odds Ratio	0.5494	
Relative Risk (95% CI)	1.19 (0.52, 2.76)	
P-value for Relative Risk	0.6774	
Heterogeneity p-value of RR	0.4529	
Risk difference (95% CI)	6.60 (-8.09, 21.29)	
P-value for Risk Difference	0.3761	
TE-SAE with any NCI grade 3/4/5	10 (12.5%)	6 (8.8%)
Odds ratio (95% CI)	1.604 (0.528, 4.880)	
P-value for Odds Ratio	0.4022	
Relative Risk (95% CI)	1.43 (0.54, 3.76)	
P-value for Relative Risk	0.4681	
Heterogeneity p-value of RR	0.5625	
Risk difference (95% CI)	5.51 (-7.36, 18.38)	
P-value for Risk Difference	0.3985	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TE-SAE	18 (25.4%)	9 (12.7%)
Odds ratio (95% CI)	2.427 (0.981, 6.003)	
P-value for Odds Ratio	0.0549	
Relative Risk (95% CI)	2.03 (0.97, 4.24)	
P-value for Relative Risk	0.0604	
Heterogeneity p-value of RR	0.4529	
Risk difference (95% CI)	14.74 (0.62, 28.87)	
P-value for Risk Difference	0.0409	
TE-SAE with any NCI grade 3/4/5	15 (21.1%)	6 (8.5%)
Odds ratio (95% CI)	2.846 (1.009, 8.026)	
P-value for Odds Ratio	0.0481	
Relative Risk (95% CI)	2.45 (0.99, 6.06)	
P-value for Relative Risk	0.0528	
Heterogeneity p-value of RR	0.5625	
Risk difference (95% CI)	13.14 (0.36, 25.92)	
P-value for Risk Difference	0.0440	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TE-SAE	31 (18.1%)	17 (9.9%)
Odds ratio (95% CI)	1.925 (1.010, 3.667)	
P-value for Odds Ratio	0.0465	
Relative Risk (95% CI)	1.70 (0.97, 2.96)	
P-value for Relative Risk	0.0621	
Heterogeneity p-value of RR	0.8036	
Risk difference (95% CI)	7.19 (-0.07, 14.44)	
P-value for Risk Difference	0.0522	
TE-SAE with any NCI grade 3/4/5	28 (16.4%)	12 (7.0%)
Odds ratio (95% CI)	2.506 (1.216, 5.164)	
P-value for Odds Ratio	0.0129	
Relative Risk (95% CI)	2.17 (1.14, 4.14)	
P-value for Relative Risk	0.0190	
Heterogeneity p-value of RR	0.5981	
Risk difference (95% CI)	8.80 (2.29, 15.32)	
P-value for Risk Difference	0.0083	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
Treatment-related TE-SAE	11 (6.4%)	1 (0.6%)
Odds ratio (95% CI)	11.807 (1.492, 93.469)	
P-value for Odds Ratio	0.0195	
Relative Risk (95% CI)	10.92 (1.41, 84.25)	
P-value for Relative Risk	0.0220	
Heterogeneity p-value of RR	0.6746	
Risk difference (95% CI)	6.60 (-5.91, 19.11)	
P-value for Risk Difference	0.3004	
TE-SAE leading to study treatment discontinuation	12 (7.0%)	2 (1.2%)
Odds ratio (95% CI)	6.318 (1.376, 28.999)	
P-value for Odds Ratio	0.0179	
Relative Risk (95% CI)	5.79 (1.31, 25.62)	
P-value for Relative Risk	0.0207	
Heterogeneity p-value of RR	0.0522	
Risk difference (95% CI)	7.38 (0.57, 14.18)	
P-value for Risk Difference	0.0338	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TE-SAE	5 (14.7%)	2 (6.3%)
Odds ratio (95% CI)	4.241 (0.632, 28.463)	
P-value for Odds Ratio	0.1344	
Relative Risk (95% CI)	3.21 (0.69, 15.04)	
P-value for Relative Risk	0.1356	
Heterogeneity p-value of RR	0.8036	
Risk difference (95% CI)	13.39 (-14.44, 41.23)	
P-value for Risk Difference	0.3398	
TE-SAE with any NCI grade 3/4/5	3 (8.8%)	2 (6.3%)
Odds ratio (95% CI)	1.740 (0.229, 13.206)	
P-value for Odds Ratio	0.5866	
Relative Risk (95% CI)	1.58 (0.29, 8.76)	
P-value for Relative Risk	0.5927	
Heterogeneity p-value of RR	0.5981	
Risk difference (95% CI)	4.97 (-20.36, 30.31)	
P-value for Risk Difference	0.6960	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
Treatment-related TE-SAE	1 (2.9%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.88 (0.22, 105.76)	
P-value for Relative Risk	0.2702	
Heterogeneity p-value of RR	0.6746	
Risk difference (95% CI)	6.50 (NE, NE)	
P-value for Risk Difference	NE	
TE-SAE leading to study treatment discontinuation	0	1 (3.1%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.54 (0.02, 11.75)	
P-value for Relative Risk	0.6956	
Heterogeneity p-value of RR	0.0522	
Risk difference (95% CI)	-5.46 (-81.79, 70.87)	
P-value for Risk Difference	0.8868	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Participant with at least one	Cemiplimab (N=37)	Placebo (N=31)
TE-SAE	7 (18.9%)	3 (9.7%)
Odds ratio (95% CI)	2.036 (0.459, 9.038)	
P-value for Odds Ratio	0.3443	
Relative Risk (95% CI)	1.78 (0.48, 6.66)	
P-value for Relative Risk	0.3846	
Heterogeneity p-value of RR	0.9981	
Risk difference (95% CI)	9.80 (-6.27, 25.86)	
P-value for Risk Difference	0.2277	
TE-SAE with any NCI grade 3/4/5	6 (16.2%)	2 (6.5%)
Odds ratio (95% CI)	2.790 (0.500, 15.560)	
P-value for Odds Ratio	0.2376	
Relative Risk (95% CI)	2.50 (0.52, 11.92)	
P-value for Relative Risk	0.2458	
Heterogeneity p-value of RR	0.7590	
Risk difference (95% CI)	10.07 (-5.89, 26.03)	
P-value for Risk Difference	0.2120	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Participant with at least one	Cemiplimab (N=87)	Placebo (N=89)
TE-SAE	18 (20.7%)	10 (11.2%)
Odds ratio (95% CI)	1.993 (0.848, 4.688)	
P-value for Odds Ratio	0.1132	
Relative Risk (95% CI)	1.71 (0.84, 3.51)	
P-value for Relative Risk	0.1395	
Heterogeneity p-value of RR	0.9981	
Risk difference (95% CI)	9.26 (-1.17, 19.68)	
P-value for Risk Difference	0.0816	
TE-SAE with any NCI grade 3/4/5	16 (18.4%)	9 (10.1%)
Odds ratio (95% CI)	1.937 (0.794, 4.727)	
P-value for Odds Ratio	0.1454	
Relative Risk (95% CI)	1.69 (0.79, 3.65)	
P-value for Relative Risk	0.1781	
Heterogeneity p-value of RR	0.7590	
Risk difference (95% CI)	8.64 (-1.31, 18.58)	
P-value for Risk Difference	0.0884	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Participant with at least one	Cemiplimab (N=81)	Placebo (N=84)
TE-SAE	11 (13.6%)	6 (7.1%)
Odds ratio (95% CI)	2.214 (0.764, 6.414)	
P-value for Odds Ratio	0.1421	
Relative Risk (95% CI)	2.00 (0.77, 5.17)	
P-value for Relative Risk	0.1507	
Heterogeneity p-value of RR	0.9981	
Risk difference (95% CI)	7.52 (-4.38, 19.42)	
P-value for Risk Difference	0.2136	
TE-SAE with any NCI grade 3/4/5	9 (11.1%)	3 (3.6%)
Odds ratio (95% CI)	3.563 (0.913, 13.905)	
P-value for Odds Ratio	0.0672	
Relative Risk (95% CI)	3.23 (0.90, 11.63)	
P-value for Relative Risk	0.0719	
Heterogeneity p-value of RR	0.7590	
Risk difference (95% CI)	7.98 (-2.03, 17.99)	
P-value for Risk Difference	0.1173	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TE-SAE	34 (18.3%)	19 (10.2%)
Odds ratio (95% CI)	1.915 (1.040, 3.529)	
P-value for Odds Ratio	0.0372	
Relative Risk (95% CI)	1.74 (1.02, 2.95)	
P-value for Relative Risk	0.0410	
Heterogeneity p-value of RR	0.2001	
Risk difference (95% CI)	7.53 (0.44, 14.62)	
P-value for Risk Difference	0.0374	
TE-SAE with any NCI grade 3/4/5	29 (15.6%)	14 (7.5%)
Odds ratio (95% CI)	2.227 (1.124, 4.414)	
P-value for Odds Ratio	0.0219	
Relative Risk (95% CI)	2.00 (1.09, 3.68)	
P-value for Relative Risk	0.0254	
Heterogeneity p-value of RR	0.2405	
Risk difference (95% CI)	7.45 (1.05, 13.86)	
P-value for Risk Difference	0.0227	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
Treatment-related TE-SAE	11 (5.9%)	1 (0.5%)
Odds ratio (95% CI)	12.361 (1.560, 97.978)	
P-value for Odds Ratio	0.0174	
Relative Risk (95% CI)	11.42 (1.48, 88.29)	
P-value for Relative Risk	0.0197	
Heterogeneity p-value of RR	0.7325	
Risk difference (95% CI)	6.57 (-5.77, 18.91)	
P-value for Risk Difference	0.2957	
TE-SAE leading to study treatment discontinuation	10 (5.4%)	3 (1.6%)
Odds ratio (95% CI)	3.328 (0.884, 12.531)	
P-value for Odds Ratio	0.0754	
Relative Risk (95% CI)	3.15 (0.87, 11.41)	
P-value for Relative Risk	0.0806	
Heterogeneity p-value of RR	0.3291	
Risk difference (95% CI)	3.86 (-2.29, 10.01)	
P-value for Risk Difference	0.2176	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TE-SAE	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.2001	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	
TE-SAE with any NCI grade 3/4/5	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.2405	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
Treatment-related TE-SAE	1 (5.3%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.00 (0.09, 43.22)	
P-value for Relative Risk	0.6564	
Heterogeneity p-value of RR	0.7325	
Risk difference (95% CI)	7.74 (NE, NE)	
P-value for Risk Difference	NE	
TE-SAE leading to study treatment discontinuation	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.3291	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TE-SAE	29 (17.7%)	15 (8.6%)
Odds ratio (95% CI)	2.290 (1.175, 4.461)	
P-value for Odds Ratio	0.0151	
Relative Risk (95% CI)	2.06 (1.14, 3.71)	
P-value for Relative Risk	0.0161	
Heterogeneity p-value of RR	0.4238	
Risk difference (95% CI)	9.12 (1.90, 16.34)	
P-value for Risk Difference	0.0134	
TE-SAE with any NCI grade 3/4/5	25 (15.2%)	11 (6.3%)
Odds ratio (95% CI)	2.666 (1.261, 5.637)	
P-value for Odds Ratio	0.0104	
Relative Risk (95% CI)	2.40 (1.22, 4.74)	
P-value for Relative Risk	0.0114	
Heterogeneity p-value of RR	0.4580	
Risk difference (95% CI)	8.75 (2.18, 15.32)	
P-value for Risk Difference	0.0092	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
Treatment-related TE-SAE	11 (6.7%)	1 (0.6%)
Odds ratio (95% CI)	12.316 (1.557, 97.418)	
P-value for Odds Ratio	0.0175	
Relative Risk (95% CI)	11.40 (1.48, 87.97)	
P-value for Relative Risk	0.0197	
Heterogeneity p-value of RR	0.7357	
Risk difference (95% CI)	6.46 (-4.50, 17.42)	
P-value for Risk Difference	0.2472	
TE-SAE leading to study treatment discontinuation	10 (6.1%)	2 (1.1%)
Odds ratio (95% CI)	5.691 (1.216, 26.637)	
P-value for Odds Ratio	0.0274	
Relative Risk (95% CI)	5.32 (1.18, 23.99)	
P-value for Relative Risk	0.0298	
Heterogeneity p-value of RR	0.3667	
Risk difference (95% CI)	6.23 (-2.24, 14.69)	
P-value for Risk Difference	0.1487	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TE-SAE	7 (17.1%)	4 (13.8%)
Odds ratio (95% CI)	1.256 (0.290, 5.450)	
P-value for Odds Ratio	0.7571	
Relative Risk (95% CI)	1.09 (0.37, 3.21)	
P-value for Relative Risk	0.8739	
Heterogeneity p-value of RR	0.4238	
Risk difference (95% CI)	6.28 (-28.19, 40.75)	
P-value for Risk Difference	0.7172	
TE-SAE with any NCI grade 3/4/5	6 (14.6%)	3 (10.3%)
Odds ratio (95% CI)	1.546 (0.315, 7.589)	
P-value for Odds Ratio	0.5863	
Relative Risk (95% CI)	1.27 (0.36, 4.46)	
P-value for Relative Risk	0.7074	
Heterogeneity p-value of RR	0.4580	
Risk difference (95% CI)	6.86 (-22.46, 36.18)	
P-value for Risk Difference	0.6420	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
Treatment-related TE-SAE	1 (2.4%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.28 (0.10, 52.92)	
P-value for Relative Risk	0.5994	
Heterogeneity p-value of RR	0.7357	
Risk difference (95% CI)	3.51 (NE, NE)	
P-value for Risk Difference	NE	
TE-SAE leading to study treatment discontinuation	2 (4.9%)	1 (3.4%)
Odds ratio (95% CI)	1.256 (0.097, 16.195)	
P-value for Odds Ratio	0.8592	
Relative Risk (95% CI)	1.10 (0.09, 12.88)	
P-value for Relative Risk	0.9359	
Heterogeneity p-value of RR	0.3667	
Risk difference (95% CI)	5.20 (-72.16, 82.57)	
P-value for Risk Difference	0.8936	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TE-SAE	23 (17.7%)	13 (9.9%)
Odds ratio (95% CI)	2.027 (0.965, 4.256)	
P-value for Odds Ratio	0.0620	
Relative Risk (95% CI)	1.80 (0.95, 3.39)	
P-value for Relative Risk	0.0698	
Heterogeneity p-value of RR	0.7855	
Risk difference (95% CI)	8.73 (-0.63, 18.10)	
P-value for Risk Difference	0.0675	
TE-SAE with any NCI grade 3/4/5	21 (16.2%)	9 (6.9%)
Odds ratio (95% CI)	2.725 (1.178, 6.302)	
P-value for Odds Ratio	0.0193	
Relative Risk (95% CI)	2.34 (1.12, 4.92)	
P-value for Relative Risk	0.0246	
Heterogeneity p-value of RR	0.7718	
Risk difference (95% CI)	10.12 (1.88, 18.36)	
P-value for Risk Difference	0.0163	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
Treatment-related TE-SAE	11 (8.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	6.47 (1.54, 27.19)	
P-value for Relative Risk	0.0030	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	9.97 (-41.00, 60.95)	
P-value for Risk Difference	0.7004	
TE-SAE leading to study treatment discontinuation	10 (7.7%)	1 (0.8%)
Odds ratio (95% CI)	11.055 (1.374, 88.940)	
P-value for Odds Ratio	0.0241	
Relative Risk (95% CI)	10.15 (1.30, 78.97)	
P-value for Relative Risk	0.0270	
Heterogeneity p-value of RR	0.0890	
Risk difference (95% CI)	8.37 (-2.65, 19.40)	
P-value for Risk Difference	0.1360	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TE-SAE	13 (17.3%)	6 (8.2%)
Odds ratio (95% CI)	2.135 (0.739, 6.172)	
P-value for Odds Ratio	0.1600	
Relative Risk (95% CI)	1.76 (0.69, 4.49)	
P-value for Relative Risk	0.2328	
Heterogeneity p-value of RR	0.7855	
Risk difference (95% CI)	8.58 (-1.55, 18.70)	
P-value for Risk Difference	0.0962	
TE-SAE with any NCI grade 3/4/5	10 (13.3%)	5 (6.8%)
Odds ratio (95% CI)	1.894 (0.595, 6.032)	
P-value for Odds Ratio	0.2776	
Relative Risk (95% CI)	1.74 (0.62, 4.85)	
P-value for Relative Risk	0.2900	
Heterogeneity p-value of RR	0.7718	
Risk difference (95% CI)	4.84 (-4.80, 14.49)	
P-value for Risk Difference	0.3223	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
Treatment-related TE-SAE	1 (1.3%)	1 (1.4%)
Odds ratio (95% CI)	0.857 (0.047, 15.603)	
P-value for Odds Ratio	0.9165	
Relative Risk (95% CI)	0.87 (0.06, 12.81)	
P-value for Relative Risk	0.9165	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-0.29 (-17.78, 17.21)	
P-value for Risk Difference	0.9743	
TE-SAE leading to study treatment discontinuation	2 (2.7%)	2 (2.7%)
Odds ratio (95% CI)	0.901 (0.115, 7.028)	
P-value for Odds Ratio	0.9199	
Relative Risk (95% CI)	0.87 (0.12, 6.27)	
P-value for Relative Risk	0.8892	
Heterogeneity p-value of RR	0.0890	
Risk difference (95% CI)	0.05 (-10.79, 10.89)	
P-value for Risk Difference	0.9931	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TE-SAE	21 (17.1%)	11 (9.5%)
Odds ratio (95% CI)	1.906 (0.859, 4.228)	
P-value for Odds Ratio	0.1122	
Relative Risk (95% CI)	1.72 (0.86, 3.42)	
P-value for Relative Risk	0.1240	
Heterogeneity p-value of RR	0.9312	
Risk difference (95% CI)	5.88 (-3.26, 15.02)	
P-value for Risk Difference	0.2062	
TE-SAE with any NCI grade 3/4/5	19 (15.4%)	8 (6.9%)
Odds ratio (95% CI)	2.445 (1.006, 5.944)	
P-value for Odds Ratio	0.0485	
Relative Risk (95% CI)	2.15 (0.98, 4.75)	
P-value for Relative Risk	0.0571	
Heterogeneity p-value of RR	0.8494	
Risk difference (95% CI)	6.91 (-1.30, 15.12)	
P-value for Risk Difference	0.0985	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TE-SAE	15 (18.3%)	8 (9.1%)
Odds ratio (95% CI)	2.289 (0.903, 5.806)	
P-value for Odds Ratio	0.0808	
Relative Risk (95% CI)	2.02 (0.90, 4.54)	
P-value for Relative Risk	0.0897	
Heterogeneity p-value of RR	0.9312	
Risk difference (95% CI)	10.79 (-0.58, 22.16)	
P-value for Risk Difference	0.0627	
TE-SAE with any NCI grade 3/4/5	12 (14.6%)	6 (6.8%)
Odds ratio (95% CI)	2.352 (0.828, 6.685)	
P-value for Odds Ratio	0.1078	
Relative Risk (95% CI)	2.10 (0.82, 5.39)	
P-value for Relative Risk	0.1207	
Heterogeneity p-value of RR	0.8494	
Risk difference (95% CI)	9.24 (-0.76, 19.24)	
P-value for Risk Difference	0.0699	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TE-SAE	28 (18.3%)	14 (9.2%)
Odds ratio (95% CI)	2.221 (1.112, 4.436)	
P-value for Odds Ratio	0.0240	
Relative Risk (95% CI)	1.99 (1.09, 3.64)	
P-value for Relative Risk	0.0261	
Heterogeneity p-value of RR	0.7219	
Risk difference (95% CI)	9.23 (1.62, 16.83)	
P-value for Risk Difference	0.0176	
TE-SAE with any NCI grade 3/4/5	23 (15.0%)	10 (6.6%)
Odds ratio (95% CI)	2.561 (1.165, 5.628)	
P-value for Odds Ratio	0.0194	
Relative Risk (95% CI)	2.30 (1.13, 4.69)	
P-value for Relative Risk	0.0217	
Heterogeneity p-value of RR	0.8534	
Risk difference (95% CI)	8.93 (2.17, 15.68)	
P-value for Risk Difference	0.0098	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
Treatment-related TE-SAE	10 (6.5%)	1 (0.7%)
Odds ratio (95% CI)	11.386 (1.419, 91.394)	
P-value for Odds Ratio	0.0222	
Relative Risk (95% CI)	10.30 (1.33, 79.78)	
P-value for Relative Risk	0.0258	
Heterogeneity p-value of RR	0.6714	
Risk difference (95% CI)	7.53 (-7.18, 22.25)	
P-value for Risk Difference	0.3147	
TE-SAE leading to study treatment discontinuation	10 (6.5%)	2 (1.3%)
Odds ratio (95% CI)	5.296 (1.125, 24.931)	
P-value for Odds Ratio	0.0351	
Relative Risk (95% CI)	4.91 (1.09, 22.13)	
P-value for Relative Risk	0.0382	
Heterogeneity p-value of RR	0.3126	
Risk difference (95% CI)	6.16 (-0.32, 12.63)	
P-value for Risk Difference	0.0622	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TE-SAE	7 (17.5%)	5 (11.6%)
Odds ratio (95% CI)	1.780 (0.467, 6.779)	
P-value for Odds Ratio	0.3932	
Relative Risk (95% CI)	1.54 (0.55, 4.32)	
P-value for Relative Risk	0.4032	
Heterogeneity p-value of RR	0.7219	
Risk difference (95% CI)	-1.08 (-22.21, 20.05)	
P-value for Risk Difference	0.9190	
TE-SAE with any NCI grade 3/4/5	7 (17.5%)	4 (9.3%)
Odds ratio (95% CI)	2.524 (0.583, 10.921)	
P-value for Odds Ratio	0.2121	
Relative Risk (95% CI)	1.84 (0.61, 5.52)	
P-value for Relative Risk	0.2721	
Heterogeneity p-value of RR	0.8534	
Treatment-related TE-SAE	1 (2.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
Treatment-related TE-SAE		
Relative Risk (95% CI)	2.00 (0.11, 37.83)	
P-value for Relative Risk	0.6460	
Heterogeneity p-value of RR	0.6714	
Risk difference (95% CI)	3.99 (-107.10, 115.08)	
P-value for Risk Difference	0.9431	
TE-SAE leading to study treatment discontinuation	1 (2.5%)	1 (2.3%)
Odds ratio (95% CI)	0.855 (0.043, 17.019)	
P-value for Odds Ratio	0.9172	
Relative Risk (95% CI)	0.94 (0.06, 14.16)	
P-value for Relative Risk	0.9643	
Heterogeneity p-value of RR	0.3126	
Risk difference (95% CI)	-3.74 (-54.06, 46.57)	
P-value for Risk Difference	0.8826	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TE-SAE	9 (23.7%)	4 (9.3%)
Odds ratio (95% CI)	3.218 (0.851, 12.174)	
P-value for Odds Ratio	0.0843	
Relative Risk (95% CI)	2.38 (0.78, 7.28)	
P-value for Relative Risk	0.1260	
Heterogeneity p-value of RR	0.5332	
Risk difference (95% CI)	20.57 (-1.64, 42.79)	
P-value for Risk Difference	0.0690	
TE-SAE with any NCI grade 3/4/5	8 (21.1%)	2 (4.7%)
Odds ratio (95% CI)	5.485 (1.032, 29.146)	
P-value for Odds Ratio	0.0459	
Relative Risk (95% CI)	4.15 (0.91, 18.87)	
P-value for Relative Risk	0.0655	
Heterogeneity p-value of RR	0.2391	
Risk difference (95% CI)	19.10 (-4.04, 42.25)	
P-value for Risk Difference	0.1044	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TE-SAE	27 (16.2%)	15 (9.3%)
Odds ratio (95% CI)	1.865 (0.945, 3.681)	
P-value for Odds Ratio	0.0722	
Relative Risk (95% CI)	1.72 (0.95, 3.13)	
P-value for Relative Risk	0.0744	
Heterogeneity p-value of RR	0.5332	
Risk difference (95% CI)	6.69 (-0.55, 13.93)	
P-value for Risk Difference	0.0701	
TE-SAE with any NCI grade 3/4/5	23 (13.8%)	12 (7.5%)
Odds ratio (95% CI)	1.933 (0.918, 4.072)	
P-value for Odds Ratio	0.0827	
Relative Risk (95% CI)	1.78 (0.91, 3.48)	
P-value for Relative Risk	0.0899	
Heterogeneity p-value of RR	0.2391	
Risk difference (95% CI)	6.18 (-0.30, 12.66)	
P-value for Risk Difference	0.0615	

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Skin and subcutaneous tissue disorders	31 (57.4%)	24 (36.9%)
Odds ratio (95% CI)	2.282 (1.081, 4.819)	
P-value for Odds Ratio	0.0308	
Relative Risk (95% CI)	1.55 (1.03, 2.32)	
P-value for Relative Risk	0.0344	
Heterogeneity p-value of RR	0.2875	
Risk difference (95% CI)	20.26 (2.43, 38.08)	
P-value for Risk Difference	0.0263	
Rash	10 (18.5%)	5 (7.7%)
Odds ratio (95% CI)	3.414 (0.993, 11.738)	
P-value for Odds Ratio	0.0513	
Relative Risk (95% CI)	2.55 (0.95, 6.86)	
P-value for Relative Risk	0.0640	
Heterogeneity p-value of RR	0.4173	
Risk difference (95% CI)	13.37 (-3.18, 29.93)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Rash		
P-value for Risk Difference	0.1122	
Endocrine disorders	12 (22.2%)	1 (1.5%)
Odds ratio (95% CI)	19.677 (2.361, 163.985)	
P-value for Odds Ratio	0.0063	
Relative Risk (95% CI)	14.37 (1.89, 108.98)	
P-value for Relative Risk	0.0104	
Heterogeneity p-value of RR	0.1228	
Risk difference (95% CI)	24.59 (-6.51, 55.69)	
P-value for Risk Difference	0.1201	
Hypothyroidism	10 (18.5%)	1 (1.5%)
Odds ratio (95% CI)	15.905 (1.869, 135.360)	
P-value for Odds Ratio	0.0118	
Relative Risk (95% CI)	11.87 (1.55, 90.93)	
P-value for Relative Risk	0.0177	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Hypothyroidism		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	20.59 (-16.18, 57.36)	
P-value for Risk Difference	0.2696	
Investigations	11 (20.4%)	12 (18.5%)
Odds ratio (95% CI)	1.101 (0.433, 2.797)	
P-value for Odds Ratio	0.8392	
Relative Risk (95% CI)	1.07 (0.51, 2.21)	
P-value for Relative Risk	0.8641	
Heterogeneity p-value of RR	0.1322	
Risk difference (95% CI)	1.53 (-13.37, 16.42)	
P-value for Risk Difference	0.8396	
Alanine aminotransferase increased	2 (3.7%)	2 (3.1%)
Odds ratio (95% CI)	1.182 (0.156, 8.962)	
P-value for Odds Ratio	0.8705	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Alanine aminotransferase increased		
Relative Risk (95% CI)	1.18 (0.17, 8.19)	
P-value for Relative Risk	0.8693	
Heterogeneity p-value of RR	0.1467	
Risk difference (95% CI)	0.63 (-9.93, 11.19)	
P-value for Risk Difference	0.9059	
Metabolism and nutrition disorders	5 (9.3%)	8 (12.3%)
Odds ratio (95% CI)	0.693 (0.205, 2.348)	
P-value for Odds Ratio	0.5532	
Relative Risk (95% CI)	0.75 (0.26, 2.14)	
P-value for Relative Risk	0.5863	
Heterogeneity p-value of RR	0.0507	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Skin and subcutaneous tissue disorders	80 (53.0%)	61 (43.9%)
Odds ratio (95% CI)	1.508 (0.929, 2.446)	
P-value for Odds Ratio	0.0959	
Relative Risk (95% CI)	1.21 (0.96, 1.53)	
P-value for Relative Risk	0.1007	
Heterogeneity p-value of RR	0.2875	
Risk difference (95% CI)	9.55 (-1.77, 20.88)	
P-value for Risk Difference	0.0980	
Rash	23 (15.2%)	13 (9.4%)
Odds ratio (95% CI)	1.709 (0.813, 3.592)	
P-value for Odds Ratio	0.1566	
Relative Risk (95% CI)	1.56 (0.82, 2.96)	
P-value for Relative Risk	0.1721	
Heterogeneity p-value of RR	0.4173	
Risk difference (95% CI)	6.05 (-1.57, 13.68)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Rash		
P-value for Risk Difference	0.1193	
Investigations	28 (18.5%)	11 (7.9%)
Odds ratio (95% CI)	2.612 (1.229, 5.552)	
P-value for Odds Ratio	0.0128	
Relative Risk (95% CI)	2.27 (1.17, 4.40)	
P-value for Relative Risk	0.0157	
Heterogeneity p-value of RR	0.1322	
Risk difference (95% CI)	11.32 (2.88, 19.77)	
P-value for Risk Difference	0.0087	
Alanine aminotransferase increased	10 (6.6%)	1 (0.7%)
Odds ratio (95% CI)	9.456 (1.169, 76.472)	
P-value for Odds Ratio	0.0353	
Relative Risk (95% CI)	8.77 (1.12, 68.65)	
P-value for Relative Risk	0.0388	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Alanine aminotransferase increased		
Heterogeneity p-value of RR	0.1467	
Risk difference (95% CI)	6.69 (-1.22, 14.61)	
P-value for Risk Difference	0.0971	
Metabolism and nutrition disorders	25 (16.6%)	9 (6.5%)
Odds ratio (95% CI)	2.954 (1.311, 6.660)	
P-value for Odds Ratio	0.0092	
Relative Risk (95% CI)	2.60 (1.25, 5.40)	
P-value for Relative Risk	0.0107	
Heterogeneity p-value of RR	0.0507	
Risk difference (95% CI)	10.79 (2.57, 19.02)	
P-value for Risk Difference	0.0103	
Endocrine disorders	21 (13.9%)	6 (4.3%)
Odds ratio (95% CI)	3.602 (1.392, 9.317)	
P-value for Odds Ratio	0.0084	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Endocrine disorders		
Relative Risk (95% CI)	3.24 (1.34, 7.87)	
P-value for Relative Risk	0.0095	
Heterogeneity p-value of RR	0.1228	
Risk difference (95% CI)	9.41 (2.87, 15.96)	
P-value for Risk Difference	0.0050	
Hypothyroidism	14 (9.3%)	5 (3.6%)
Odds ratio (95% CI)	2.667 (0.921, 7.724)	
P-value for Odds Ratio	0.0706	
Relative Risk (95% CI)	2.51 (0.91, 6.88)	
P-value for Relative Risk	0.0738	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.53 (0.05, 13.01)	
P-value for Risk Difference	0.0481	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Skin and subcutaneous tissue disorders	31 (57.4%)	24 (36.9%)
Odds ratio (95% CI)	2.282 (1.081, 4.819)	
P-value for Odds Ratio	0.0308	
Relative Risk (95% CI)	1.55 (1.03, 2.32)	
P-value for Relative Risk	0.0344	
Heterogeneity p-value of RR	0.5313	
Risk difference (95% CI)	20.26 (2.43, 38.08)	
P-value for Risk Difference	0.0263	
Rash	10 (18.5%)	5 (7.7%)
Odds ratio (95% CI)	3.414 (0.993, 11.738)	
P-value for Odds Ratio	0.0513	
Relative Risk (95% CI)	2.55 (0.95, 6.86)	
P-value for Relative Risk	0.0640	
Heterogeneity p-value of RR	0.6878	
Risk difference (95% CI)	13.37 (-3.18, 29.93)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Rash		
P-value for Risk Difference	0.1122	
Endocrine disorders	12 (22.2%)	1 (1.5%)
Odds ratio (95% CI)	19.677 (2.361, 163.985)	
P-value for Odds Ratio	0.0063	
Relative Risk (95% CI)	14.37 (1.89, 108.98)	
P-value for Relative Risk	0.0104	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	24.59 (-6.51, 55.69)	
P-value for Risk Difference	0.1201	
Hypothyroidism	10 (18.5%)	1 (1.5%)
Odds ratio (95% CI)	15.905 (1.869, 135.360)	
P-value for Odds Ratio	0.0118	
Relative Risk (95% CI)	11.87 (1.55, 90.93)	
P-value for Relative Risk	0.0177	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Hypothyroidism		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	20.59 (-16.18, 57.36)	
P-value for Risk Difference	0.2696	
Investigations	11 (20.4%)	12 (18.5%)
Odds ratio (95% CI)	1.101 (0.433, 2.797)	
P-value for Odds Ratio	0.8392	
Relative Risk (95% CI)	1.07 (0.51, 2.21)	
P-value for Relative Risk	0.8641	
Heterogeneity p-value of RR	0.0470	
Risk difference (95% CI)	1.53 (-13.37, 16.42)	
P-value for Risk Difference	0.8396	
Metabolism and nutrition disorders	5 (9.3%)	8 (12.3%)
Odds ratio (95% CI)	0.693 (0.205, 2.348)	
P-value for Odds Ratio	0.5532	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	0.75 (0.26, 2.14)	
P-value for Relative Risk	0.5863	
Heterogeneity p-value of RR	0.0917	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Skin and subcutaneous tissue disorders	40 (50.0%)	27 (39.7%)
Odds ratio (95% CI)	1.758 (0.881, 3.508)	
P-value for Odds Ratio	0.1087	
Relative Risk (95% CI)	1.27 (0.88, 1.81)	
P-value for Relative Risk	0.1971	
Heterogeneity p-value of RR	0.5313	
Risk difference (95% CI)	14.90 (-1.34, 31.13)	
P-value for Risk Difference	0.0718	
Rash	11 (13.8%)	7 (10.3%)
Odds ratio (95% CI)	1.428 (0.507, 4.019)	
P-value for Odds Ratio	0.4973	
Relative Risk (95% CI)	1.35 (0.55, 3.33)	
P-value for Relative Risk	0.5117	
Heterogeneity p-value of RR	0.6878	
Risk difference (95% CI)	4.86 (-6.36, 16.07)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Rash		
P-value for Risk Difference	0.3936	
Investigations	18 (22.5%)	3 (4.4%)
Odds ratio (95% CI)	5.902 (1.619, 21.521)	
P-value for Odds Ratio	0.0075	
Relative Risk (95% CI)	4.84 (1.47, 15.95)	
P-value for Relative Risk	0.0100	
Heterogeneity p-value of RR	0.0470	
Risk difference (95% CI)	18.63 (4.99, 32.28)	
P-value for Risk Difference	0.0078	
Endocrine disorders	11 (13.8%)	4 (5.9%)
Odds ratio (95% CI)	2.480 (0.733, 8.392)	
P-value for Odds Ratio	0.1432	
Relative Risk (95% CI)	2.27 (0.74, 6.95)	
P-value for Relative Risk	0.1483	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Endocrine disorders		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	8.14 (-2.79, 19.06)	
P-value for Risk Difference	0.1433	
Hypothyroidism	11 (13.8%)	3 (4.4%)
Odds ratio (95% CI)	3.390 (0.882, 13.020)	
P-value for Odds Ratio	0.0751	
Relative Risk (95% CI)	3.06 (0.87, 10.75)	
P-value for Relative Risk	0.0801	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	11.41 (-1.75, 24.57)	
P-value for Risk Difference	0.0888	
Metabolism and nutrition disorders	10 (12.5%)	5 (7.4%)
Odds ratio (95% CI)	1.936 (0.612, 6.121)	
P-value for Odds Ratio	0.2585	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	1.80 (0.64, 5.10)	
P-value for Relative Risk	0.2635	
Heterogeneity p-value of RR	0.0917	
Risk difference (95% CI)	6.96 (-4.04, 17.96)	
P-value for Risk Difference	0.2132	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Skin and subcutaneous tissue disorders	40 (56.3%)	34 (47.9%)
Odds ratio (95% CI)	1.294 (0.639, 2.620)	
P-value for Odds Ratio	0.4719	
Relative Risk (95% CI)	1.17 (0.87, 1.57)	
P-value for Relative Risk	0.3048	
Heterogeneity p-value of RR	0.5313	
Risk difference (95% CI)	6.31 (-10.00, 22.61)	
P-value for Risk Difference	0.4457	
Rash	12 (16.9%)	6 (8.5%)
Odds ratio (95% CI)	1.937 (0.647, 5.797)	
P-value for Odds Ratio	0.2353	
Relative Risk (95% CI)	1.72 (0.69, 4.34)	
P-value for Relative Risk	0.2451	
Heterogeneity p-value of RR	0.6878	
Risk difference (95% CI)	5.69 (-6.05, 17.42)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Rash		
P-value for Risk Difference	0.3397	
Metabolism and nutrition disorders	15 (21.1%)	4 (5.6%)
Odds ratio (95% CI)	4.345 (1.327, 14.229)	
P-value for Odds Ratio	0.0156	
Relative Risk (95% CI)	3.58 (1.23, 10.41)	
P-value for Relative Risk	0.0197	
Heterogeneity p-value of RR	0.0917	
Risk difference (95% CI)	15.17 (2.48, 27.86)	
P-value for Risk Difference	0.0195	
Endocrine disorders	10 (14.1%)	2 (2.8%)
Odds ratio (95% CI)	5.893 (1.209, 28.736)	
P-value for Odds Ratio	0.0285	
Relative Risk (95% CI)	5.26 (1.17, 23.65)	
P-value for Relative Risk	0.0308	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Endocrine disorders		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	12.94 (-0.69, 26.57)	
P-value for Risk Difference	0.0627	
Hypothyroidism	3 (4.2%)	2 (2.8%)
Odds ratio (95% CI)	1.402 (0.208, 9.425)	
P-value for Odds Ratio	0.7267	
Relative Risk (95% CI)	1.37 (0.22, 8.67)	
P-value for Relative Risk	0.7356	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	2.89 (-8.02, 13.80)	
P-value for Risk Difference	0.6015	
Investigations	10 (14.1%)	8 (11.3%)
Odds ratio (95% CI)	1.270 (0.451, 3.572)	
P-value for Odds Ratio	0.6488	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Investigations		
Relative Risk (95% CI)	1.13 (0.47, 2.74)	
P-value for Relative Risk	0.7820	
Heterogeneity p-value of RR	0.0470	
Risk difference (95% CI)	5.46 (-7.06, 17.99)	
P-value for Risk Difference	0.3900	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Skin and subcutaneous tissue disorders	95 (55.6%)	70 (40.7%)
Odds ratio (95% CI)	1.871 (1.206, 2.901)	
P-value for Odds Ratio	0.0053	
Relative Risk (95% CI)	1.36 (1.09, 1.70)	
P-value for Relative Risk	0.0060	
Heterogeneity p-value of RR	0.3181	
Risk difference (95% CI)	15.17 (4.78, 25.56)	
P-value for Risk Difference	0.0043	
Rash	29 (17.0%)	14 (8.1%)
Odds ratio (95% CI)	2.248 (1.131, 4.467)	
P-value for Odds Ratio	0.0209	
Relative Risk (95% CI)	2.02 (1.10, 3.68)	
P-value for Relative Risk	0.0225	
Heterogeneity p-value of RR	0.2441	
Risk difference (95% CI)	6.97 (-0.03, 13.98)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Rash		
P-value for Risk Difference	0.0511	
Investigations	32 (18.7%)	20 (11.6%)
Odds ratio (95% CI)	1.786 (0.969, 3.290)	
P-value for Odds Ratio	0.0627	
Relative Risk (95% CI)	1.61 (0.96, 2.70)	
P-value for Relative Risk	0.0706	
Heterogeneity p-value of RR	0.5844	
Risk difference (95% CI)	8.60 (1.05, 16.16)	
P-value for Risk Difference	0.0258	
Alanine aminotransferase increased	11 (6.4%)	2 (1.2%)
Odds ratio (95% CI)	5.941 (1.283, 27.500)	
P-value for Odds Ratio	0.0228	
Relative Risk (95% CI)	5.58 (1.25, 24.93)	
P-value for Relative Risk	0.0245	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Alanine aminotransferase increased		
Heterogeneity p-value of RR	0.2737	
Risk difference (95% CI)	5.81 (0.45, 11.18)	
P-value for Risk Difference	0.0337	
Metabolism and nutrition disorders	28 (16.4%)	13 (7.6%)
Odds ratio (95% CI)	2.450 (1.211, 4.959)	
P-value for Odds Ratio	0.0129	
Relative Risk (95% CI)	2.19 (1.17, 4.07)	
P-value for Relative Risk	0.0138	
Heterogeneity p-value of RR	0.0670	
Risk difference (95% CI)	8.43 (0.76, 16.10)	
P-value for Risk Difference	0.0314	
Endocrine disorders	25 (14.6%)	3 (1.7%)
Odds ratio (95% CI)	9.789 (2.874, 33.338)	
P-value for Odds Ratio	0.0003	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Endocrine disorders		
Relative Risk (95% CI)	8.38 (2.57, 27.35)	
P-value for Relative Risk	0.0005	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	13.50 (5.73, 21.27)	
P-value for Risk Difference	0.0007	
Hypothyroidism	17 (9.9%)	2 (1.2%)
Odds ratio (95% CI)	9.525 (2.144, 42.326)	
P-value for Odds Ratio	0.0032	
Relative Risk (95% CI)	8.51 (1.99, 36.46)	
P-value for Relative Risk	0.0040	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	9.70 (1.49, 17.90)	
P-value for Risk Difference	0.0207	
Hepatobiliary disorders	10 (5.8%)	2 (1.2%)

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Hepatobiliary disorders		
Odds ratio (95% CI)	5.426 (1.162, 25.343)	
P-value for Odds Ratio	0.0316	
Relative Risk (95% CI)	5.17 (1.14, 23.37)	
P-value for Relative Risk	0.0331	
Heterogeneity p-value of RR	0.9937	
Risk difference (95% CI)	5.54 (-3.04, 14.11)	
P-value for Risk Difference	0.2048	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Skin and subcutaneous tissue disorders	16 (47.1%)	15 (46.9%)
Odds ratio (95% CI)	1.093 (0.398, 3.006)	
P-value for Odds Ratio	0.8607	
Relative Risk (95% CI)	1.05 (0.63, 1.76)	
P-value for Relative Risk	0.8361	
Heterogeneity p-value of RR	0.3181	
Risk difference (95% CI)	2.01 (-22.66, 26.68)	
P-value for Risk Difference	0.8713	
Rash	4 (11.8%)	4 (12.5%)
Odds ratio (95% CI)	0.791 (0.152, 4.118)	
P-value for Odds Ratio	0.7777	
Relative Risk (95% CI)	0.83 (0.25, 2.80)	
P-value for Relative Risk	0.7589	
Heterogeneity p-value of RR	0.2441	
Risk difference (95% CI)	3.82 (-26.50, 34.14)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Rash		
P-value for Risk Difference	0.8018	
Endocrine disorders	8 (23.5%)	4 (12.5%)
Odds ratio (95% CI)	2.424 (0.598, 9.827)	
P-value for Odds Ratio	0.2107	
Relative Risk (95% CI)	2.31 (0.74, 7.22)	
P-value for Relative Risk	0.1461	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	9.61 (-14.61, 33.82)	
P-value for Risk Difference	0.4308	
Hypothyroidism	7 (20.6%)	4 (12.5%)
Odds ratio (95% CI)	1.895 (0.464, 7.738)	
P-value for Odds Ratio	0.3672	
Relative Risk (95% CI)	1.82 (0.56, 5.93)	
P-value for Relative Risk	0.3163	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Hypothyroidism		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.37 (-17.28, 30.02)	
P-value for Risk Difference	0.5922	
Investigations	7 (20.6%)	3 (9.4%)
Odds ratio (95% CI)	2.121 (0.463, 9.707)	
P-value for Odds Ratio	0.3270	
Relative Risk (95% CI)	1.90 (0.51, 7.13)	
P-value for Relative Risk	0.3330	
Heterogeneity p-value of RR	0.5844	
Risk difference (95% CI)	6.80 (-12.47, 26.07)	
P-value for Risk Difference	0.4833	
Alanine aminotransferase increased	1 (2.9%)	1 (3.1%)
Odds ratio (95% CI)	1.090 (0.047, 25.322)	
P-value for Odds Ratio	0.9563	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Alanine aminotransferase increased		
Relative Risk (95% CI)	0.98 (0.06, 14.95)	
P-value for Relative Risk	0.9880	
Heterogeneity p-value of RR	0.2737	
Risk difference (95% CI)	0.35 (-62.41, 63.12)	
P-value for Risk Difference	0.9911	
Metabolism and nutrition disorders	2 (5.9%)	4 (12.5%)
Odds ratio (95% CI)	0.524 (0.081, 3.394)	
P-value for Odds Ratio	0.4921	
Relative Risk (95% CI)	0.55 (0.10, 2.97)	
P-value for Relative Risk	0.4856	
Heterogeneity p-value of RR	0.0670	
Risk difference (95% CI)	-7.97 (-34.60, 18.66)	
P-value for Risk Difference	0.5518	
Hepatobiliary disorders	0	0

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Hepatobiliary disorders		
Odds ratio (95% CI)	1.000 (0.000, NE)	
P-value for Odds Ratio	1.0000	
Relative Risk (95% CI)	1.00 (0.00, NE)	
P-value for Relative Risk	1.0000	
Heterogeneity p-value of RR	0.9937	
Risk difference (95% CI)	0.00 (NE, NE)	
P-value for Risk Difference	NE	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Skin and subcutaneous tissue disorders	20 (54.1%)	12 (38.7%)
Odds ratio (95% CI)	1.907 (0.704, 5.168)	
P-value for Odds Ratio	0.2006	
Relative Risk (95% CI)	1.40 (0.81, 2.41)	
P-value for Relative Risk	0.2230	
Heterogeneity p-value of RR	0.8994	
Risk difference (95% CI)	16.27 (-8.10, 40.65)	
P-value for Risk Difference	0.1871	
Rash	8 (21.6%)	3 (9.7%)
Odds ratio (95% CI)	2.316 (0.524, 10.231)	
P-value for Odds Ratio	0.2631	
Relative Risk (95% CI)	2.12 (0.62, 7.28)	
P-value for Relative Risk	0.2284	
Heterogeneity p-value of RR	0.6124	
Risk difference (95% CI)	7.61 (-9.35, 24.56)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Rash		
P-value for Risk Difference	0.3735	
Investigations	10 (27.0%)	4 (12.9%)
Odds ratio (95% CI)	2.611 (0.705, 9.677)	
P-value for Odds Ratio	0.1482	
Relative Risk (95% CI)	2.15 (0.73, 6.30)	
P-value for Relative Risk	0.1609	
Heterogeneity p-value of RR	0.6367	
Risk difference (95% CI)	15.87 (-4.26, 36.01)	
P-value for Risk Difference	0.1202	
Metabolism and nutrition disorders	7 (18.9%)	4 (12.9%)
Odds ratio (95% CI)	1.602 (0.408, 6.286)	
P-value for Odds Ratio	0.4940	
Relative Risk (95% CI)	1.48 (0.47, 4.71)	
P-value for Relative Risk	0.5000	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Metabolism and nutrition disorders		
Heterogeneity p-value of RR	0.6214	
Risk difference (95% CI)	6.88 (-11.74, 25.49)	
P-value for Risk Difference	0.4634	
Endocrine disorders	6 (16.2%)	1 (3.2%)
Odds ratio (95% CI)	6.462 (0.699, 59.772)	
P-value for Odds Ratio	0.0987	
Relative Risk (95% CI)	5.44 (0.67, 44.20)	
P-value for Relative Risk	0.1114	
Heterogeneity p-value of RR	0.6848	
Risk difference (95% CI)	14.30 (-0.90, 29.49)	
P-value for Risk Difference	0.0647	
Hypothyroidism	3 (8.1%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Hypothyroidism		
Relative Risk (95% CI)	6.36 (0.34, 118.18)	
P-value for Relative Risk	0.1494	
Heterogeneity p-value of RR	0.3795	
Risk difference (95% CI)	9.09 (-29.32, 47.50)	
P-value for Risk Difference	0.6382	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Skin and subcutaneous tissue disorders	56 (64.4%)	43 (48.3%)
Odds ratio (95% CI)	2.000 (1.081, 3.700)	
P-value for Odds Ratio	0.0275	
Relative Risk (95% CI)	1.33 (1.02, 1.73)	
P-value for Relative Risk	0.0364	
Heterogeneity p-value of RR	0.8994	
Risk difference (95% CI)	16.69 (2.21, 31.18)	
P-value for Risk Difference	0.0241	
Rash	17 (19.5%)	12 (13.5%)
Odds ratio (95% CI)	1.597 (0.706, 3.611)	
P-value for Odds Ratio	0.2588	
Relative Risk (95% CI)	1.48 (0.75, 2.93)	
P-value for Relative Risk	0.2553	
Heterogeneity p-value of RR	0.6124	
Risk difference (95% CI)	5.73 (-5.24, 16.70)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Rash		
P-value for Risk Difference	0.3039	
Metabolism and nutrition disorders	16 (18.4%)	7 (7.9%)
Odds ratio (95% CI)	2.687 (1.037, 6.963)	
P-value for Odds Ratio	0.0420	
Relative Risk (95% CI)	2.36 (1.02, 5.48)	
P-value for Relative Risk	0.0461	
Heterogeneity p-value of RR	0.6214	
Risk difference (95% CI)	11.63 (0.66, 22.60)	
P-value for Risk Difference	0.0379	
Investigations	14 (16.1%)	7 (7.9%)
Odds ratio (95% CI)	2.199 (0.833, 5.803)	
P-value for Odds Ratio	0.1109	
Relative Risk (95% CI)	1.98 (0.83, 4.71)	
P-value for Relative Risk	0.1221	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Investigations		
Heterogeneity p-value of RR	0.6367	
Risk difference (95% CI)	8.56 (-0.84, 17.97)	
P-value for Risk Difference	0.0741	
Endocrine disorders	13 (14.9%)	4 (4.5%)
Odds ratio (95% CI)	3.750 (1.161, 12.117)	
P-value for Odds Ratio	0.0274	
Relative Risk (95% CI)	3.35 (1.13, 9.96)	
P-value for Relative Risk	0.0300	
Heterogeneity p-value of RR	0.6848	
Risk difference (95% CI)	10.66 (1.97, 19.34)	
P-value for Risk Difference	0.0164	
Hypothyroidism	10 (11.5%)	4 (4.5%)
Odds ratio (95% CI)	2.745 (0.819, 9.203)	
P-value for Odds Ratio	0.1014	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Hypothyroidism		
Relative Risk (95% CI)	2.54 (0.82, 7.89)	
P-value for Relative Risk	0.1054	
Heterogeneity p-value of RR	0.3795	
Risk difference (95% CI)	7.21 (-0.76, 15.17)	
P-value for Risk Difference	0.0759	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Skin and subcutaneous tissue disorders	35 (43.2%)	30 (35.7%)
Odds ratio (95% CI)	1.367 (0.725, 2.576)	
P-value for Odds Ratio	0.3321	
Relative Risk (95% CI)	1.21 (0.82, 1.77)	
P-value for Relative Risk	0.3322	
Heterogeneity p-value of RR	0.8994	
Risk difference (95% CI)	7.45 (-7.63, 22.52)	
P-value for Risk Difference	0.3310	
Rash	8 (9.9%)	3 (3.6%)
Odds ratio (95% CI)	2.753 (0.690, 10.993)	
P-value for Odds Ratio	0.1505	
Relative Risk (95% CI)	2.57 (0.70, 9.44)	
P-value for Relative Risk	0.1542	
Heterogeneity p-value of RR	0.6124	
Risk difference (95% CI)	5.09 (-2.59, 12.78)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Rash		
P-value for Risk Difference	0.1924	
Investigations	15 (18.5%)	12 (14.3%)
Odds ratio (95% CI)	1.420 (0.612, 3.294)	
P-value for Odds Ratio	0.4118	
Relative Risk (95% CI)	1.33 (0.66, 2.67)	
P-value for Relative Risk	0.4261	
Heterogeneity p-value of RR	0.6367	
Risk difference (95% CI)	5.61 (-5.75, 16.97)	
P-value for Risk Difference	0.3307	
Endocrine disorders	14 (17.3%)	2 (2.4%)
Odds ratio (95% CI)	8.266 (1.788, 38.213)	
P-value for Odds Ratio	0.0072	
Relative Risk (95% CI)	6.98 (1.61, 30.19)	
P-value for Relative Risk	0.0096	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Endocrine disorders		
Heterogeneity p-value of RR	0.6848	
Risk difference (95% CI)	14.48 (5.54, 23.43)	
P-value for Risk Difference	0.0017	
Hypothyroidism	11 (13.6%)	2 (2.4%)
Odds ratio (95% CI)	6.049 (1.272, 28.757)	
P-value for Odds Ratio	0.0239	
Relative Risk (95% CI)	5.27 (1.19, 23.35)	
P-value for Relative Risk	0.0288	
Heterogeneity p-value of RR	0.3795	
Risk difference (95% CI)	10.05 (1.78, 18.33)	
P-value for Risk Difference	0.0176	
Metabolism and nutrition disorders	7 (8.6%)	6 (7.1%)
Odds ratio (95% CI)	1.344 (0.423, 4.267)	
P-value for Odds Ratio	0.6140	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	1.30 (0.45, 3.70)	
P-value for Relative Risk	0.6255	
Heterogeneity p-value of RR	0.6214	
Risk difference (95% CI)	3.11 (-7.43, 13.66)	
P-value for Risk Difference	0.5607	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Skin and subcutaneous tissue disorders	104 (55.9%)	78 (41.7%)
Odds ratio (95% CI)	1.868 (1.223, 2.852)	
P-value for Odds Ratio	0.0039	
Relative Risk (95% CI)	1.36 (1.10, 1.67)	
P-value for Relative Risk	0.0038	
Heterogeneity p-value of RR	0.1837	
Risk difference (95% CI)	14.88 (4.89, 24.87)	
P-value for Risk Difference	0.0036	
Rash	31 (16.7%)	16 (8.6%)
Odds ratio (95% CI)	2.113 (1.097, 4.068)	
P-value for Odds Ratio	0.0253	
Relative Risk (95% CI)	1.89 (1.07, 3.32)	
P-value for Relative Risk	0.0279	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.78 (0.45, 13.11)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Rash		
P-value for Risk Difference	0.0359	
Investigations	34 (18.3%)	18 (9.6%)
Odds ratio (95% CI)	2.117 (1.138, 3.938)	
P-value for Odds Ratio	0.0180	
Relative Risk (95% CI)	1.91 (1.11, 3.26)	
P-value for Relative Risk	0.0189	
Heterogeneity p-value of RR	0.1767	
Risk difference (95% CI)	8.35 (1.39, 15.30)	
P-value for Risk Difference	0.0188	
Alanine aminotransferase increased	10 (5.4%)	3 (1.6%)
Odds ratio (95% CI)	3.301 (0.879, 12.392)	
P-value for Odds Ratio	0.0767	
Relative Risk (95% CI)	3.14 (0.87, 11.33)	
P-value for Relative Risk	0.0807	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Alanine aminotransferase increased		
Heterogeneity p-value of RR	0.2991	
Risk difference (95% CI)	3.65 (-0.70, 8.00)	
P-value for Risk Difference	0.0994	
Endocrine disorders	30 (16.1%)	6 (3.2%)
Odds ratio (95% CI)	5.799 (2.334, 14.406)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	5.04 (2.13, 11.89)	
P-value for Relative Risk	0.0002	
Heterogeneity p-value of RR	0.6216	
Risk difference (95% CI)	13.12 (7.21, 19.03)	
P-value for Risk Difference	<0.0001	
Hypothyroidism	23 (12.4%)	5 (2.7%)
Odds ratio (95% CI)	5.083 (1.868, 13.827)	
P-value for Odds Ratio	0.0015	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Hypothyroidism		
Relative Risk (95% CI)	4.53 (1.75, 11.76)	
P-value for Relative Risk	0.0019	
Heterogeneity p-value of RR	0.3313	
Risk difference (95% CI)	10.26 (4.06, 16.45)	
P-value for Risk Difference	0.0012	
Hyperthyroidism	11 (5.9%)	1 (0.5%)
Odds ratio (95% CI)	10.917 (1.370, 87.031)	
P-value for Odds Ratio	0.0241	
Relative Risk (95% CI)	10.19 (1.31, 79.19)	
P-value for Relative Risk	0.0266	
Heterogeneity p-value of RR	0.6554	
Risk difference (95% CI)	6.07 (-1.71, 13.86)	
P-value for Risk Difference	0.1258	
Metabolism and nutrition disorders	27 (14.5%)	14 (7.5%)

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Metabolism and nutrition disorders		
Odds ratio (95% CI)	2.192 (1.100, 4.369)	
P-value for Odds Ratio	0.0259	
Relative Risk (95% CI)	1.99 (1.08, 3.68)	
P-value for Relative Risk	0.0280	
Heterogeneity p-value of RR	0.1620	
Risk difference (95% CI)	8.02 (0.72, 15.32)	
P-value for Risk Difference	0.0315	
Hepatobiliary disorders	10 (5.4%)	1 (0.5%)
Odds ratio (95% CI)	12.090 (1.516, 96.430)	
P-value for Odds Ratio	0.0188	
Relative Risk (95% CI)	11.30 (1.45, 87.85)	
P-value for Relative Risk	0.0206	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.15 (-2.61, 14.91)	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Hepatobiliary disorders		
P-value for Risk Difference	0.1680	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Skin and subcutaneous tissue disorders	7 (36.8%)	7 (41.2%)
Odds ratio (95% CI)	0.942 (0.207, 4.295)	
P-value for Odds Ratio	0.9365	
Relative Risk (95% CI)	0.92 (0.35, 2.42)	
P-value for Relative Risk	0.8674	
Heterogeneity p-value of RR	0.1837	
Risk difference (95% CI)	-1.34 (-36.43, 33.75)	
P-value for Risk Difference	0.9382	
Rash	2 (10.5%)	2 (11.8%)
Odds ratio (95% CI)	0.853 (0.088, 8.293)	
P-value for Odds Ratio	0.8875	
Relative Risk (95% CI)	0.79 (0.10, 6.26)	
P-value for Relative Risk	0.8181	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	4.41 (-23.32, 32.14)	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Rash		
P-value for Risk Difference	0.7479	
Investigations	5 (26.3%)	5 (29.4%)
Odds ratio (95% CI)	0.564 (0.103, 3.091)	
P-value for Odds Ratio	0.4977	
Relative Risk (95% CI)	0.64 (0.19, 2.19)	
P-value for Relative Risk	0.4617	
Heterogeneity p-value of RR	0.1767	
Risk difference (95% CI)	-13.51 (-46.46, 19.44)	
P-value for Risk Difference	0.4093	
Alanine aminotransferase increased	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.44 (0.21, 9.83)	
P-value for Relative Risk	0.7208	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Alanine aminotransferase increased		
Heterogeneity p-value of RR	0.2991	
Risk difference (95% CI)	7.73 (NE, NE)	
P-value for Risk Difference	NE	
Endocrine disorders	3 (15.8%)	1 (5.9%)
Odds ratio (95% CI)	2.092 (0.133, 32.964)	
P-value for Odds Ratio	0.5889	
Relative Risk (95% CI)	1.90 (0.16, 21.93)	
P-value for Relative Risk	0.5971	
Heterogeneity p-value of RR	0.6216	
Risk difference (95% CI)	8.91 (-68.85, 86.67)	
P-value for Risk Difference	0.8167	
Hyperthyroidism	1 (5.3%)	0
Odds ratio (95% CI)	1.000 (0.000, NE)	
P-value for Odds Ratio	1.0000	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Hyperthyroidism		
Relative Risk (95% CI)	1.00 (0.10, 9.61)	
P-value for Relative Risk	1.0000	
Heterogeneity p-value of RR	0.6554	
Risk difference (95% CI)	0.00 (NE, NE)	
P-value for Risk Difference	NE	
Hypothyroidism	1 (5.3%)	1 (5.9%)
Odds ratio (95% CI)	0.804 (0.029, 22.601)	
P-value for Odds Ratio	0.8948	
Relative Risk (95% CI)	0.79 (0.04, 14.75)	
P-value for Relative Risk	0.8736	
Heterogeneity p-value of RR	0.3313	
Risk difference (95% CI)	-0.14 (-91.64, 91.35)	
P-value for Risk Difference	0.9975	
Metabolism and nutrition disorders	3 (15.8%)	3 (17.6%)

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Metabolism and nutrition disorders		
Odds ratio (95% CI)	0.314 (0.035, 2.846)	
P-value for Odds Ratio	0.2922	
Relative Risk (95% CI)	0.46 (0.09, 2.28)	
P-value for Relative Risk	0.3267	
Heterogeneity p-value of RR	0.1620	
Risk difference (95% CI)	-18.55 (-54.81, 17.71)	
P-value for Risk Difference	0.3047	
Hepatobiliary disorders	0	1 (5.9%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.00 (0.05, 18.57)	
P-value for Relative Risk	1.0000	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-6.88 (-147.69, 133.94)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Hepatobiliary disorders		
P-value for Risk Difference	0.9213	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Skin and subcutaneous tissue disorders	90 (54.9%)	77 (44.0%)
Odds ratio (95% CI)	1.553 (1.003, 2.405)	
P-value for Odds Ratio	0.0483	
Relative Risk (95% CI)	1.25 (1.01, 1.54)	
P-value for Relative Risk	0.0403	
Heterogeneity p-value of RR	0.2206	
Risk difference (95% CI)	10.62 (0.12, 21.11)	
P-value for Risk Difference	0.0474	
Rash	25 (15.2%)	16 (9.1%)
Odds ratio (95% CI)	1.778 (0.901, 3.512)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	1.63 (0.91, 2.92)	
P-value for Relative Risk	0.1024	
Heterogeneity p-value of RR	0.5159	
Risk difference (95% CI)	5.13 (-1.19, 11.46)	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Rash		
P-value for Risk Difference	0.1114	
Investigations	32 (19.5%)	20 (11.4%)
Odds ratio (95% CI)	1.883 (1.021, 3.471)	
P-value for Odds Ratio	0.0427	
Relative Risk (95% CI)	1.68 (1.01, 2.82)	
P-value for Relative Risk	0.0474	
Heterogeneity p-value of RR	0.9676	
Risk difference (95% CI)	8.32 (0.86, 15.78)	
P-value for Risk Difference	0.0289	
Endocrine disorders	27 (16.5%)	5 (2.9%)
Odds ratio (95% CI)	6.651 (2.485, 17.802)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	5.71 (2.25, 14.54)	
P-value for Relative Risk	0.0003	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Endocrine disorders		
Heterogeneity p-value of RR	0.3007	
Risk difference (95% CI)	13.58 (7.39, 19.78)	
P-value for Risk Difference	<0.0001	
Hypothyroidism	18 (11.0%)	4 (2.3%)
Odds ratio (95% CI)	5.321 (1.751, 16.166)	
P-value for Odds Ratio	0.0033	
Relative Risk (95% CI)	4.81 (1.66, 13.96)	
P-value for Relative Risk	0.0040	
Heterogeneity p-value of RR	0.4154	
Risk difference (95% CI)	8.81 (2.78, 14.83)	
P-value for Risk Difference	0.0043	
Metabolism and nutrition disorders	26 (15.9%)	17 (9.7%)
Odds ratio (95% CI)	1.726 (0.895, 3.330)	
P-value for Odds Ratio	0.1029	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	1.61 (0.91, 2.86)	
P-value for Relative Risk	0.1025	
Heterogeneity p-value of RR	0.0917	
Risk difference (95% CI)	5.64 (-1.54, 12.83)	
P-value for Risk Difference	0.1233	
Hepatobiliary disorders	10 (6.1%)	1 (0.6%)
Odds ratio (95% CI)	11.332 (1.423, 90.277)	
P-value for Odds Ratio	0.0220	
Relative Risk (95% CI)	10.69 (1.37, 83.26)	
P-value for Relative Risk	0.0238	
Heterogeneity p-value of RR	0.0273	
Risk difference (95% CI)	5.82 (-1.57, 13.20)	
P-value for Risk Difference	0.1221	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Skin and subcutaneous tissue disorders	21 (51.2%)	8 (27.6%)
Odds ratio (95% CI)	2.769 (0.977, 7.853)	
P-value for Odds Ratio	0.0553	
Relative Risk (95% CI)	1.87 (0.95, 3.67)	
P-value for Relative Risk	0.0680	
Heterogeneity p-value of RR	0.2206	
Risk difference (95% CI)	24.04 (0.82, 47.26)	
P-value for Risk Difference	0.0427	
Rash	8 (19.5%)	2 (6.9%)
Odds ratio (95% CI)	3.055 (0.556, 16.770)	
P-value for Odds Ratio	0.1950	
Relative Risk (95% CI)	2.71 (0.62, 11.77)	
P-value for Relative Risk	0.1800	
Heterogeneity p-value of RR	0.5159	
Risk difference (95% CI)	8.33 (-7.29, 23.96)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Rash		
P-value for Risk Difference	0.2909	
Investigations	7 (17.1%)	3 (10.3%)
Odds ratio (95% CI)	1.800 (0.408, 7.937)	
P-value for Odds Ratio	0.4316	
Relative Risk (95% CI)	1.62 (0.45, 5.87)	
P-value for Relative Risk	0.4595	
Heterogeneity p-value of RR	0.9676	
Risk difference (95% CI)	8.75 (-7.62, 25.11)	
P-value for Risk Difference	0.2899	
Endocrine disorders	6 (14.6%)	2 (6.9%)
Odds ratio (95% CI)	2.510 (0.449, 14.029)	
P-value for Odds Ratio	0.2896	
Relative Risk (95% CI)	2.28 (0.49, 10.71)	
P-value for Relative Risk	0.2906	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Endocrine disorders		
Heterogeneity p-value of RR	0.3007	
Risk difference (95% CI)	8.37 (-8.88, 25.62)	
P-value for Risk Difference	0.3363	
Hypothyroidism	6 (14.6%)	2 (6.9%)
Odds ratio (95% CI)	2.510 (0.449, 14.029)	
P-value for Odds Ratio	0.2896	
Relative Risk (95% CI)	2.28 (0.49, 10.71)	
P-value for Relative Risk	0.2906	
Heterogeneity p-value of RR	0.4154	
Risk difference (95% CI)	8.37 (-8.88, 25.62)	
P-value for Risk Difference	0.3363	
Metabolism and nutrition disorders	4 (9.8%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	2.48 (0.45, 13.63)	
P-value for Relative Risk	0.2819	
Heterogeneity p-value of RR	0.0917	
Risk difference (95% CI)	13.61 (-48.36, 75.57)	
P-value for Risk Difference	0.6625	
Hepatobiliary disorders	0	1 (3.4%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.25 (0.01, 5.88)	
P-value for Relative Risk	0.3580	
Heterogeneity p-value of RR	0.0273	
Risk difference (95% CI)	-4.36 (NE, NE)	
P-value for Risk Difference	NE	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Skin and subcutaneous tissue disorders	73 (56.2%)	55 (42.0%)
Odds ratio (95% CI)	1.856 (1.123, 3.067)	
P-value for Odds Ratio	0.0160	
Relative Risk (95% CI)	1.33 (1.03, 1.70)	
P-value for Relative Risk	0.0265	
Heterogeneity p-value of RR	0.9114	
Risk difference (95% CI)	15.07 (3.10, 27.03)	
P-value for Risk Difference	0.0138	
Rash	18 (13.8%)	12 (9.2%)
Odds ratio (95% CI)	1.577 (0.714, 3.480)	
P-value for Odds Ratio	0.2585	
Relative Risk (95% CI)	1.45 (0.73, 2.89)	
P-value for Relative Risk	0.2839	
Heterogeneity p-value of RR	0.3954	
Risk difference (95% CI)	4.79 (-2.18, 11.75)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Rash		
P-value for Risk Difference	0.1770	
Investigations	27 (20.8%)	14 (10.7%)
Odds ratio (95% CI)	2.166 (1.070, 4.384)	
P-value for Odds Ratio	0.0318	
Relative Risk (95% CI)	1.93 (1.06, 3.52)	
P-value for Relative Risk	0.0328	
Heterogeneity p-value of RR	0.4037	
Risk difference (95% CI)	9.85 (0.98, 18.71)	
P-value for Risk Difference	0.0296	
Alanine aminotransferase increased	10 (7.7%)	3 (2.3%)
Odds ratio (95% CI)	3.596 (0.954, 13.553)	
P-value for Odds Ratio	0.0586	
Relative Risk (95% CI)	3.36 (0.94, 12.04)	
P-value for Relative Risk	0.0623	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Alanine aminotransferase increased		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	5.42 (-0.39, 11.24)	
P-value for Risk Difference	0.0674	
Endocrine disorders	23 (17.7%)	5 (3.8%)
Odds ratio (95% CI)	5.339 (1.948, 14.635)	
P-value for Odds Ratio	0.0012	
Relative Risk (95% CI)	4.57 (1.78, 11.73)	
P-value for Relative Risk	0.0017	
Heterogeneity p-value of RR	0.9572	
Risk difference (95% CI)	14.00 (6.57, 21.43)	
P-value for Risk Difference	0.0003	
Hypothyroidism	17 (13.1%)	4 (3.1%)
Odds ratio (95% CI)	4.623 (1.494, 14.308)	
P-value for Odds Ratio	0.0081	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Hypothyroidism		
Relative Risk (95% CI)	4.08 (1.40, 11.89)	
P-value for Relative Risk	0.0101	
Heterogeneity p-value of RR	0.8237	
Risk difference (95% CI)	9.49 (1.91, 17.07)	
P-value for Risk Difference	0.0144	
Metabolism and nutrition disorders	19 (14.6%)	8 (6.1%)
Odds ratio (95% CI)	2.981 (1.230, 7.226)	
P-value for Odds Ratio	0.0158	
Relative Risk (95% CI)	2.60 (1.19, 5.67)	
P-value for Relative Risk	0.0169	
Heterogeneity p-value of RR	0.1904	
Risk difference (95% CI)	9.29 (0.41, 18.17)	
P-value for Risk Difference	0.0405	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Skin and subcutaneous tissue disorders	38 (50.7%)	30 (41.1%)
Odds ratio (95% CI)	1.464 (0.746, 2.871)	
P-value for Odds Ratio	0.2657	
Relative Risk (95% CI)	1.30 (0.92, 1.83)	
P-value for Relative Risk	0.1298	
Heterogeneity p-value of RR	0.9114	
Risk difference (95% CI)	8.07 (-7.99, 24.12)	
P-value for Risk Difference	0.3222	
Rash	15 (20.0%)	6 (8.2%)
Odds ratio (95% CI)	2.723 (0.961, 7.716)	
P-value for Odds Ratio	0.0592	
Relative Risk (95% CI)	2.30 (0.95, 5.56)	
P-value for Relative Risk	0.0650	
Heterogeneity p-value of RR	0.3954	
Risk difference (95% CI)	8.50 (-4.02, 21.03)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Rash		
P-value for Risk Difference	0.1817	
Investigations	12 (16.0%)	9 (12.3%)
Odds ratio (95% CI)	1.393 (0.535, 3.626)	
P-value for Odds Ratio	0.4947	
Relative Risk (95% CI)	1.29 (0.58, 2.86)	
P-value for Relative Risk	0.5284	
Heterogeneity p-value of RR	0.4037	
Risk difference (95% CI)	6.18 (-6.26, 18.63)	
P-value for Risk Difference	0.3276	
Alanine aminotransferase increased	2 (2.7%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.60 (0.31, 21.62)	
P-value for Relative Risk	0.3664	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Alanine aminotransferase increased		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	3.65 (-129.53, 136.82)	
P-value for Risk Difference	0.9569	
Metabolism and nutrition disorders	11 (14.7%)	9 (12.3%)
Odds ratio (95% CI)	1.145 (0.432, 3.036)	
P-value for Odds Ratio	0.7838	
Relative Risk (95% CI)	1.14 (0.50, 2.56)	
P-value for Relative Risk	0.7564	
Heterogeneity p-value of RR	0.1904	
Risk difference (95% CI)	0.49 (-10.84, 11.81)	
P-value for Risk Difference	0.9325	
Endocrine disorders	10 (13.3%)	2 (2.7%)
Odds ratio (95% CI)	5.636 (1.168, 27.204)	
P-value for Odds Ratio	0.0316	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Endocrine disorders		
Relative Risk (95% CI)	5.06 (1.13, 22.61)	
P-value for Relative Risk	0.0340	
Heterogeneity p-value of RR	0.9572	
Risk difference (95% CI)	12.36 (-0.26, 24.97)	
P-value for Risk Difference	0.0548	
Hypothyroidism	7 (9.3%)	2 (2.7%)
Odds ratio (95% CI)	3.935 (0.770, 20.094)	
P-value for Odds Ratio	0.0990	
Relative Risk (95% CI)	3.64 (0.77, 17.17)	
P-value for Relative Risk	0.1012	
Heterogeneity p-value of RR	0.8237	
Risk difference (95% CI)	7.50 (-3.59, 18.59)	
P-value for Risk Difference	0.1832	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Skin and subcutaneous tissue disorders	70 (56.9%)	46 (39.7%)
Odds ratio (95% CI)	2.196 (1.285, 3.754)	
P-value for Odds Ratio	0.0042	
Relative Risk (95% CI)	1.46 (1.12, 1.90)	
P-value for Relative Risk	0.0058	
Heterogeneity p-value of RR	0.2549	
Risk difference (95% CI)	18.77 (6.45, 31.08)	
P-value for Risk Difference	0.0030	
Rash	18 (14.6%)	11 (9.5%)
Odds ratio (95% CI)	1.606 (0.709, 3.637)	
P-value for Odds Ratio	0.2550	
Relative Risk (95% CI)	1.52 (0.75, 3.06)	
P-value for Relative Risk	0.2412	
Heterogeneity p-value of RR	0.5720	
Risk difference (95% CI)	3.01 (-4.70, 10.72)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Rash		
P-value for Risk Difference	0.4429	
Investigations	23 (18.7%)	14 (12.1%)
Odds ratio (95% CI)	1.666 (0.800, 3.470)	
P-value for Odds Ratio	0.1714	
Relative Risk (95% CI)	1.48 (0.80, 2.74)	
P-value for Relative Risk	0.2106	
Heterogeneity p-value of RR	0.5930	
Risk difference (95% CI)	7.97 (-0.64, 16.58)	
P-value for Risk Difference	0.0695	
Metabolism and nutrition disorders	19 (15.4%)	9 (7.8%)
Odds ratio (95% CI)	2.288 (0.974, 5.375)	
P-value for Odds Ratio	0.0574	
Relative Risk (95% CI)	2.03 (0.96, 4.31)	
P-value for Relative Risk	0.0637	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Metabolism and nutrition disorders		
Heterogeneity p-value of RR	0.5307	
Risk difference (95% CI)	7.88 (-1.70, 17.46)	
P-value for Risk Difference	0.1064	
Endocrine disorders	17 (13.8%)	2 (1.7%)
Odds ratio (95% CI)	9.579 (2.134, 42.992)	
P-value for Odds Ratio	0.0033	
Relative Risk (95% CI)	8.31 (1.95, 35.48)	
P-value for Relative Risk	0.0044	
Heterogeneity p-value of RR	0.3210	
Risk difference (95% CI)	13.45 (4.27, 22.62)	
P-value for Risk Difference	0.0043	
Hypothyroidism	12 (9.8%)	1 (0.9%)
Odds ratio (95% CI)	13.322 (1.675, 105.966)	
P-value for Odds Ratio	0.0146	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Hypothyroidism		
Relative Risk (95% CI)	11.86 (1.55, 90.61)	
P-value for Relative Risk	0.0174	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	10.83 (1.35, 20.32)	
P-value for Risk Difference	0.0254	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Skin and subcutaneous tissue disorders	41 (50.0%)	39 (44.3%)
Odds ratio (95% CI)	1.224 (0.658, 2.276)	
P-value for Odds Ratio	0.5207	
Relative Risk (95% CI)	1.15 (0.84, 1.57)	
P-value for Relative Risk	0.3759	
Heterogeneity p-value of RR	0.2549	
Risk difference (95% CI)	4.83 (-10.07, 19.73)	
P-value for Risk Difference	0.5231	
Rash	15 (18.3%)	7 (8.0%)
Odds ratio (95% CI)	2.513 (0.951, 6.643)	
P-value for Odds Ratio	0.0631	
Relative Risk (95% CI)	2.16 (0.93, 5.03)	
P-value for Relative Risk	0.0746	
Heterogeneity p-value of RR	0.5720	
Risk difference (95% CI)	10.94 (0.23, 21.65)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Rash		
P-value for Risk Difference	0.0453	
Endocrine disorders	16 (19.5%)	5 (5.7%)
Odds ratio (95% CI)	3.962 (1.352, 11.611)	
P-value for Odds Ratio	0.0124	
Relative Risk (95% CI)	3.19 (1.21, 8.40)	
P-value for Relative Risk	0.0190	
Heterogeneity p-value of RR	0.3210	
Risk difference (95% CI)	14.86 (3.93, 25.80)	
P-value for Risk Difference	0.0080	
Hypothyroidism	12 (14.6%)	5 (5.7%)
Odds ratio (95% CI)	2.773 (0.903, 8.521)	
P-value for Odds Ratio	0.0746	
Relative Risk (95% CI)	2.32 (0.85, 6.30)	
P-value for Relative Risk	0.0987	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Hypothyroidism		
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	9.91 (-0.56, 20.39)	
P-value for Risk Difference	0.0634	
Investigations	16 (19.5%)	9 (10.2%)
Odds ratio (95% CI)	2.105 (0.859, 5.156)	
P-value for Odds Ratio	0.1028	
Relative Risk (95% CI)	1.89 (0.88, 4.05)	
P-value for Relative Risk	0.0997	
Heterogeneity p-value of RR	0.5930	
Risk difference (95% CI)	7.90 (-2.89, 18.69)	
P-value for Risk Difference	0.1500	
Metabolism and nutrition disorders	11 (13.4%)	8 (9.1%)
Odds ratio (95% CI)	1.518 (0.569, 4.051)	
P-value for Odds Ratio	0.4024	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	1.45 (0.61, 3.42)	
P-value for Relative Risk	0.3965	
Heterogeneity p-value of RR	0.5307	
Risk difference (95% CI)	5.04 (-5.81, 15.89)	
P-value for Risk Difference	0.3601	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Skin and subcutaneous tissue disorders	82 (53.6%)	69 (45.4%)
Odds ratio (95% CI)	1.436 (0.906, 2.276)	
P-value for Odds Ratio	0.1234	
Relative Risk (95% CI)	1.18 (0.95, 1.48)	
P-value for Relative Risk	0.1377	
Heterogeneity p-value of RR	0.0257	
Risk difference (95% CI)	8.75 (-2.37, 19.86)	
P-value for Risk Difference	0.1226	
Rash	24 (15.7%)	14 (9.2%)
Odds ratio (95% CI)	1.821 (0.891, 3.722)	
P-value for Odds Ratio	0.1002	
Relative Risk (95% CI)	1.68 (0.91, 3.11)	
P-value for Relative Risk	0.1000	
Heterogeneity p-value of RR	0.7402	
Risk difference (95% CI)	5.16 (-1.92, 12.23)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Rash		
P-value for Risk Difference	0.1527	
Investigations	32 (20.9%)	16 (10.5%)
Odds ratio (95% CI)	2.293 (1.188, 4.424)	
P-value for Odds Ratio	0.0135	
Relative Risk (95% CI)	1.98 (1.14, 3.46)	
P-value for Relative Risk	0.0159	
Heterogeneity p-value of RR	0.3841	
Risk difference (95% CI)	11.04 (2.88, 19.20)	
P-value for Risk Difference	0.0082	
Endocrine disorders	26 (17.0%)	3 (2.0%)
Odds ratio (95% CI)	10.315 (3.026, 35.168)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	8.66 (2.66, 28.13)	
P-value for Relative Risk	0.0004	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Endocrine disorders		
Heterogeneity p-value of RR	0.0348	
Risk difference (95% CI)	15.48 (7.81, 23.16)	
P-value for Risk Difference	<0.0001	
Hypothyroidism	18 (11.8%)	2 (1.3%)
Odds ratio (95% CI)	10.001 (2.255, 44.363)	
P-value for Odds Ratio	0.0026	
Relative Risk (95% CI)	8.80 (2.07, 37.51)	
P-value for Relative Risk	0.0034	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	11.50 (3.45, 19.55)	
P-value for Risk Difference	0.0052	
Hyperthyroidism	10 (6.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Hyperthyroidism		
Relative Risk (95% CI)	5.89 (1.35, 25.74)	
P-value for Relative Risk	0.0068	
Heterogeneity p-value of RR	0.0093	
Risk difference (95% CI)	9.66 (-43.97, 63.29)	
P-value for Risk Difference	0.7232	
Metabolism and nutrition disorders	25 (16.3%)	11 (7.2%)
Odds ratio (95% CI)	2.668 (1.247, 5.708)	
P-value for Odds Ratio	0.0116	
Relative Risk (95% CI)	2.35 (1.20, 4.59)	
P-value for Relative Risk	0.0126	
Heterogeneity p-value of RR	0.0328	
Risk difference (95% CI)	8.90 (0.44, 17.36)	
P-value for Risk Difference	0.0392	
Hepatobiliary disorders	10 (6.5%)	1 (0.7%)

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Hepatobiliary disorders		
Odds ratio (95% CI)	10.989 (1.374, 87.884)	
P-value for Odds Ratio	0.0240	
Relative Risk (95% CI)	10.38 (1.33, 80.81)	
P-value for Relative Risk	0.0256	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.85 (-15.79, 29.49)	
P-value for Risk Difference	0.5521	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Skin and subcutaneous tissue disorders	25 (62.5%)	13 (30.2%)
Odds ratio (95% CI)	4.226 (1.558, 11.466)	
P-value for Odds Ratio	0.0052	
Relative Risk (95% CI)	2.03 (1.23, 3.37)	
P-value for Relative Risk	0.0065	
Heterogeneity p-value of RR	0.0257	
Risk difference (95% CI)	29.93 (9.33, 50.53)	
P-value for Risk Difference	0.0050	
Rash	8 (20.0%)	4 (9.3%)
Odds ratio (95% CI)	2.465 (0.635, 9.571)	
P-value for Odds Ratio	0.1895	
Relative Risk (95% CI)	2.02 (0.66, 6.19)	
P-value for Relative Risk	0.2172	
Heterogeneity p-value of RR	0.7402	
Risk difference (95% CI)	11.01 (-13.61, 35.62)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Rash		
P-value for Risk Difference	0.3761	
Investigations	4 (10.0%)	4 (9.3%)
Odds ratio (95% CI)	1.271 (0.280, 5.779)	
P-value for Odds Ratio	0.7532	
Relative Risk (95% CI)	1.21 (0.32, 4.53)	
P-value for Relative Risk	0.7729	
Heterogeneity p-value of RR	0.3841	
Risk difference (95% CI)	1.23 (-12.56, 15.03)	
P-value for Risk Difference	0.8590	
Endocrine disorders	3 (7.5%)	3 (7.0%)
Odds ratio (95% CI)	1.225 (0.221, 6.805)	
P-value for Odds Ratio	0.8144	
Relative Risk (95% CI)	1.19 (0.25, 5.61)	
P-value for Relative Risk	0.8225	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Endocrine disorders		
Heterogeneity p-value of RR	0.0348	
Risk difference (95% CI)	-0.90 (-15.74, 13.95)	
P-value for Risk Difference	0.9046	
Hypothyroidism	3 (7.5%)	3 (7.0%)
Odds ratio (95% CI)	1.225 (0.221, 6.805)	
P-value for Odds Ratio	0.8144	
Relative Risk (95% CI)	1.19 (0.25, 5.61)	
P-value for Relative Risk	0.8225	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-0.90 (-15.74, 13.95)	
P-value for Risk Difference	0.9046	
Hyperthyroidism	0	1 (2.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Hyperthyroidism		
Relative Risk (95% CI)	0.41 (0.02, 9.25)	
P-value for Relative Risk	0.5658	
Heterogeneity p-value of RR	0.0093	
Risk difference (95% CI)	-4.38 (-62.49, 53.73)	
P-value for Risk Difference	0.8811	
Metabolism and nutrition disorders	2 (5.0%)	5 (11.6%)
Odds ratio (95% CI)	0.315 (0.050, 1.979)	
P-value for Odds Ratio	0.2147	
Relative Risk (95% CI)	0.37 (0.08, 1.79)	
P-value for Relative Risk	0.2129	
Heterogeneity p-value of RR	0.0328	
Risk difference (95% CI)	-9.42 (-31.98, 13.14)	
P-value for Risk Difference	0.4083	
Hepatobiliary disorders	0	1 (2.3%)

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Hepatobiliary disorders		
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.41 (0.02, 9.25)	
P-value for Relative Risk	0.5658	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-4.38 (-62.49, 53.73)	
P-value for Risk Difference	0.8811	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Skin and subcutaneous tissue disorders	21 (55.3%)	21 (48.8%)
Odds ratio (95% CI)	1.303 (0.500, 3.399)	
P-value for Odds Ratio	0.5841	
Relative Risk (95% CI)	1.18 (0.80, 1.74)	
P-value for Relative Risk	0.4075	
Heterogeneity p-value of RR	0.6505	
Risk difference (95% CI)	5.67 (-15.63, 26.98)	
P-value for Risk Difference	0.5975	
Rash	5 (13.2%)	2 (4.7%)
Odds ratio (95% CI)	2.932 (0.509, 16.892)	
P-value for Odds Ratio	0.2250	
Relative Risk (95% CI)	2.65 (0.54, 13.07)	
P-value for Relative Risk	0.2267	
Heterogeneity p-value of RR	0.5204	
Risk difference (95% CI)	10.90 (-10.22, 32.01)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Rash		
P-value for Risk Difference	0.3073	
Endocrine disorders	10 (26.3%)	2 (4.7%)
Odds ratio (95% CI)	7.306 (1.412, 37.793)	
P-value for Odds Ratio	0.0184	
Relative Risk (95% CI)	5.11 (1.16, 22.54)	
P-value for Relative Risk	0.0316	
Heterogeneity p-value of RR	0.7831	
Risk difference (95% CI)	25.59 (1.93, 49.25)	
P-value for Risk Difference	0.0344	
Hypothyroidism	8 (21.1%)	2 (4.7%)
Odds ratio (95% CI)	5.268 (0.994, 27.926)	
P-value for Odds Ratio	0.0508	
Relative Risk (95% CI)	4.01 (0.88, 18.33)	
P-value for Relative Risk	0.0727	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Hypothyroidism		
Heterogeneity p-value of RR	0.9069	
Risk difference (95% CI)	19.60 (-2.98, 42.18)	
P-value for Risk Difference	0.0879	
Investigations	8 (21.1%)	7 (16.3%)
Odds ratio (95% CI)	1.444 (0.455, 4.588)	
P-value for Odds Ratio	0.5284	
Relative Risk (95% CI)	1.34 (0.53, 3.39)	
P-value for Relative Risk	0.5259	
Heterogeneity p-value of RR	0.5574	
Risk difference (95% CI)	6.09 (-11.58, 23.76)	
P-value for Risk Difference	0.4946	
Metabolism and nutrition disorders	7 (18.4%)	4 (9.3%)
Odds ratio (95% CI)	2.384 (0.611, 9.299)	
P-value for Odds Ratio	0.2075	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	2.07 (0.65, 6.54)	
P-value for Relative Risk	0.2131	
Heterogeneity p-value of RR	0.7778	
Risk difference (95% CI)	9.38 (-9.69, 28.45)	
P-value for Risk Difference	0.3303	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Skin and subcutaneous tissue disorders	90 (53.9%)	64 (39.8%)
Odds ratio (95% CI)	1.773 (1.131, 2.777)	
P-value for Odds Ratio	0.0126	
Relative Risk (95% CI)	1.34 (1.06, 1.69)	
P-value for Relative Risk	0.0153	
Heterogeneity p-value of RR	0.6505	
Risk difference (95% CI)	13.76 (3.09, 24.43)	
P-value for Risk Difference	0.0116	
Rash	28 (16.8%)	16 (9.9%)
Odds ratio (95% CI)	1.730 (0.880, 3.403)	
P-value for Odds Ratio	0.1119	
Relative Risk (95% CI)	1.58 (0.89, 2.79)	
P-value for Relative Risk	0.1154	
Heterogeneity p-value of RR	0.5204	
Risk difference (95% CI)	4.53 (-2.13, 11.19)	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Rash		
P-value for Risk Difference	0.1816	
Investigations	31 (18.6%)	16 (9.9%)
Odds ratio (95% CI)	2.082 (1.080, 4.017)	
P-value for Odds Ratio	0.0288	
Relative Risk (95% CI)	1.85 (1.05, 3.25)	
P-value for Relative Risk	0.0334	
Heterogeneity p-value of RR	0.5574	
Risk difference (95% CI)	9.21 (1.90, 16.52)	
P-value for Risk Difference	0.0137	
Endocrine disorders	23 (13.8%)	5 (3.1%)
Odds ratio (95% CI)	5.066 (1.859, 13.807)	
P-value for Odds Ratio	0.0016	
Relative Risk (95% CI)	4.49 (1.74, 11.60)	
P-value for Relative Risk	0.0020	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Endocrine disorders		
Heterogeneity p-value of RR	0.7831	
Risk difference (95% CI)	10.37 (4.33, 16.41)	
P-value for Risk Difference	0.0008	
Hypothyroidism	16 (9.6%)	4 (2.5%)
Odds ratio (95% CI)	4.273 (1.383, 13.199)	
P-value for Odds Ratio	0.0118	
Relative Risk (95% CI)	3.93 (1.33, 11.58)	
P-value for Relative Risk	0.0132	
Heterogeneity p-value of RR	0.9069	
Risk difference (95% CI)	7.35 (1.51, 13.20)	
P-value for Risk Difference	0.0138	
Metabolism and nutrition disorders	23 (13.8%)	13 (8.1%)
Odds ratio (95% CI)	1.839 (0.888, 3.810)	
P-value for Odds Ratio	0.1008	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Metabolism and nutrition disorders		
Relative Risk (95% CI)	1.70 (0.89, 3.25)	
P-value for Relative Risk	0.1055	
Heterogeneity p-value of RR	0.7778	
Risk difference (95% CI)	5.98 (-1.70, 13.67)	
P-value for Risk Difference	0.1266	

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.5.2.1 Treatment-Emergent Adverse Events with Grade >=3 by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

.

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)

No record met criteria

Data cut-off as of October 4, 2024. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency of all grades in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency of all grades in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.2.2.1 Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

.

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)

No record met criteria

Data cut-off as of October 4, 2024.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

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Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE	53 (98.1%)	59 (90.8%)
Odds ratio (95% CI)	6.676 (0.718, 62.043)	
P-value for Odds Ratio	0.0943	
Relative Risk (95% CI)	1.07 (0.87, 1.31)	
P-value for Relative Risk	0.5459	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	9.02 (-14.65, 32.69)	
P-value for Risk Difference	0.4518	
TEAE with any NCI grade 3/4/5	13 (24.1%)	9 (13.8%)
Odds ratio (95% CI)	2.010 (0.771, 5.244)	
P-value for Odds Ratio	0.1519	
Relative Risk (95% CI)	1.74 (0.80, 3.81)	
P-value for Relative Risk	0.1638	
Heterogeneity p-value of RR	0.5689	
Risk difference (95% CI)	14.27 (-1.60, 30.13)	
P-value for Risk Difference	0.0775	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	7 (13.0%)	3 (4.6%)
Odds ratio (95% CI)	3.428 (0.797, 14.746)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	3.01 (0.81, 11.17)	
P-value for Relative Risk	0.0988	
Heterogeneity p-value of RR	0.3619	
Risk difference (95% CI)	8.50 (-4.13, 21.12)	
P-value for Risk Difference	0.1852	
TEAE leading to study treatment discontinuation	3 (5.6%)	1 (1.5%)
Odds ratio (95% CI)	4.403 (0.411, 47.193)	
P-value for Odds Ratio	0.2183	
Relative Risk (95% CI)	3.87 (0.41, 36.82)	
P-value for Relative Risk	0.2360	
Heterogeneity p-value of RR	0.7864	
Risk difference (95% CI)	6.10 (-20.63, 32.82)	
P-value for Risk Difference	0.6523	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE leading to study treatment interruption/delay	12 (22.2%)	7 (10.8%)
Odds ratio (95% CI)	2.430 (0.866, 6.814)	
P-value for Odds Ratio	0.0908	
Relative Risk (95% CI)	2.09 (0.88, 4.98)	
P-value for Relative Risk	0.0958	
Heterogeneity p-value of RR	0.6213	
Risk difference (95% CI)	12.52 (-0.91, 25.95)	
P-value for Risk Difference	0.0674	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TEAE	138 (91.4%)	126 (90.6%)
Odds ratio (95% CI)	1.031 (0.448, 2.376)	
P-value for Odds Ratio	0.9418	
Relative Risk (95% CI)	1.02 (0.96, 1.09)	
P-value for Relative Risk	0.4602	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	1.99 (-3.64, 7.62)	
P-value for Risk Difference	0.4875	
TEAE with any NCI grade 3/4/5	39 (25.8%)	24 (17.3%)
Odds ratio (95% CI)	1.536 (0.855, 2.760)	
P-value for Odds Ratio	0.1506	
Relative Risk (95% CI)	1.36 (0.86, 2.17)	
P-value for Relative Risk	0.1875	
Heterogeneity p-value of RR	0.5689	
Risk difference (95% CI)	7.65 (-1.54, 16.85)	
P-value for Risk Difference	0.1025	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TE-SAE	31 (20.5%)	18 (12.9%)
Odds ratio (95% CI)	1.682 (0.883, 3.204)	
P-value for Odds Ratio	0.1136	
Relative Risk (95% CI)	1.53 (0.89, 2.64)	
P-value for Relative Risk	0.1200	
Heterogeneity p-value of RR	0.3619	
Risk difference (95% CI)	7.20 (-1.43, 15.82)	
P-value for Risk Difference	0.1016	
TEAE leading to study treatment discontinuation	17 (11.3%)	3 (2.2%)
Odds ratio (95% CI)	5.868 (1.660, 20.743)	
P-value for Odds Ratio	0.0062	
Relative Risk (95% CI)	5.32 (1.58, 17.96)	
P-value for Relative Risk	0.0072	
Heterogeneity p-value of RR	0.7864	
Risk difference (95% CI)	9.86 (1.62, 18.09)	
P-value for Risk Difference	0.0192	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TEAE leading to study treatment interruption/delay	36 (23.8%)	20 (14.4%)
Odds ratio (95% CI)	1.721 (0.927, 3.194)	
P-value for Odds Ratio	0.0852	
Relative Risk (95% CI)	1.56 (0.95, 2.57)	
P-value for Relative Risk	0.0794	
Heterogeneity p-value of RR	0.6213	
Risk difference (95% CI)	7.26 (-1.70, 16.22)	
P-value for Risk Difference	0.1116	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE	53 (98.1%)	59 (90.8%)
Odds ratio (95% CI)	6.676 (0.718, 62.043)	
P-value for Odds Ratio	0.0943	
Relative Risk (95% CI)	1.07 (0.87, 1.31)	
P-value for Relative Risk	0.5459	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	9.02 (-14.65, 32.69)	
P-value for Risk Difference	0.4518	
TEAE with any NCI grade 3/4/5	13 (24.1%)	9 (13.8%)
Odds ratio (95% CI)	2.010 (0.771, 5.244)	
P-value for Odds Ratio	0.1519	
Relative Risk (95% CI)	1.74 (0.80, 3.81)	
P-value for Relative Risk	0.1638	
Heterogeneity p-value of RR	0.3825	
Risk difference (95% CI)	14.27 (-1.60, 30.13)	
P-value for Risk Difference	0.0775	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	7 (13.0%)	3 (4.6%)
Odds ratio (95% CI)	3.428 (0.797, 14.746)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	3.01 (0.81, 11.17)	
P-value for Relative Risk	0.0988	
Heterogeneity p-value of RR	0.4109	
Risk difference (95% CI)	8.50 (-4.13, 21.12)	
P-value for Risk Difference	0.1852	
TEAE leading to study treatment discontinuation	3 (5.6%)	1 (1.5%)
Odds ratio (95% CI)	4.403 (0.411, 47.193)	
P-value for Odds Ratio	0.2183	
Relative Risk (95% CI)	3.87 (0.41, 36.82)	
P-value for Relative Risk	0.2360	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.10 (-20.63, 32.82)	
P-value for Risk Difference	0.6523	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TEAE leading to study treatment interruption/delay	12 (22.2%)	7 (10.8%)
Odds ratio (95% CI)	2.430 (0.866, 6.814)	
P-value for Odds Ratio	0.0908	
Relative Risk (95% CI)	2.09 (0.88, 4.98)	
P-value for Relative Risk	0.0958	
Heterogeneity p-value of RR	0.6282	
Risk difference (95% CI)	12.52 (-0.91, 25.95)	
P-value for Risk Difference	0.0674	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TEAE	73 (91.3%)	62 (91.2%)
Odds ratio (95% CI)	1.149 (0.341, 3.867)	
P-value for Odds Ratio	0.8215	
Relative Risk (95% CI)	1.00 (0.92, 1.09)	
P-value for Relative Risk	0.9271	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	0.83 (-6.93, 8.58)	
P-value for Risk Difference	0.8334	
TEAE with any NCI grade 3/4/5	16 (20.0%)	13 (19.1%)
Odds ratio (95% CI)	0.955 (0.401, 2.271)	
P-value for Odds Ratio	0.9156	
Relative Risk (95% CI)	0.93 (0.48, 1.79)	
P-value for Relative Risk	0.8240	
Heterogeneity p-value of RR	0.3825	
Risk difference (95% CI)	0.64 (-11.86, 13.14)	
P-value for Risk Difference	0.9197	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TE-SAE	12 (15.0%)	9 (13.2%)
Odds ratio (95% CI)	1.234 (0.466, 3.267)	
P-value for Odds Ratio	0.6695	
Relative Risk (95% CI)	1.15 (0.52, 2.56)	
P-value for Relative Risk	0.7308	
Heterogeneity p-value of RR	0.4109	
Risk difference (95% CI)	6.54 (-8.86, 21.93)	
P-value for Risk Difference	0.4027	
TEAE leading to study treatment discontinuation	6 (7.5%)	1 (1.5%)
Odds ratio (95% CI)	5.167 (0.584, 45.742)	
P-value for Odds Ratio	0.1388	
Relative Risk (95% CI)	4.92 (0.58, 41.46)	
P-value for Relative Risk	0.1421	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	7.35 (-34.74, 49.45)	
P-value for Risk Difference	0.7304	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TEAE leading to study treatment interruption/delay	16 (20.0%)	10 (14.7%)
Odds ratio (95% CI)	1.281 (0.521, 3.147)	
P-value for Odds Ratio	0.5870	
Relative Risk (95% CI)	1.25 (0.60, 2.58)	
P-value for Relative Risk	0.5474	
Heterogeneity p-value of RR	0.6282	
Risk difference (95% CI)	2.59 (-10.07, 15.25)	
P-value for Risk Difference	0.6865	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TEAE	65 (91.5%)	64 (90.1%)
Odds ratio (95% CI)	1.036 (0.317, 3.383)	
P-value for Odds Ratio	0.9529	
Relative Risk (95% CI)	1.05 (0.88, 1.25)	
P-value for Relative Risk	0.5893	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	4.34 (-11.11, 19.79)	
P-value for Risk Difference	0.5796	
TEAE with any NCI grade 3/4/5	23 (32.4%)	11 (15.5%)
Odds ratio (95% CI)	2.419 (1.048, 5.586)	
P-value for Odds Ratio	0.0387	
Relative Risk (95% CI)	1.97 (1.03, 3.78)	
P-value for Relative Risk	0.0412	
Heterogeneity p-value of RR	0.3825	
Risk difference (95% CI)	14.74 (0.48, 29.00)	
P-value for Risk Difference	0.0428	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TE-SAE	19 (26.8%)	9 (12.7%)
Odds ratio (95% CI)	2.518 (1.025, 6.182)	
P-value for Odds Ratio	0.0440	
Relative Risk (95% CI)	2.10 (1.01, 4.36)	
P-value for Relative Risk	0.0479	
Heterogeneity p-value of RR	0.4109	
Risk difference (95% CI)	14.92 (0.74, 29.10)	
P-value for Risk Difference	0.0394	
TEAE leading to study treatment discontinuation	11 (15.5%)	2 (2.8%)
Odds ratio (95% CI)	6.466 (1.340, 31.195)	
P-value for Odds Ratio	0.0204	
Relative Risk (95% CI)	5.55 (1.26, 24.53)	
P-value for Relative Risk	0.0240	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	14.52 (-4.88, 33.91)	
P-value for Risk Difference	0.1411	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TEAE leading to study treatment interruption/delay	20 (28.2%)	10 (14.1%)
Odds ratio (95% CI)	2.400 (0.993, 5.801)	
P-value for Odds Ratio	0.0518	
Relative Risk (95% CI)	2.06 (1.03, 4.10)	
P-value for Relative Risk	0.0403	
Heterogeneity p-value of RR	0.6282	
Risk difference (95% CI)	12.40 (-1.38, 26.19)	
P-value for Risk Difference	0.0774	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TEAE	160 (93.6%)	156 (90.7%)
Odds ratio (95% CI)	1.477 (0.648, 3.366)	
P-value for Odds Ratio	0.3528	
Relative Risk (95% CI)	1.03 (0.98, 1.08)	
P-value for Relative Risk	0.2289	
Heterogeneity p-value of RR	0.4783	
Risk difference (95% CI)	2.91 (-1.79, 7.61)	
P-value for Risk Difference	0.2237	
TEAE with any NCI grade 3/4/5	42 (24.6%)	27 (15.7%)
Odds ratio (95% CI)	1.706 (0.988, 2.945)	
P-value for Odds Ratio	0.0552	
Relative Risk (95% CI)	1.49 (0.96, 2.31)	
P-value for Relative Risk	0.0729	
Heterogeneity p-value of RR	0.9292	
Risk difference (95% CI)	8.85 (0.51, 17.20)	
P-value for Risk Difference	0.0377	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TE-SAE	32 (18.7%)	18 (10.5%)
Odds ratio (95% CI)	1.899 (1.012, 3.564)	
P-value for Odds Ratio	0.0457	
Relative Risk (95% CI)	1.71 (1.00, 2.94)	
P-value for Relative Risk	0.0502	
Heterogeneity p-value of RR	0.9695	
Risk difference (95% CI)	7.12 (-0.44, 14.68)	
P-value for Risk Difference	0.0648	
TEAE leading to study treatment discontinuation	20 (11.7%)	3 (1.7%)
Odds ratio (95% CI)	7.299 (2.113, 25.219)	
P-value for Odds Ratio	0.0018	
Relative Risk (95% CI)	6.49 (1.95, 21.57)	
P-value for Relative Risk	0.0024	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	10.19 (2.68, 17.69)	
P-value for Risk Difference	0.0080	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TEAE leading to study treatment interruption/delay	36 (21.1%)	21 (12.2%)
Odds ratio (95% CI)	1.853 (1.025, 3.352)	
P-value for Odds Ratio	0.0413	
Relative Risk (95% CI)	1.66 (1.01, 2.73)	
P-value for Relative Risk	0.0446	
Heterogeneity p-value of RR	0.9245	
Risk difference (95% CI)	8.30 (0.54, 16.05)	
P-value for Risk Difference	0.0361	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TEAE	31 (91.2%)	29 (90.6%)
Odds ratio (95% CI)	1.184 (0.187, 7.490)	
P-value for Odds Ratio	0.8552	
Relative Risk (95% CI)	1.01 (0.71, 1.44)	
P-value for Relative Risk	0.9524	
Heterogeneity p-value of RR	0.4783	
Risk difference (95% CI)	1.15 (-26.89, 29.20)	
P-value for Risk Difference	0.9348	
TEAE with any NCI grade 3/4/5	10 (29.4%)	6 (18.8%)
Odds ratio (95% CI)	1.823 (0.548, 6.072)	
P-value for Odds Ratio	0.3219	
Relative Risk (95% CI)	1.71 (0.69, 4.23)	
P-value for Relative Risk	0.2410	
Heterogeneity p-value of RR	0.9292	
Risk difference (95% CI)	7.66 (-14.66, 29.99)	
P-value for Risk Difference	0.4950	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TE-SAE	6 (17.6%)	3 (9.4%)
Odds ratio (95% CI)	2.580 (0.530, 12.564)	
P-value for Odds Ratio	0.2360	
Relative Risk (95% CI)	2.18 (0.58, 8.20)	
P-value for Relative Risk	0.2445	
Heterogeneity p-value of RR	0.9695	
Risk difference (95% CI)	11.98 (-14.79, 38.76)	
P-value for Risk Difference	0.3744	
TEAE leading to study treatment discontinuation	0	1 (3.1%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.54 (0.02, 11.75)	
P-value for Relative Risk	0.6956	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-5.46 (-81.79, 70.87)	
P-value for Risk Difference	0.8868	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TEAE leading to study treatment interruption/delay	12 (35.3%)	6 (18.8%)
Odds ratio (95% CI)	2.447 (0.747, 8.015)	
P-value for Odds Ratio	0.1367	
Relative Risk (95% CI)	1.96 (0.81, 4.73)	
P-value for Relative Risk	0.1303	
Heterogeneity p-value of RR	0.9245	
Risk difference (95% CI)	16.90 (-6.13, 39.93)	
P-value for Risk Difference	0.1475	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Participant with at least one	Cemiplimab (N=37)	Placebo (N=31)
TEAE	35 (94.6%)	29 (93.5%)
Odds ratio (95% CI)	1.111 (0.141, 8.772)	
P-value for Odds Ratio	0.9192	
Relative Risk (95% CI)	1.01 (0.88, 1.15)	
P-value for Relative Risk	0.9212	
Heterogeneity p-value of RR	0.9486	
Risk difference (95% CI)	0.59 (-12.11, 13.29)	
P-value for Risk Difference	0.9261	
TEAE with any NCI grade 3/4/5	10 (27.0%)	4 (12.9%)
Odds ratio (95% CI)	2.439 (0.659, 9.023)	
P-value for Odds Ratio	0.1781	
Relative Risk (95% CI)	2.05 (0.69, 6.11)	
P-value for Relative Risk	0.1949	
Heterogeneity p-value of RR	0.6447	
Risk difference (95% CI)	14.50 (-4.18, 33.19)	
P-value for Risk Difference	0.1260	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Participant with at least one	Cemiplimab (N=37)	Placebo (N=31)
TE-SAE	8 (21.6%)	3 (9.7%)
Odds ratio (95% CI)	2.633 (0.612, 11.336)	
P-value for Odds Ratio	0.1900	
Relative Risk (95% CI)	2.27 (0.64, 8.02)	
P-value for Relative Risk	0.2009	
Heterogeneity p-value of RR	0.9179	
Risk difference (95% CI)	13.27 (-5.09, 31.63)	
P-value for Risk Difference	0.1537	
TEAE leading to study treatment interruption/delay	9 (24.3%)	4 (12.9%)
Odds ratio (95% CI)	1.983 (0.519, 7.574)	
P-value for Odds Ratio	0.3111	
Relative Risk (95% CI)	1.83 (0.62, 5.36)	
P-value for Relative Risk	0.2668	
Heterogeneity p-value of RR	0.9694	
Risk difference (95% CI)	7.75 (-10.75, 26.25)	
P-value for Risk Difference	0.4056	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Participant with at least one	Cemiplimab (N=87)	Placebo (N=89)
TEAE	86 (98.9%)	86 (96.6%)
Odds ratio (95% CI)	2.883 (0.289, 28.804)	
P-value for Odds Ratio	0.3651	
Relative Risk (95% CI)	1.03 (0.97, 1.08)	
P-value for Relative Risk	0.3369	
Heterogeneity p-value of RR	0.9486	
Risk difference (95% CI)	2.20 (-2.67, 7.07)	
P-value for Risk Difference	0.3741	
TEAE with any NCI grade 3/4/5	24 (27.6%)	19 (21.3%)
Odds ratio (95% CI)	1.348 (0.663, 2.743)	
P-value for Odds Ratio	0.4076	
Relative Risk (95% CI)	1.23 (0.74, 2.06)	
P-value for Relative Risk	0.4256	
Heterogeneity p-value of RR	0.6447	
Risk difference (95% CI)	5.28 (-7.18, 17.73)	
P-value for Risk Difference	0.4042	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Participant with at least one	Cemiplimab (N=87)	Placebo (N=89)
TE-SAE	19 (21.8%)	11 (12.4%)
Odds ratio (95% CI)	1.913 (0.832, 4.397)	
P-value for Odds Ratio	0.1258	
Relative Risk (95% CI)	1.65 (0.84, 3.25)	
P-value for Relative Risk	0.1469	
Heterogeneity p-value of RR	0.9179	
Risk difference (95% CI)	8.64 (-2.06, 19.35)	
P-value for Risk Difference	0.1128	
TEAE leading to study treatment interruption/delay	18 (20.7%)	11 (12.4%)
Odds ratio (95% CI)	1.800 (0.786, 4.121)	
P-value for Odds Ratio	0.1632	
Relative Risk (95% CI)	1.59 (0.79, 3.20)	
P-value for Relative Risk	0.1894	
Heterogeneity p-value of RR	0.9694	
Risk difference (95% CI)	8.59 (-2.15, 19.34)	
P-value for Risk Difference	0.1163	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Participant with at least one	Cemiplimab (N=81)	Placebo (N=84)
TEAE	70 (86.4%)	70 (83.3%)
Odds ratio (95% CI)	1.266 (0.532, 3.011)	
P-value for Odds Ratio	0.5918	
Relative Risk (95% CI)	1.04 (0.91, 1.18)	
P-value for Relative Risk	0.5626	
Heterogeneity p-value of RR	0.9486	
Risk difference (95% CI)	3.19 (-7.83, 14.22)	
P-value for Risk Difference	0.5683	
TEAE with any NCI grade 3/4/5	18 (22.2%)	10 (11.9%)
Odds ratio (95% CI)	2.094 (0.893, 4.913)	
P-value for Odds Ratio	0.0888	
Relative Risk (95% CI)	1.85 (0.90, 3.80)	
P-value for Relative Risk	0.0918	
Heterogeneity p-value of RR	0.6447	
Risk difference (95% CI)	10.18 (-1.43, 21.79)	
P-value for Risk Difference	0.0854	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Participant with at least one	Cemiplimab (N=81)	Placebo (N=84)
TE-SAE	11 (13.6%)	7 (8.3%)
Odds ratio (95% CI)	1.876 (0.677, 5.201)	
P-value for Odds Ratio	0.2247	
Relative Risk (95% CI)	1.72 (0.70, 4.21)	
P-value for Relative Risk	0.2366	
Heterogeneity p-value of RR	0.9179	
Risk difference (95% CI)	6.85 (-5.02, 18.73)	
P-value for Risk Difference	0.2560	
TEAE leading to study treatment interruption/delay	21 (25.9%)	12 (14.3%)
Odds ratio (95% CI)	2.033 (0.915, 4.516)	
P-value for Odds Ratio	0.0810	
Relative Risk (95% CI)	1.77 (0.93, 3.37)	
P-value for Relative Risk	0.0833	
Heterogeneity p-value of RR	0.9694	
Risk difference (95% CI)	10.81 (-1.51, 23.13)	
P-value for Risk Difference	0.0851	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TEAE	176 (94.6%)	171 (91.4%)
Odds ratio (95% CI)	1.583 (0.679, 3.688)	
P-value for Odds Ratio	0.2867	
Relative Risk (95% CI)	1.03 (0.98, 1.07)	
P-value for Relative Risk	0.2806	
Heterogeneity p-value of RR	0.7904	
Risk difference (95% CI)	2.48 (-1.87, 6.82)	
P-value for Risk Difference	0.2629	
TEAE with any NCI grade 3/4/5	49 (26.3%)	31 (16.6%)
Odds ratio (95% CI)	1.708 (1.021, 2.858)	
P-value for Odds Ratio	0.0416	
Relative Risk (95% CI)	1.49 (0.99, 2.23)	
P-value for Relative Risk	0.0542	
Heterogeneity p-value of RR	0.9795	
Risk difference (95% CI)	9.30 (1.07, 17.53)	
P-value for Risk Difference	0.0268	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TE-SAE	36 (19.4%)	20 (10.7%)
Odds ratio (95% CI)	1.961 (1.079, 3.564)	
P-value for Odds Ratio	0.0273	
Relative Risk (95% CI)	1.77 (1.06, 2.96)	
P-value for Relative Risk	0.0280	
Heterogeneity p-value of RR	0.9528	
Risk difference (95% CI)	8.08 (0.68, 15.48)	
P-value for Risk Difference	0.0324	
TEAE leading to study treatment discontinuation	18 (9.7%)	4 (2.1%)
Odds ratio (95% CI)	4.835 (1.588, 14.724)	
P-value for Odds Ratio	0.0057	
Relative Risk (95% CI)	4.42 (1.51, 12.93)	
P-value for Relative Risk	0.0067	
Heterogeneity p-value of RR	0.4175	
Risk difference (95% CI)	8.14 (1.17, 15.11)	
P-value for Risk Difference	0.0222	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TEAE leading to study treatment interruption/delay	44 (23.7%)	26 (13.9%)
Odds ratio (95% CI)	1.776 (1.030, 3.065)	
P-value for Odds Ratio	0.0390	
Relative Risk (95% CI)	1.57 (1.01, 2.45)	
P-value for Relative Risk	0.0465	
Heterogeneity p-value of RR	0.2988	
Risk difference (95% CI)	8.55 (0.81, 16.29)	
P-value for Risk Difference	0.0306	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TEAE	15 (78.9%)	14 (82.4%)
Odds ratio (95% CI)	0.398 (0.050, 3.163)	
P-value for Odds Ratio	0.3717	
Relative Risk (95% CI)	0.76 (0.48, 1.19)	
P-value for Relative Risk	0.2151	
Heterogeneity p-value of RR	0.7904	
Risk difference (95% CI)	-26.74 (-101.87, 48.40)	
P-value for Risk Difference	0.4735	
TEAE with any NCI grade 3/4/5	3 (15.8%)	2 (11.8%)
Odds ratio (95% CI)	1.355 (0.165, 11.131)	
P-value for Odds Ratio	0.7708	
Relative Risk (95% CI)	1.24 (0.19, 8.11)	
P-value for Relative Risk	0.8180	
Heterogeneity p-value of RR	0.9795	
Risk difference (95% CI)	10.44 (-22.87, 43.75)	
P-value for Risk Difference	0.5274	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TE-SAE	2 (10.5%)	1 (5.9%)
Odds ratio (95% CI)	1.346 (0.092, 19.672)	
P-value for Odds Ratio	0.8225	
Relative Risk (95% CI)	1.18 (0.11, 12.59)	
P-value for Relative Risk	0.8891	
Heterogeneity p-value of RR	0.9528	
Risk difference (95% CI)	9.18 (-48.82, 67.18)	
P-value for Risk Difference	0.7489	
TEAE leading to study treatment discontinuation	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.4175	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TEAE leading to study treatment interruption/delay	4 (21.1%)	1 (5.9%)
Odds ratio (95% CI)	3.310 (0.247, 44.303)	
P-value for Odds Ratio	0.3540	
Relative Risk (95% CI)	3.10 (0.28, 34.40)	
P-value for Relative Risk	0.3450	
Heterogeneity p-value of RR	0.2988	
Risk difference (95% CI)	11.55 (-14.32, 37.43)	
P-value for Risk Difference	0.3695	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TEAE	152 (92.7%)	160 (91.4%)
Odds ratio (95% CI)	1.153 (0.511, 2.601)	
P-value for Odds Ratio	0.7302	
Relative Risk (95% CI)	1.02 (0.98, 1.07)	
P-value for Relative Risk	0.3756	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	1.88 (-2.36, 6.11)	
P-value for Risk Difference	0.3844	
TEAE with any NCI grade 3/4/5	39 (23.8%)	26 (14.9%)
Odds ratio (95% CI)	1.781 (1.024, 3.098)	
P-value for Odds Ratio	0.0410	
Relative Risk (95% CI)	1.59 (1.01, 2.49)	
P-value for Relative Risk	0.0438	
Heterogeneity p-value of RR	0.6556	
Risk difference (95% CI)	9.05 (0.63, 17.47)	
P-value for Risk Difference	0.0352	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TE-SAE	30 (18.3%)	18 (10.3%)
Odds ratio (95% CI)	1.940 (1.032, 3.647)	
P-value for Odds Ratio	0.0396	
Relative Risk (95% CI)	1.77 (1.03, 3.06)	
P-value for Relative Risk	0.0405	
Heterogeneity p-value of RR	0.9377	
Risk difference (95% CI)	7.85 (0.35, 15.35)	
P-value for Risk Difference	0.0404	
TEAE leading to study treatment discontinuation	17 (10.4%)	3 (1.7%)
Odds ratio (95% CI)	6.579 (1.880, 23.020)	
P-value for Odds Ratio	0.0033	
Relative Risk (95% CI)	5.97 (1.78, 20.10)	
P-value for Relative Risk	0.0040	
Heterogeneity p-value of RR	0.4315	
Risk difference (95% CI)	9.07 (1.82, 16.32)	
P-value for Risk Difference	0.0143	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TEAE leading to study treatment interruption/delay	34 (20.7%)	21 (12.0%)
Odds ratio (95% CI)	1.929 (1.064, 3.498)	
P-value for Odds Ratio	0.0307	
Relative Risk (95% CI)	1.73 (1.05, 2.86)	
P-value for Relative Risk	0.0321	
Heterogeneity p-value of RR	0.9430	
Risk difference (95% CI)	8.82 (0.97, 16.67)	
P-value for Risk Difference	0.0277	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TEAE	39 (95.1%)	25 (86.2%)
Odds ratio (95% CI)	3.143 (0.490, 20.167)	
P-value for Odds Ratio	0.2231	
Relative Risk (95% CI)	1.05 (0.84, 1.32)	
P-value for Relative Risk	0.6363	
Heterogeneity p-value of RR	1.0000	
TEAE with any NCI grade 3/4/5	13 (31.7%)	7 (24.1%)
Odds ratio (95% CI)	1.514 (0.480, 4.773)	
P-value for Odds Ratio	0.4734	
Relative Risk (95% CI)	1.26 (0.59, 2.71)	
P-value for Relative Risk	0.5420	
Heterogeneity p-value of RR	0.6556	
Risk difference (95% CI)	8.95 (-10.96, 28.87)	
P-value for Risk Difference	0.3726	
TE-SAE	8 (19.5%)	3 (10.3%)
Odds ratio (95% CI)	2.475 (0.503, 12.178)	
P-value for Odds Ratio	0.2601	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TE-SAE		
Relative Risk (95% CI)	1.72 (0.54, 5.52)	
P-value for Relative Risk	0.3550	
Heterogeneity p-value of RR	0.9377	
Risk difference (95% CI)	12.09 (-27.93, 52.11)	
P-value for Risk Difference	0.5484	
TEAE leading to study treatment discontinuation	3 (7.3%)	1 (3.4%)
Odds ratio (95% CI)	2.044 (0.189, 22.053)	
P-value for Odds Ratio	0.5505	
Relative Risk (95% CI)	1.83 (0.18, 18.32)	
P-value for Relative Risk	0.6016	
Heterogeneity p-value of RR	0.4315	
Risk difference (95% CI)	6.31 (-34.30, 46.92)	
P-value for Risk Difference	0.7574	
TEAE leading to study treatment interruption/delay	14 (34.1%)	6 (20.7%)
Odds ratio (95% CI)	1.927 (0.620, 5.988)	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TEAE leading to study treatment interruption/delay		
P-value for Odds Ratio	0.2523	
Relative Risk (95% CI)	1.65 (0.71, 3.82)	
P-value for Relative Risk	0.2414	
Heterogeneity p-value of RR	0.9430	
Risk difference (95% CI)	12.47 (-8.94, 33.87)	
P-value for Risk Difference	0.2492	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TEAE	122 (93.8%)	120 (91.6%)
Odds ratio (95% CI)	1.461 (0.545, 3.919)	
P-value for Odds Ratio	0.4499	
Relative Risk (95% CI)	1.02 (0.89, 1.16)	
P-value for Relative Risk	0.8059	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	1.84 (-9.76, 13.43)	
P-value for Risk Difference	0.7555	
TEAE with any NCI grade 3/4/5	34 (26.2%)	19 (14.5%)
Odds ratio (95% CI)	2.158 (1.141, 4.084)	
P-value for Odds Ratio	0.0183	
Relative Risk (95% CI)	1.75 (1.06, 2.90)	
P-value for Relative Risk	0.0299	
Heterogeneity p-value of RR	0.4179	
Risk difference (95% CI)	14.22 (3.51, 24.94)	
P-value for Risk Difference	0.0095	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TE-SAE	24 (18.5%)	14 (10.7%)
Odds ratio (95% CI)	1.956 (0.952, 4.020)	
P-value for Odds Ratio	0.0679	
Relative Risk (95% CI)	1.74 (0.94, 3.22)	
P-value for Relative Risk	0.0752	
Heterogeneity p-value of RR	0.8394	
Risk difference (95% CI)	9.83 (0.40, 19.26)	
P-value for Risk Difference	0.0411	
TEAE leading to study treatment discontinuation	14 (10.8%)	2 (1.5%)
Odds ratio (95% CI)	7.857 (1.730, 35.681)	
P-value for Odds Ratio	0.0078	
Relative Risk (95% CI)	7.07 (1.63, 30.78)	
P-value for Relative Risk	0.0093	
Heterogeneity p-value of RR	0.4184	
Risk difference (95% CI)	10.10 (1.24, 18.95)	
P-value for Risk Difference	0.0255	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TEAE leading to study treatment interruption/delay	31 (23.8%)	17 (13.0%)
Odds ratio (95% CI)	1.988 (1.026, 3.850)	
P-value for Odds Ratio	0.0417	
Relative Risk (95% CI)	1.75 (1.02, 2.99)	
P-value for Relative Risk	0.0427	
Heterogeneity p-value of RR	0.8599	
Risk difference (95% CI)	9.66 (0.43, 18.89)	
P-value for Risk Difference	0.0402	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TEAE	69 (92.0%)	65 (89.0%)
Odds ratio (95% CI)	1.331 (0.422, 4.197)	
P-value for Odds Ratio	0.6237	
Relative Risk (95% CI)	1.03 (0.93, 1.13)	
P-value for Relative Risk	0.5633	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	2.52 (-6.29, 11.32)	
P-value for Risk Difference	0.5730	
TEAE with any NCI grade 3/4/5	18 (24.0%)	14 (19.2%)
Odds ratio (95% CI)	1.193 (0.520, 2.733)	
P-value for Odds Ratio	0.6752	
Relative Risk (95% CI)	1.06 (0.56, 1.99)	
P-value for Relative Risk	0.8659	
Heterogeneity p-value of RR	0.4179	
Risk difference (95% CI)	1.58 (-11.47, 14.64)	
P-value for Risk Difference	0.8110	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TE-SAE	14 (18.7%)	7 (9.6%)
Odds ratio (95% CI)	1.988 (0.730, 5.414)	
P-value for Odds Ratio	0.1776	
Relative Risk (95% CI)	1.74 (0.75, 4.07)	
P-value for Relative Risk	0.1966	
Heterogeneity p-value of RR	0.8394	
Risk difference (95% CI)	7.52 (-3.07, 18.11)	
P-value for Risk Difference	0.1627	
TEAE leading to study treatment discontinuation	6 (8.0%)	2 (2.7%)
Odds ratio (95% CI)	2.996 (0.571, 15.728)	
P-value for Odds Ratio	0.1929	
Relative Risk (95% CI)	2.82 (0.58, 13.79)	
P-value for Relative Risk	0.1994	
Heterogeneity p-value of RR	0.4184	
Risk difference (95% CI)	6.11 (-8.13, 20.35)	
P-value for Risk Difference	0.3978	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TEAE leading to study treatment interruption/delay	17 (22.7%)	10 (13.7%)
Odds ratio (95% CI)	1.839 (0.768, 4.400)	
P-value for Odds Ratio	0.1699	
Relative Risk (95% CI)	1.66 (0.81, 3.40)	
P-value for Relative Risk	0.1634	
Heterogeneity p-value of RR	0.8599	
Risk difference (95% CI)	8.28 (-4.32, 20.87)	
P-value for Risk Difference	0.1961	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TEAE	113 (91.9%)	109 (94.0%)
Odds ratio (95% CI)	0.768 (0.271, 2.178)	
P-value for Odds Ratio	0.6187	
Relative Risk (95% CI)	1.00 (0.94, 1.07)	
P-value for Relative Risk	0.9996	
Heterogeneity p-value of RR	0.3553	
Risk difference (95% CI)	-0.32 (-6.19, 5.56)	
P-value for Risk Difference	0.9155	
TEAE with any NCI grade 3/4/5	36 (29.3%)	21 (18.1%)
Odds ratio (95% CI)	1.828 (0.981, 3.406)	
P-value for Odds Ratio	0.0575	
Relative Risk (95% CI)	1.56 (0.97, 2.52)	
P-value for Relative Risk	0.0692	
Heterogeneity p-value of RR	0.7554	
Risk difference (95% CI)	10.42 (-0.37, 21.22)	
P-value for Risk Difference	0.0584	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TE-SAE	23 (18.7%)	12 (10.3%)
Odds ratio (95% CI)	1.965 (0.914, 4.226)	
P-value for Odds Ratio	0.0835	
Relative Risk (95% CI)	1.80 (0.94, 3.46)	
P-value for Relative Risk	0.0762	
Heterogeneity p-value of RR	0.8611	
Risk difference (95% CI)	6.22 (-3.44, 15.87)	
P-value for Risk Difference	0.2058	
TEAE leading to study treatment discontinuation	13 (10.6%)	3 (2.6%)
Odds ratio (95% CI)	4.416 (1.204, 16.193)	
P-value for Odds Ratio	0.0252	
Relative Risk (95% CI)	3.93 (1.14, 13.58)	
P-value for Relative Risk	0.0306	
Heterogeneity p-value of RR	0.6081	
Risk difference (95% CI)	8.74 (-0.41, 17.89)	
P-value for Risk Difference	0.0611	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TEAE leading to study treatment interruption/delay	29 (23.6%)	15 (12.9%)
Odds ratio (95% CI)	1.947 (0.968, 3.919)	
P-value for Odds Ratio	0.0617	
Relative Risk (95% CI)	1.72 (0.98, 3.04)	
P-value for Relative Risk	0.0608	
Heterogeneity p-value of RR	0.9113	
Risk difference (95% CI)	8.72 (-0.84, 18.28)	
P-value for Risk Difference	0.0736	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TEAE	78 (95.1%)	76 (86.4%)
Odds ratio (95% CI)	2.916 (0.865, 9.830)	
P-value for Odds Ratio	0.0840	
Relative Risk (95% CI)	1.08 (0.93, 1.26)	
P-value for Relative Risk	0.3182	
Heterogeneity p-value of RR	0.3553	
Risk difference (95% CI)	8.04 (-5.49, 21.56)	
P-value for Risk Difference	0.2425	
TEAE with any NCI grade 3/4/5	16 (19.5%)	12 (13.6%)
Odds ratio (95% CI)	1.493 (0.651, 3.424)	
P-value for Odds Ratio	0.3414	
Relative Risk (95% CI)	1.37 (0.69, 2.74)	
P-value for Relative Risk	0.3666	
Heterogeneity p-value of RR	0.7554	
Risk difference (95% CI)	7.11 (-3.89, 18.11)	
P-value for Risk Difference	0.2038	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TE-SAE	15 (18.3%)	9 (10.2%)
Odds ratio (95% CI)	1.995 (0.811, 4.912)	
P-value for Odds Ratio	0.1319	
Relative Risk (95% CI)	1.79 (0.82, 3.89)	
P-value for Relative Risk	0.1428	
Heterogeneity p-value of RR	0.8611	
Risk difference (95% CI)	9.41 (-2.33, 21.15)	
P-value for Risk Difference	0.1154	
TEAE leading to study treatment discontinuation	7 (8.5%)	1 (1.1%)
Odds ratio (95% CI)	8.279 (0.976, 70.194)	
P-value for Odds Ratio	0.0526	
Relative Risk (95% CI)	7.60 (0.94, 61.43)	
P-value for Relative Risk	0.0570	
Heterogeneity p-value of RR	0.6081	
Risk difference (95% CI)	8.44 (-5.00, 21.87)	
P-value for Risk Difference	0.2169	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TEAE leading to study treatment interruption/delay	19 (23.2%)	12 (13.6%)
Odds ratio (95% CI)	1.874 (0.838, 4.190)	
P-value for Odds Ratio	0.1253	
Relative Risk (95% CI)	1.68 (0.86, 3.26)	
P-value for Relative Risk	0.1253	
Heterogeneity p-value of RR	0.9113	
Risk difference (95% CI)	9.34 (-2.64, 21.32)	
P-value for Risk Difference	0.1258	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TEAE	144 (94.1%)	139 (91.4%)
Odds ratio (95% CI)	1.506 (0.613, 3.699)	
P-value for Odds Ratio	0.3707	
Relative Risk (95% CI)	1.03 (0.98, 1.09)	
P-value for Relative Risk	0.2481	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	2.95 (-2.08, 7.98)	
P-value for Risk Difference	0.2490	
TEAE with any NCI grade 3/4/5	40 (26.1%)	25 (16.4%)
Odds ratio (95% CI)	1.751 (0.994, 3.084)	
P-value for Odds Ratio	0.0526	
Relative Risk (95% CI)	1.54 (0.99, 2.42)	
P-value for Relative Risk	0.0581	
Heterogeneity p-value of RR	0.9354	
Risk difference (95% CI)	9.25 (0.09, 18.42)	
P-value for Risk Difference	0.0479	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TE-SAE	30 (19.6%)	16 (10.5%)
Odds ratio (95% CI)	2.099 (1.085, 4.064)	
P-value for Odds Ratio	0.0279	
Relative Risk (95% CI)	1.87 (1.06, 3.30)	
P-value for Relative Risk	0.0300	
Heterogeneity p-value of RR	0.7806	
Risk difference (95% CI)	9.59 (1.60, 17.58)	
P-value for Risk Difference	0.0188	
TEAE leading to study treatment discontinuation	16 (10.5%)	2 (1.3%)
Odds ratio (95% CI)	8.773 (1.963, 39.214)	
P-value for Odds Ratio	0.0046	
Relative Risk (95% CI)	7.89 (1.83, 33.98)	
P-value for Relative Risk	0.0057	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	9.13 (1.78, 16.47)	
P-value for Risk Difference	0.0151	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TEAE leading to study treatment interruption/delay	39 (25.5%)	20 (13.2%)
Odds ratio (95% CI)	2.218 (1.216, 4.048)	
P-value for Odds Ratio	0.0096	
Relative Risk (95% CI)	1.89 (1.16, 3.09)	
P-value for Relative Risk	0.0110	
Heterogeneity p-value of RR	0.3295	
Risk difference (95% CI)	11.62 (2.84, 20.40)	
P-value for Risk Difference	0.0097	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TEAE	36 (90.0%)	37 (86.0%)
Odds ratio (95% CI)	1.579 (0.352, 7.081)	
P-value for Odds Ratio	0.5464	
Relative Risk (95% CI)	1.05 (0.78, 1.42)	
P-value for Relative Risk	0.7565	
Heterogeneity p-value of RR	1.0000	
Risk difference (95% CI)	5.03 (-24.94, 34.99)	
P-value for Risk Difference	0.7392	
TEAE with any NCI grade 3/4/5	10 (25.0%)	7 (16.3%)
Odds ratio (95% CI)	2.231 (0.642, 7.758)	
P-value for Odds Ratio	0.2037	
Relative Risk (95% CI)	1.52 (0.71, 3.26)	
P-value for Relative Risk	0.2755	
Heterogeneity p-value of RR	0.9354	
Risk difference (95% CI)	4.61 (-11.39, 20.61)	
P-value for Risk Difference	0.5678	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TE-SAE	7 (17.5%)	5 (11.6%)
Odds ratio (95% CI)	1.780 (0.467, 6.779)	
P-value for Odds Ratio	0.3932	
Relative Risk (95% CI)	1.54 (0.55, 4.32)	
P-value for Relative Risk	0.4032	
Heterogeneity p-value of RR	0.7806	
Risk difference (95% CI)	-1.08 (-22.21, 20.05)	
P-value for Risk Difference	0.9190	
TEAE leading to study treatment discontinuation	2 (5.0%)	2 (4.7%)
Odds ratio (95% CI)	0.888 (0.108, 7.335)	
P-value for Odds Ratio	0.9112	
Relative Risk (95% CI)	0.84 (0.11, 6.31)	
P-value for Relative Risk	0.8678	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	3.02 (-36.03, 42.07)	
P-value for Risk Difference	0.8781	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TEAE leading to study treatment interruption/delay	6 (15.0%)	6 (14.0%)
Odds ratio (95% CI)	1.251 (0.327, 4.796)	
P-value for Odds Ratio	0.7405	
Relative Risk (95% CI)	1.04 (0.39, 2.76)	
P-value for Relative Risk	0.9423	
Heterogeneity p-value of RR	0.3295	
Risk difference (95% CI)	-4.34 (-23.65, 14.97)	
P-value for Risk Difference	0.6560	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TEAE	36 (94.7%)	38 (88.4%)
Odds ratio (95% CI)	2.456 (0.416, 14.489)	
P-value for Odds Ratio	0.3165	
Relative Risk (95% CI)	1.09 (0.77, 1.55)	
P-value for Relative Risk	0.6054	
Heterogeneity p-value of RR	0.6604	
Risk difference (95% CI)	8.04 (-17.78, 33.87)	
P-value for Risk Difference	0.5369	
TEAE with any NCI grade 3/4/5	11 (28.9%)	7 (16.3%)
Odds ratio (95% CI)	2.087 (0.682, 6.390)	
P-value for Odds Ratio	0.1941	
Relative Risk (95% CI)	1.60 (0.68, 3.80)	
P-value for Relative Risk	0.2785	
Heterogeneity p-value of RR	0.7851	
Risk difference (95% CI)	15.13 (-6.32, 36.57)	
P-value for Risk Difference	0.1641	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TE-SAE	9 (23.7%)	3 (7.0%)
Odds ratio (95% CI)	4.306 (1.023, 18.122)	
P-value for Odds Ratio	0.0465	
Relative Risk (95% CI)	3.28 (0.93, 11.51)	
P-value for Relative Risk	0.0637	
Heterogeneity p-value of RR	0.2233	
Risk difference (95% CI)	20.23 (-5.00, 45.47)	
P-value for Risk Difference	0.1145	
TEAE leading to study treatment discontinuation	6 (15.8%)	1 (2.3%)
Odds ratio (95% CI)	8.443 (0.912, 78.149)	
P-value for Odds Ratio	0.0600	
Relative Risk (95% CI)	6.79 (0.83, 55.82)	
P-value for Relative Risk	0.0741	
Heterogeneity p-value of RR	0.7067	
Risk difference (95% CI)	16.56 (-28.26, 61.38)	
P-value for Risk Difference	0.4641	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TEAE leading to study treatment interruption/delay	9 (23.7%)	6 (14.0%)
Odds ratio (95% CI)	1.794 (0.538, 5.976)	
P-value for Odds Ratio	0.3368	
Relative Risk (95% CI)	1.61 (0.63, 4.09)	
P-value for Relative Risk	0.3117	
Heterogeneity p-value of RR	0.9897	
Risk difference (95% CI)	5.10 (-12.45, 22.66)	
P-value for Risk Difference	0.5644	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TEAE	155 (92.8%)	147 (91.3%)
Odds ratio (95% CI)	1.153 (0.501, 2.652)	
P-value for Odds Ratio	0.7376	
Relative Risk (95% CI)	1.01 (0.97, 1.06)	
P-value for Relative Risk	0.5600	
Heterogeneity p-value of RR	0.6604	
Risk difference (95% CI)	1.22 (-3.36, 5.80)	
P-value for Risk Difference	0.6014	
TEAE with any NCI grade 3/4/5	41 (24.6%)	26 (16.1%)
Odds ratio (95% CI)	1.636 (0.938, 2.853)	
P-value for Odds Ratio	0.0828	
Relative Risk (95% CI)	1.47 (0.94, 2.29)	
P-value for Relative Risk	0.0894	
Heterogeneity p-value of RR	0.7851	
Risk difference (95% CI)	7.87 (-0.82, 16.56)	
P-value for Risk Difference	0.0758	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TE-SAE	29 (17.4%)	18 (11.2%)
Odds ratio (95% CI)	1.632 (0.860, 3.098)	
P-value for Odds Ratio	0.1334	
Relative Risk (95% CI)	1.52 (0.88, 2.64)	
P-value for Relative Risk	0.1345	
Heterogeneity p-value of RR	0.2233	
Risk difference (95% CI)	5.77 (-1.86, 13.40)	
P-value for Risk Difference	0.1376	
TEAE leading to study treatment discontinuation	14 (8.4%)	3 (1.9%)
Odds ratio (95% CI)	4.887 (1.363, 17.522)	
P-value for Odds Ratio	0.0150	
Relative Risk (95% CI)	4.52 (1.31, 15.56)	
P-value for Relative Risk	0.0168	
Heterogeneity p-value of RR	0.7067	
Risk difference (95% CI)	7.40 (0.33, 14.47)	
P-value for Risk Difference	0.0402	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.1.1 Overview of Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TEAE leading to study treatment interruption/delay	39 (23.4%)	21 (13.0%)
Odds ratio (95% CI)	1.965 (1.090, 3.543)	
P-value for Odds Ratio	0.0248	
Relative Risk (95% CI)	1.73 (1.06, 2.83)	
P-value for Relative Risk	0.0276	
Heterogeneity p-value of RR	0.9897	
Risk difference (95% CI)	9.80 (1.53, 18.06)	
P-value for Risk Difference	0.0203	

Data cut-off as of April 07, 2025.
TEAE = Treatment-emergent adverse event. SAE = Serious Adverse Event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	7 (13.0%)	3 (4.6%)
Odds ratio (95% CI)	3.428 (0.797, 14.746)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	3.01 (0.81, 11.17)	
P-value for Relative Risk	0.0988	
Heterogeneity p-value of RR	0.3619	
Risk difference (95% CI)	8.50 (-4.13, 21.12)	
P-value for Risk Difference	0.1852	
TE-SAE with any NCI grade 3/4/5	7 (13.0%)	3 (4.6%)
Odds ratio (95% CI)	3.428 (0.797, 14.746)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	3.01 (0.81, 11.17)	
P-value for Relative Risk	0.0988	
Heterogeneity p-value of RR	0.4598	
Risk difference (95% CI)	8.50 (-4.13, 21.12)	
P-value for Risk Difference	0.1852	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Participant with at least one	Cemiplimab (N=151)	Placebo (N=139)
TE-SAE	31 (20.5%)	18 (12.9%)
Odds ratio (95% CI)	1.682 (0.883, 3.204)	
P-value for Odds Ratio	0.1136	
Relative Risk (95% CI)	1.53 (0.89, 2.64)	
P-value for Relative Risk	0.1200	
Heterogeneity p-value of RR	0.3619	
Risk difference (95% CI)	7.20 (-1.43, 15.82)	
P-value for Risk Difference	0.1016	
TE-SAE with any NCI grade 3/4/5	26 (17.2%)	13 (9.4%)
Odds ratio (95% CI)	1.907 (0.924, 3.936)	
P-value for Odds Ratio	0.0805	
Relative Risk (95% CI)	1.73 (0.92, 3.26)	
P-value for Relative Risk	0.0913	
Heterogeneity p-value of RR	0.4598	
Risk difference (95% CI)	7.54 (-0.04, 15.13)	
P-value for Risk Difference	0.0512	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Participant with at least one	Cemiplimab (N=54)	Placebo (N=65)
TE-SAE	7 (13.0%)	3 (4.6%)
Odds ratio (95% CI)	3.428 (0.797, 14.746)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	3.01 (0.81, 11.17)	
P-value for Relative Risk	0.0988	
Heterogeneity p-value of RR	0.4109	
Risk difference (95% CI)	8.50 (-4.13, 21.12)	
P-value for Risk Difference	0.1852	
TE-SAE with any NCI grade 3/4/5	7 (13.0%)	3 (4.6%)
Odds ratio (95% CI)	3.428 (0.797, 14.746)	
P-value for Odds Ratio	0.0970	
Relative Risk (95% CI)	3.01 (0.81, 11.17)	
P-value for Relative Risk	0.0988	
Heterogeneity p-value of RR	0.4553	
Risk difference (95% CI)	8.50 (-4.13, 21.12)	
P-value for Risk Difference	0.1852	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Participant with at least one	Cemiplimab (N=80)	Placebo (N=68)
TE-SAE	12 (15.0%)	9 (13.2%)
Odds ratio (95% CI)	1.234 (0.466, 3.267)	
P-value for Odds Ratio	0.6695	
Relative Risk (95% CI)	1.15 (0.52, 2.56)	
P-value for Relative Risk	0.7308	
Heterogeneity p-value of RR	0.4109	
Risk difference (95% CI)	6.54 (-8.86, 21.93)	
P-value for Risk Difference	0.4027	
TE-SAE with any NCI grade 3/4/5	10 (12.5%)	7 (10.3%)
Odds ratio (95% CI)	1.321 (0.455, 3.836)	
P-value for Odds Ratio	0.6067	
Relative Risk (95% CI)	1.22 (0.49, 3.06)	
P-value for Relative Risk	0.6702	
Heterogeneity p-value of RR	0.4553	
Risk difference (95% CI)	4.54 (-9.58, 18.66)	
P-value for Risk Difference	0.5260	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Participant with at least one	Cemiplimab (N=71)	Placebo (N=71)
TE-SAE	19 (26.8%)	9 (12.7%)
Odds ratio (95% CI)	2.518 (1.025, 6.182)	
P-value for Odds Ratio	0.0440	
Relative Risk (95% CI)	2.10 (1.01, 4.36)	
P-value for Relative Risk	0.0479	
Heterogeneity p-value of RR	0.4109	
Risk difference (95% CI)	14.92 (0.74, 29.10)	
P-value for Risk Difference	0.0394	
TE-SAE with any NCI grade 3/4/5	16 (22.5%)	6 (8.5%)
Odds ratio (95% CI)	2.966 (1.059, 8.308)	
P-value for Odds Ratio	0.0387	
Relative Risk (95% CI)	2.54 (1.03, 6.24)	
P-value for Relative Risk	0.0426	
Heterogeneity p-value of RR	0.4553	
Risk difference (95% CI)	13.28 (0.47, 26.08)	
P-value for Risk Difference	0.0422	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
TE-SAE	32 (18.7%)	18 (10.5%)
Odds ratio (95% CI)	1.899 (1.012, 3.564)	
P-value for Odds Ratio	0.0457	
Relative Risk (95% CI)	1.71 (1.00, 2.94)	
P-value for Relative Risk	0.0502	
Heterogeneity p-value of RR	0.9695	
Risk difference (95% CI)	7.12 (-0.44, 14.68)	
P-value for Risk Difference	0.0648	
TE-SAE with any NCI grade 3/4/5	29 (17.0%)	13 (7.6%)
Odds ratio (95% CI)	2.399 (1.190, 4.836)	
P-value for Odds Ratio	0.0146	
Relative Risk (95% CI)	2.10 (1.13, 3.92)	
P-value for Relative Risk	0.0194	
Heterogeneity p-value of RR	0.4725	
Risk difference (95% CI)	8.62 (1.81, 15.42)	
P-value for Risk Difference	0.0133	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Participant with at least one	Cemiplimab (N=171)	Placebo (N=172)
Treatment-related TE-SAE	12 (7.0%)	1 (0.6%)
Odds ratio (95% CI)	12.988 (1.650, 102.242)	
P-value for Odds Ratio	0.0150	
Relative Risk (95% CI)	11.80 (1.54, 90.28)	
P-value for Relative Risk	0.0176	
Heterogeneity p-value of RR	0.6872	
Risk difference (95% CI)	7.31 (-4.75, 19.37)	
P-value for Risk Difference	0.2343	
TE-SAE leading to study treatment discontinuation	12 (7.0%)	1 (0.6%)
Odds ratio (95% CI)	13.058 (1.660, 102.727)	
P-value for Odds Ratio	0.0148	
Relative Risk (95% CI)	11.98 (1.57, 91.65)	
P-value for Relative Risk	0.0169	
Heterogeneity p-value of RR	0.0329	
Risk difference (95% CI)	8.01 (-1.51, 17.53)	
P-value for Risk Difference	0.0987	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
TE-SAE	6 (17.6%)	3 (9.4%)
Odds ratio (95% CI)	2.580 (0.530, 12.564)	
P-value for Odds Ratio	0.2360	
Relative Risk (95% CI)	2.18 (0.58, 8.20)	
P-value for Relative Risk	0.2445	
Heterogeneity p-value of RR	0.9695	
Risk difference (95% CI)	11.98 (-14.79, 38.76)	
P-value for Risk Difference	0.3744	
TE-SAE with any NCI grade 3/4/5	4 (11.8%)	3 (9.4%)
Odds ratio (95% CI)	1.356 (0.252, 7.297)	
P-value for Odds Ratio	0.7188	
Relative Risk (95% CI)	1.26 (0.31, 5.12)	
P-value for Relative Risk	0.7432	
Heterogeneity p-value of RR	0.4725	
Risk difference (95% CI)	3.98 (-18.90, 26.86)	
P-value for Risk Difference	0.7292	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Participant with at least one	Cemiplimab (N=34)	Placebo (N=32)
Treatment-related TE-SAE	1 (2.9%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.88 (0.22, 105.76)	
P-value for Relative Risk	0.2702	
Heterogeneity p-value of RR	0.6872	
Risk difference (95% CI)	6.50 (NE, NE)	
P-value for Risk Difference	NE	
TE-SAE leading to study treatment discontinuation	0	1 (3.1%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.54 (0.02, 11.75)	
P-value for Relative Risk	0.6956	
Heterogeneity p-value of RR	0.0329	
Risk difference (95% CI)	-5.46 (-81.79, 70.87)	
P-value for Risk Difference	0.8868	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Participant with at least one	Cemiplimab (N=37)	Placebo (N=31)
TE-SAE	8 (21.6%)	3 (9.7%)
Odds ratio (95% CI)	2.633 (0.612, 11.336)	
P-value for Odds Ratio	0.1900	
Relative Risk (95% CI)	2.27 (0.64, 8.02)	
P-value for Relative Risk	0.2009	
Heterogeneity p-value of RR	0.9179	
Risk difference (95% CI)	13.27 (-5.09, 31.63)	
P-value for Risk Difference	0.1537	
TE-SAE with any NCI grade 3/4/5	7 (18.9%)	3 (9.7%)
Odds ratio (95% CI)	2.204 (0.500, 9.709)	
P-value for Odds Ratio	0.2910	
Relative Risk (95% CI)	1.97 (0.54, 7.18)	
P-value for Relative Risk	0.2992	
Heterogeneity p-value of RR	0.9659	
Risk difference (95% CI)	10.08 (-7.66, 27.82)	
P-value for Risk Difference	0.2606	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Participant with at least one	Cemiplimab (N=87)	Placebo (N=89)
TE-SAE	19 (21.8%)	11 (12.4%)
Odds ratio (95% CI)	1.913 (0.832, 4.397)	
P-value for Odds Ratio	0.1258	
Relative Risk (95% CI)	1.65 (0.84, 3.25)	
P-value for Relative Risk	0.1469	
Heterogeneity p-value of RR	0.9179	
Risk difference (95% CI)	8.64 (-2.06, 19.35)	
P-value for Risk Difference	0.1128	
TE-SAE with any NCI grade 3/4/5	17 (19.5%)	9 (10.1%)
Odds ratio (95% CI)	2.085 (0.856, 5.075)	
P-value for Odds Ratio	0.1050	
Relative Risk (95% CI)	1.78 (0.84, 3.78)	
P-value for Relative Risk	0.1340	
Heterogeneity p-value of RR	0.9659	
Risk difference (95% CI)	9.23 (-0.79, 19.24)	
P-value for Risk Difference	0.0707	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Participant with at least one	Cemiplimab (N=81)	Placebo (N=84)
TE-SAE	11 (13.6%)	7 (8.3%)
Odds ratio (95% CI)	1.876 (0.677, 5.201)	
P-value for Odds Ratio	0.2247	
Relative Risk (95% CI)	1.72 (0.70, 4.21)	
P-value for Relative Risk	0.2366	
Heterogeneity p-value of RR	0.9179	
Risk difference (95% CI)	6.85 (-5.02, 18.73)	
P-value for Risk Difference	0.2560	
TE-SAE with any NCI grade 3/4/5	9 (11.1%)	4 (4.8%)
Odds ratio (95% CI)	2.651 (0.770, 9.131)	
P-value for Odds Ratio	0.1214	
Relative Risk (95% CI)	2.43 (0.77, 7.64)	
P-value for Relative Risk	0.1275	
Heterogeneity p-value of RR	0.9659	
Risk difference (95% CI)	7.17 (-3.33, 17.68)	
P-value for Risk Difference	0.1795	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
TE-SAE	36 (19.4%)	20 (10.7%)
Odds ratio (95% CI)	1.961 (1.079, 3.564)	
P-value for Odds Ratio	0.0273	
Relative Risk (95% CI)	1.77 (1.06, 2.96)	
P-value for Relative Risk	0.0280	
Heterogeneity p-value of RR	0.9528	
Risk difference (95% CI)	8.08 (0.68, 15.48)	
P-value for Risk Difference	0.0324	
TE-SAE with any NCI grade 3/4/5	31 (16.7%)	15 (8.0%)
Odds ratio (95% CI)	2.220 (1.143, 4.313)	
P-value for Odds Ratio	0.0187	
Relative Risk (95% CI)	2.00 (1.11, 3.58)	
P-value for Relative Risk	0.0208	
Heterogeneity p-value of RR	0.8360	
Risk difference (95% CI)	7.62 (0.89, 14.35)	
P-value for Risk Difference	0.0267	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Participant with at least one	Cemiplimab (N=186)	Placebo (N=187)
Treatment-related TE-SAE	12 (6.5%)	1 (0.5%)
Odds ratio (95% CI)	13.598 (1.726, 107.145)	
P-value for Odds Ratio	0.0134	
Relative Risk (95% CI)	12.35 (1.61, 94.59)	
P-value for Relative Risk	0.0157	
Heterogeneity p-value of RR	0.7444	
Risk difference (95% CI)	7.32 (-4.56, 19.20)	
P-value for Risk Difference	0.2264	
TE-SAE leading to study treatment discontinuation	10 (5.4%)	2 (1.1%)
Odds ratio (95% CI)	5.377 (1.143, 25.306)	
P-value for Odds Ratio	0.0334	
Relative Risk (95% CI)	5.05 (1.11, 22.93)	
P-value for Relative Risk	0.0360	
Heterogeneity p-value of RR	0.4441	
Risk difference (95% CI)	6.30 (-5.11, 17.70)	
P-value for Risk Difference	0.2783	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
TE-SAE	2 (10.5%)	1 (5.9%)
Odds ratio (95% CI)	1.346 (0.092, 19.672)	
P-value for Odds Ratio	0.8225	
Relative Risk (95% CI)	1.18 (0.11, 12.59)	
P-value for Relative Risk	0.8891	
Heterogeneity p-value of RR	0.9528	
Risk difference (95% CI)	9.18 (-48.82, 67.18)	
P-value for Risk Difference	0.7489	
TE-SAE with any NCI grade 3/4/5	2 (10.5%)	1 (5.9%)
Odds ratio (95% CI)	1.346 (0.092, 19.672)	
P-value for Odds Ratio	0.8225	
Relative Risk (95% CI)	1.18 (0.11, 12.59)	
P-value for Relative Risk	0.8891	
Heterogeneity p-value of RR	0.8360	
Risk difference (95% CI)	9.18 (-48.82, 67.18)	
P-value for Risk Difference	0.7489	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Participant with at least one	Cemiplimab (N=19)	Placebo (N=17)
Treatment-related TE-SAE	1 (5.3%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.00 (0.09, 43.22)	
P-value for Relative Risk	0.6564	
Heterogeneity p-value of RR	0.7444	
Risk difference (95% CI)	7.74 (NE, NE)	
P-value for Risk Difference	NE	
TE-SAE leading to study treatment discontinuation	2 (10.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.33 (0.18, 60.68)	
P-value for Relative Risk	0.3831	
Heterogeneity p-value of RR	0.4441	
Risk difference (95% CI)	15.50 (-64.35, 95.36)	
P-value for Risk Difference	0.6948	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
TE-SAE	30 (18.3%)	18 (10.3%)
Odds ratio (95% CI)	1.940 (1.032, 3.647)	
P-value for Odds Ratio	0.0396	
Relative Risk (95% CI)	1.77 (1.03, 3.06)	
P-value for Relative Risk	0.0405	
Heterogeneity p-value of RR	0.9377	
Risk difference (95% CI)	7.85 (0.35, 15.35)	
P-value for Risk Difference	0.0404	
TE-SAE with any NCI grade 3/4/5	26 (15.9%)	13 (7.4%)
Odds ratio (95% CI)	2.319 (1.143, 4.705)	
P-value for Odds Ratio	0.0199	
Relative Risk (95% CI)	2.11 (1.12, 3.96)	
P-value for Relative Risk	0.0213	
Heterogeneity p-value of RR	0.7003	
Risk difference (95% CI)	8.12 (1.29, 14.94)	
P-value for Risk Difference	0.0200	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Participant with at least one	Cemiplimab (N=164)	Placebo (N=175)
Treatment-related TE-SAE	12 (7.3%)	1 (0.6%)
Odds ratio (95% CI)	13.499 (1.716, 106.164)	
P-value for Odds Ratio	0.0135	
Relative Risk (95% CI)	12.28 (1.60, 94.02)	
P-value for Relative Risk	0.0159	
Heterogeneity p-value of RR	0.7469	
Risk difference (95% CI)	7.46 (-5.53, 20.45)	
P-value for Risk Difference	0.2593	
TE-SAE leading to study treatment discontinuation	10 (6.1%)	2 (1.1%)
Odds ratio (95% CI)	5.691 (1.216, 26.637)	
P-value for Odds Ratio	0.0274	
Relative Risk (95% CI)	5.32 (1.18, 23.99)	
P-value for Relative Risk	0.0298	
Heterogeneity p-value of RR	0.4911	
Risk difference (95% CI)	6.23 (-2.24, 14.69)	
P-value for Risk Difference	0.1487	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
TE-SAE	8 (19.5%)	3 (10.3%)
Odds ratio (95% CI)	2.475 (0.503, 12.178)	
P-value for Odds Ratio	0.2601	
Relative Risk (95% CI)	1.72 (0.54, 5.52)	
P-value for Relative Risk	0.3550	
Heterogeneity p-value of RR	0.9377	
Risk difference (95% CI)	12.09 (-27.93, 52.11)	
P-value for Risk Difference	0.5484	
TE-SAE with any NCI grade 3/4/5	7 (17.1%)	3 (10.3%)
Odds ratio (95% CI)	1.960 (0.401, 9.569)	
P-value for Odds Ratio	0.3998	
Relative Risk (95% CI)	1.49 (0.45, 4.99)	
P-value for Relative Risk	0.5095	
Heterogeneity p-value of RR	0.7003	
Risk difference (95% CI)	8.61 (-30.17, 47.40)	
P-value for Risk Difference	0.6590	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Participant with at least one	Cemiplimab (N=41)	Placebo (N=29)
Treatment-related TE-SAE	1 (2.4%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.28 (0.10, 52.92)	
P-value for Relative Risk	0.5994	
Heterogeneity p-value of RR	0.7469	
Risk difference (95% CI)	3.51 (NE, NE)	
P-value for Risk Difference	NE	
TE-SAE leading to study treatment discontinuation	2 (4.9%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.80 (0.19, 74.60)	
P-value for Relative Risk	0.3424	
Heterogeneity p-value of RR	0.4911	
Risk difference (95% CI)	7.02 (-41.01, 55.05)	
P-value for Risk Difference	0.7714	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
TE-SAE	24 (18.5%)	14 (10.7%)
Odds ratio (95% CI)	1.956 (0.952, 4.020)	
P-value for Odds Ratio	0.0679	
Relative Risk (95% CI)	1.74 (0.94, 3.22)	
P-value for Relative Risk	0.0752	
Heterogeneity p-value of RR	0.8394	
Risk difference (95% CI)	9.83 (0.40, 19.26)	
P-value for Risk Difference	0.0411	
TE-SAE with any NCI grade 3/4/5	22 (16.9%)	10 (7.6%)
Odds ratio (95% CI)	2.552 (1.142, 5.703)	
P-value for Odds Ratio	0.0226	
Relative Risk (95% CI)	2.23 (1.10, 4.52)	
P-value for Relative Risk	0.0271	
Heterogeneity p-value of RR	0.7221	
Risk difference (95% CI)	10.63 (1.95, 19.31)	
P-value for Risk Difference	0.0166	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Participant with at least one	Cemiplimab (N=130)	Placebo (N=131)
Treatment-related TE-SAE	12 (9.2%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	6.95 (1.66, 29.03)	
P-value for Relative Risk	0.0017	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	13.21 (-38.02, 64.44)	
P-value for Risk Difference	0.6121	
TE-SAE leading to study treatment discontinuation	10 (7.7%)	1 (0.8%)
Odds ratio (95% CI)	11.055 (1.374, 88.940)	
P-value for Odds Ratio	0.0241	
Relative Risk (95% CI)	10.15 (1.30, 78.97)	
P-value for Relative Risk	0.0270	
Heterogeneity p-value of RR	0.3183	
Risk difference (95% CI)	8.37 (-2.65, 19.40)	
P-value for Risk Difference	0.1360	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
TE-SAE	14 (18.7%)	7 (9.6%)
Odds ratio (95% CI)	1.988 (0.730, 5.414)	
P-value for Odds Ratio	0.1776	
Relative Risk (95% CI)	1.74 (0.75, 4.07)	
P-value for Relative Risk	0.1966	
Heterogeneity p-value of RR	0.8394	
Risk difference (95% CI)	7.52 (-3.07, 18.11)	
P-value for Risk Difference	0.1627	
TE-SAE with any NCI grade 3/4/5	11 (14.7%)	6 (8.2%)
Odds ratio (95% CI)	1.696 (0.568, 5.066)	
P-value for Odds Ratio	0.3413	
Relative Risk (95% CI)	1.55 (0.61, 3.94)	
P-value for Relative Risk	0.3559	
Heterogeneity p-value of RR	0.7221	
Risk difference (95% CI)	4.69 (-5.19, 14.58)	
P-value for Risk Difference	0.3496	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Participant with at least one	Cemiplimab (N=75)	Placebo (N=73)
Treatment-related TE-SAE	1 (1.3%)	1 (1.4%)
Odds ratio (95% CI)	0.857 (0.047, 15.603)	
P-value for Odds Ratio	0.9165	
Relative Risk (95% CI)	0.87 (0.06, 12.81)	
P-value for Relative Risk	0.9165	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-0.29 (-17.78, 17.21)	
P-value for Risk Difference	0.9743	
TE-SAE leading to study treatment discontinuation	2 (2.7%)	1 (1.4%)
Odds ratio (95% CI)	2.214 (0.185, 26.491)	
P-value for Odds Ratio	0.5277	
Relative Risk (95% CI)	2.11 (0.20, 22.63)	
P-value for Relative Risk	0.5336	
Heterogeneity p-value of RR	0.3183	
Risk difference (95% CI)	2.16 (-11.17, 15.48)	
P-value for Risk Difference	0.7493	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Participant with at least one	Cemiplimab (N=123)	Placebo (N=116)
TE-SAE	23 (18.7%)	12 (10.3%)
Odds ratio (95% CI)	1.965 (0.914, 4.226)	
P-value for Odds Ratio	0.0835	
Relative Risk (95% CI)	1.80 (0.94, 3.46)	
P-value for Relative Risk	0.0762	
Heterogeneity p-value of RR	0.8611	
Risk difference (95% CI)	6.22 (-3.44, 15.87)	
P-value for Risk Difference	0.2058	
TE-SAE with any NCI grade 3/4/5	21 (17.1%)	9 (7.8%)
Odds ratio (95% CI)	2.403 (1.032, 5.592)	
P-value for Odds Ratio	0.0421	
Relative Risk (95% CI)	2.13 (1.01, 4.47)	
P-value for Relative Risk	0.0457	
Heterogeneity p-value of RR	0.6590	
Risk difference (95% CI)	7.30 (-1.56, 16.17)	
P-value for Risk Difference	0.1060	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Participant with at least one	Cemiplimab (N=82)	Placebo (N=88)
TE-SAE	15 (18.3%)	9 (10.2%)
Odds ratio (95% CI)	1.995 (0.811, 4.912)	
P-value for Odds Ratio	0.1319	
Relative Risk (95% CI)	1.79 (0.82, 3.89)	
P-value for Relative Risk	0.1428	
Heterogeneity p-value of RR	0.8611	
Risk difference (95% CI)	9.41 (-2.33, 21.15)	
P-value for Risk Difference	0.1154	
TE-SAE with any NCI grade 3/4/5	12 (14.6%)	7 (8.0%)
Odds ratio (95% CI)	1.976 (0.728, 5.363)	
P-value for Odds Ratio	0.1801	
Relative Risk (95% CI)	1.79 (0.74, 4.37)	
P-value for Relative Risk	0.1977	
Heterogeneity p-value of RR	0.6590	
Risk difference (95% CI)	8.29 (-2.02, 18.60)	
P-value for Risk Difference	0.1145	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
TE-SAE	30 (19.6%)	16 (10.5%)
Odds ratio (95% CI)	2.099 (1.085, 4.064)	
P-value for Odds Ratio	0.0279	
Relative Risk (95% CI)	1.87 (1.06, 3.30)	
P-value for Relative Risk	0.0300	
Heterogeneity p-value of RR	0.7806	
Risk difference (95% CI)	9.59 (1.60, 17.58)	
P-value for Risk Difference	0.0188	
TE-SAE with any NCI grade 3/4/5	25 (16.3%)	12 (7.9%)
Odds ratio (95% CI)	2.297 (1.100, 4.800)	
P-value for Odds Ratio	0.0271	
Relative Risk (95% CI)	2.06 (1.07, 3.97)	
P-value for Relative Risk	0.0297	
Heterogeneity p-value of RR	0.9452	
Risk difference (95% CI)	8.71 (1.54, 15.87)	
P-value for Risk Difference	0.0174	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Participant with at least one	Cemiplimab (N=153)	Placebo (N=152)
Treatment-related TE-SAE	11 (7.2%)	1 (0.7%)
Odds ratio (95% CI)	12.726 (1.595, 101.555)	
P-value for Odds Ratio	0.0166	
Relative Risk (95% CI)	11.22 (1.46, 86.09)	
P-value for Relative Risk	0.0202	
Heterogeneity p-value of RR	0.6884	
Risk difference (95% CI)	8.54 (-7.37, 24.44)	
P-value for Risk Difference	0.2916	
TE-SAE leading to study treatment discontinuation	10 (6.5%)	1 (0.7%)
Odds ratio (95% CI)	11.069 (1.379, 88.834)	
P-value for Odds Ratio	0.0238	
Relative Risk (95% CI)	10.13 (1.31, 78.51)	
P-value for Relative Risk	0.0269	
Heterogeneity p-value of RR	0.1896	
Risk difference (95% CI)	8.02 (-1.86, 17.90)	
P-value for Risk Difference	0.1111	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
TE-SAE	7 (17.5%)	5 (11.6%)
Odds ratio (95% CI)	1.780 (0.467, 6.779)	
P-value for Odds Ratio	0.3932	
Relative Risk (95% CI)	1.54 (0.55, 4.32)	
P-value for Relative Risk	0.4032	
Heterogeneity p-value of RR	0.7806	
Risk difference (95% CI)	-1.08 (-22.21, 20.05)	
P-value for Risk Difference	0.9190	
TE-SAE with any NCI grade 3/4/5	7 (17.5%)	4 (9.3%)
Odds ratio (95% CI)	2.524 (0.583, 10.921)	
P-value for Odds Ratio	0.2121	
Relative Risk (95% CI)	1.84 (0.61, 5.52)	
P-value for Relative Risk	0.2721	
Heterogeneity p-value of RR	0.9452	
Treatment-related TE-SAE	1 (2.5%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Participant with at least one	Cemiplimab (N=40)	Placebo (N=43)
Treatment-related TE-SAE		
Relative Risk (95% CI)	2.00 (0.11, 37.83)	
P-value for Relative Risk	0.6460	
Heterogeneity p-value of RR	0.6884	
Risk difference (95% CI)	3.99 (-107.10, 115.08)	
P-value for Risk Difference	0.9431	
TE-SAE leading to study treatment discontinuation	1 (2.5%)	1 (2.3%)
Odds ratio (95% CI)	0.855 (0.043, 17.019)	
P-value for Odds Ratio	0.9172	
Relative Risk (95% CI)	0.94 (0.06, 14.16)	
P-value for Relative Risk	0.9643	
Heterogeneity p-value of RR	0.1896	
Risk difference (95% CI)	-3.74 (-54.06, 46.57)	
P-value for Risk Difference	0.8826	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
TE-SAE	9 (23.7%)	3 (7.0%)
Odds ratio (95% CI)	4.306 (1.023, 18.122)	
P-value for Odds Ratio	0.0465	
Relative Risk (95% CI)	3.28 (0.93, 11.51)	
P-value for Relative Risk	0.0637	
Heterogeneity p-value of RR	0.2233	
Risk difference (95% CI)	20.23 (-5.00, 45.47)	
P-value for Risk Difference	0.1145	
TE-SAE with any NCI grade 3/4/5	8 (21.1%)	2 (4.7%)
Odds ratio (95% CI)	5.485 (1.032, 29.146)	
P-value for Odds Ratio	0.0459	
Relative Risk (95% CI)	4.15 (0.91, 18.87)	
P-value for Relative Risk	0.0655	
Heterogeneity p-value of RR	0.1900	
Risk difference (95% CI)	19.10 (-4.04, 42.25)	
P-value for Risk Difference	0.1044	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Participant with at least one	Cemiplimab (N=38)	Placebo (N=43)
Treatment-related TE-SAE	3 (7.9%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.62 (0.62, 21.32)	
P-value for Relative Risk	0.1322	
Heterogeneity p-value of RR	0.4267	
Risk difference (95% CI)	13.01 (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
TE-SAE	29 (17.4%)	18 (11.2%)
Odds ratio (95% CI)	1.632 (0.860, 3.098)	
P-value for Odds Ratio	0.1334	
Relative Risk (95% CI)	1.52 (0.88, 2.64)	
P-value for Relative Risk	0.1345	
Heterogeneity p-value of RR	0.2233	
Risk difference (95% CI)	5.77 (-1.86, 13.40)	
P-value for Risk Difference	0.1376	
TE-SAE with any NCI grade 3/4/5	25 (15.0%)	14 (8.7%)
Odds ratio (95% CI)	1.767 (0.873, 3.576)	
P-value for Odds Ratio	0.1129	
Relative Risk (95% CI)	1.64 (0.88, 3.05)	
P-value for Relative Risk	0.1202	
Heterogeneity p-value of RR	0.1900	
Risk difference (95% CI)	5.66 (-1.18, 12.51)	
P-value for Risk Difference	0.1045	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.2.1.1 Overview of Serious Treatment-Emergent Adverse Events (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Participant with at least one	Cemiplimab (N=167)	Placebo (N=161)
Treatment-related TE-SAE	10 (6.0%)	1 (0.6%)
Odds ratio (95% CI)	10.199 (1.271, 81.834)	
P-value for Odds Ratio	0.0289	
Relative Risk (95% CI)	9.42 (1.21, 73.51)	
P-value for Relative Risk	0.0324	
Heterogeneity p-value of RR	0.4267	
Risk difference (95% CI)	6.18 (-5.95, 18.30)	
P-value for Risk Difference	0.3170	

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. NCI grades were coded using CTCAE Version 5.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events.

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Skin and subcutaneous tissue disorders	33 (61.1%)	25 (38.5%)
Odds ratio (95% CI)	2.518 (1.188, 5.336)	
P-value for Odds Ratio	0.0164	
Relative Risk (95% CI)	1.61 (1.09, 2.36)	
P-value for Relative Risk	0.0166	
Heterogeneity p-value of RR	0.2349	
Risk difference (95% CI)	22.63 (4.87, 40.40)	
P-value for Risk Difference	0.0130	
Rash	12 (22.2%)	6 (9.2%)
Odds ratio (95% CI)	3.941 (1.200, 12.942)	
P-value for Odds Ratio	0.0242	
Relative Risk (95% CI)	3.10 (1.11, 8.61)	
P-value for Relative Risk	0.0307	
Heterogeneity p-value of RR	0.3881	
Risk difference (95% CI)	13.92 (-2.41, 30.24)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Rash		
P-value for Risk Difference	0.0940	
Rash maculo-papular	7 (13.0%)	2 (3.1%)
Odds ratio (95% CI)	5.642 (1.034, 30.781)	
P-value for Odds Ratio	0.0457	
Relative Risk (95% CI)	4.49 (0.98, 20.63)	
P-value for Relative Risk	0.0533	
Heterogeneity p-value of RR	0.2339	
Risk difference (95% CI)	10.60 (-4.09, 25.30)	
P-value for Risk Difference	0.1556	
Investigations	14 (25.9%)	13 (20.0%)
Odds ratio (95% CI)	1.375 (0.570, 3.313)	
P-value for Odds Ratio	0.4749	
Relative Risk (95% CI)	1.23 (0.63, 2.38)	
P-value for Relative Risk	0.5442	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Investigations		
Heterogeneity p-value of RR	0.3524	
Risk difference (95% CI)	6.17 (-9.42, 21.75)	
P-value for Risk Difference	0.4349	
Endocrine disorders	12 (22.2%)	3 (4.6%)
Odds ratio (95% CI)	6.029 (1.563, 23.259)	
P-value for Odds Ratio	0.0096	
Relative Risk (95% CI)	4.76 (1.40, 16.16)	
P-value for Relative Risk	0.0128	
Heterogeneity p-value of RR	0.6086	
Risk difference (95% CI)	18.29 (4.27, 32.30)	
P-value for Risk Difference	0.0110	
Hypothyroidism	10 (18.5%)	3 (4.6%)
Odds ratio (95% CI)	4.835 (1.215, 19.237)	
P-value for Odds Ratio	0.0257	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Hypothyroidism		
Relative Risk (95% CI)	3.96 (1.15, 13.70)	
P-value for Relative Risk	0.0298	
Heterogeneity p-value of RR	0.6127	
Risk difference (95% CI)	14.23 (0.44, 28.03)	
P-value for Risk Difference	0.0433	
Metabolism and nutrition disorders	5 (9.3%)	8 (12.3%)
Odds ratio (95% CI)	0.693 (0.205, 2.348)	
P-value for Odds Ratio	0.5532	
Relative Risk (95% CI)	0.75 (0.26, 2.14)	
P-value for Relative Risk	0.5863	
Heterogeneity p-value of RR	0.0493	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Skin and subcutaneous tissue disorders	82 (54.3%)	62 (44.6%)
Odds ratio (95% CI)	1.538 (0.951, 2.489)	
P-value for Odds Ratio	0.0792	
Relative Risk (95% CI)	1.22 (0.97, 1.53)	
P-value for Relative Risk	0.0928	
Heterogeneity p-value of RR	0.2349	
Risk difference (95% CI)	10.18 (-1.22, 21.57)	
P-value for Risk Difference	0.0798	
Rash	25 (16.6%)	13 (9.4%)
Odds ratio (95% CI)	1.855 (0.892, 3.861)	
P-value for Odds Ratio	0.0980	
Relative Risk (95% CI)	1.67 (0.89, 3.14)	
P-value for Relative Risk	0.1087	
Heterogeneity p-value of RR	0.3881	
Risk difference (95% CI)	7.38 (-0.62, 15.37)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Rash		
P-value for Risk Difference	0.0704	
Rash maculo-papular	18 (11.9%)	10 (7.2%)
Odds ratio (95% CI)	1.821 (0.783, 4.238)	
P-value for Odds Ratio	0.1636	
Relative Risk (95% CI)	1.63 (0.79, 3.38)	
P-value for Relative Risk	0.1855	
Heterogeneity p-value of RR	0.2339	
Risk difference (95% CI)	5.35 (-5.09, 15.79)	
P-value for Risk Difference	0.3141	
Investigations	28 (18.5%)	13 (9.4%)
Odds ratio (95% CI)	2.186 (1.068, 4.476)	
P-value for Odds Ratio	0.0325	
Relative Risk (95% CI)	1.94 (1.04, 3.60)	
P-value for Relative Risk	0.0366	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Investigations		
Heterogeneity p-value of RR	0.3524	
Risk difference (95% CI)	9.99 (1.29, 18.68)	
P-value for Risk Difference	0.0245	
Metabolism and nutrition disorders	26 (17.2%)	9 (6.5%)
Odds ratio (95% CI)	3.008 (1.339, 6.758)	
P-value for Odds Ratio	0.0078	
Relative Risk (95% CI)	2.63 (1.27, 5.45)	
P-value for Relative Risk	0.0094	
Heterogeneity p-value of RR	0.0493	
Risk difference (95% CI)	10.84 (2.68, 19.01)	
P-value for Risk Difference	0.0094	
Endocrine disorders	25 (16.6%)	7 (5.0%)
Odds ratio (95% CI)	3.748 (1.546, 9.084)	
P-value for Odds Ratio	0.0036	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 1: >=65

Primary System Organ Class Preferred Term	Cemiplimab (N=151)	Placebo (N=139)
Endocrine disorders		
Relative Risk (95% CI)	3.29 (1.46, 7.41)	
P-value for Relative Risk	0.0043	
Heterogeneity p-value of RR	0.6086	
Risk difference (95% CI)	11.12 (3.97, 18.27)	
P-value for Risk Difference	0.0024	
Hypothyroidism	18 (11.9%)	6 (4.3%)
Odds ratio (95% CI)	2.928 (1.109, 7.727)	
P-value for Odds Ratio	0.0302	
Relative Risk (95% CI)	2.68 (1.08, 6.62)	
P-value for Relative Risk	0.0327	
Heterogeneity p-value of RR	0.6127	
Risk difference (95% CI)	7.81 (0.58, 15.03)	
P-value for Risk Difference	0.0343	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Skin and subcutaneous tissue disorders	33 (61.1%)	25 (38.5%)
Odds ratio (95% CI)	2.518 (1.188, 5.336)	
P-value for Odds Ratio	0.0164	
Relative Risk (95% CI)	1.61 (1.09, 2.36)	
P-value for Relative Risk	0.0166	
Heterogeneity p-value of RR	0.4581	
Risk difference (95% CI)	22.63 (4.87, 40.40)	
P-value for Risk Difference	0.0130	
Rash	12 (22.2%)	6 (9.2%)
Odds ratio (95% CI)	3.941 (1.200, 12.942)	
P-value for Odds Ratio	0.0242	
Relative Risk (95% CI)	3.10 (1.11, 8.61)	
P-value for Relative Risk	0.0307	
Heterogeneity p-value of RR	0.6647	
Risk difference (95% CI)	13.92 (-2.41, 30.24)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Rash		
P-value for Risk Difference	0.0940	
Rash maculo-papular	7 (13.0%)	2 (3.1%)
Odds ratio (95% CI)	5.642 (1.034, 30.781)	
P-value for Odds Ratio	0.0457	
Relative Risk (95% CI)	4.49 (0.98, 20.63)	
P-value for Relative Risk	0.0533	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	10.60 (-4.09, 25.30)	
P-value for Risk Difference	0.1556	
Investigations	14 (25.9%)	13 (20.0%)
Odds ratio (95% CI)	1.375 (0.570, 3.313)	
P-value for Odds Ratio	0.4749	
Relative Risk (95% CI)	1.23 (0.63, 2.38)	
P-value for Relative Risk	0.5442	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Investigations		
Heterogeneity p-value of RR	0.2601	
Risk difference (95% CI)	6.17 (-9.42, 21.75)	
P-value for Risk Difference	0.4349	
Endocrine disorders	12 (22.2%)	3 (4.6%)
Odds ratio (95% CI)	6.029 (1.563, 23.259)	
P-value for Odds Ratio	0.0096	
Relative Risk (95% CI)	4.76 (1.40, 16.16)	
P-value for Relative Risk	0.0128	
Heterogeneity p-value of RR	0.3111	
Risk difference (95% CI)	18.29 (4.27, 32.30)	
P-value for Risk Difference	0.0110	
Hypothyroidism	10 (18.5%)	3 (4.6%)
Odds ratio (95% CI)	4.835 (1.215, 19.237)	
P-value for Odds Ratio	0.0257	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: <65

Primary System Organ Class Preferred Term	Cemiplimab (N=54)	Placebo (N=65)
Hypothyroidism		
Relative Risk (95% CI)	3.96 (1.15, 13.70)	
P-value for Relative Risk	0.0298	
Heterogeneity p-value of RR	0.8249	
Risk difference (95% CI)	14.23 (0.44, 28.03)	
P-value for Risk Difference	0.0433	
Metabolism and nutrition disorders	5 (9.3%)	8 (12.3%)
Odds ratio (95% CI)	0.693 (0.205, 2.348)	
P-value for Odds Ratio	0.5532	
Relative Risk (95% CI)	0.75 (0.26, 2.14)	
P-value for Relative Risk	0.5863	
Heterogeneity p-value of RR	0.0828	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Skin and subcutaneous tissue disorders	40 (50.0%)	27 (39.7%)
Odds ratio (95% CI)	1.758 (0.881, 3.508)	
P-value for Odds Ratio	0.1087	
Relative Risk (95% CI)	1.27 (0.88, 1.81)	
P-value for Relative Risk	0.1971	
Heterogeneity p-value of RR	0.4581	
Risk difference (95% CI)	14.90 (-1.34, 31.13)	
P-value for Risk Difference	0.0718	
Rash	12 (15.0%)	7 (10.3%)
Odds ratio (95% CI)	1.580 (0.568, 4.395)	
P-value for Odds Ratio	0.3780	
Relative Risk (95% CI)	1.47 (0.61, 3.54)	
P-value for Relative Risk	0.3921	
Heterogeneity p-value of RR	0.6647	
Risk difference (95% CI)	5.66 (-5.71, 17.03)	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Rash		
P-value for Risk Difference	0.3267	
Rash maculo-papular	10 (12.5%)	8 (11.8%)
Odds ratio (95% CI)	1.281 (0.458, 3.582)	
P-value for Odds Ratio	0.6346	
Relative Risk (95% CI)	1.21 (0.51, 2.86)	
P-value for Relative Risk	0.6692	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.79 (-12.32, 25.90)	
P-value for Risk Difference	0.4835	
Investigations	18 (22.5%)	5 (7.4%)
Odds ratio (95% CI)	3.457 (1.182, 10.111)	
P-value for Odds Ratio	0.0238	
Relative Risk (95% CI)	2.94 (1.14, 7.58)	
P-value for Relative Risk	0.0264	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Investigations		
Heterogeneity p-value of RR	0.2601	
Risk difference (95% CI)	15.55 (1.48, 29.62)	
P-value for Risk Difference	0.0306	
Endocrine disorders	12 (15.0%)	5 (7.4%)
Odds ratio (95% CI)	2.053 (0.666, 6.323)	
P-value for Odds Ratio	0.2085	
Relative Risk (95% CI)	1.90 (0.69, 5.21)	
P-value for Relative Risk	0.2130	
Heterogeneity p-value of RR	0.3111	
Risk difference (95% CI)	6.91 (-4.20, 18.01)	
P-value for Risk Difference	0.2208	
Hypothyroidism	12 (15.0%)	4 (5.9%)
Odds ratio (95% CI)	2.629 (0.785, 8.805)	
P-value for Odds Ratio	0.1162	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=65 and <75

Primary System Organ Class Preferred Term	Cemiplimab (N=80)	Placebo (N=68)
Hypothyroidism		
Relative Risk (95% CI)	2.38 (0.79, 7.18)	
P-value for Relative Risk	0.1232	
Heterogeneity p-value of RR	0.8249	
Risk difference (95% CI)	10.56 (-2.64, 23.77)	
P-value for Risk Difference	0.1160	
Metabolism and nutrition disorders	10 (12.5%)	5 (7.4%)
Odds ratio (95% CI)	1.936 (0.612, 6.121)	
P-value for Odds Ratio	0.2585	
Relative Risk (95% CI)	1.80 (0.64, 5.10)	
P-value for Relative Risk	0.2635	
Heterogeneity p-value of RR	0.0828	
Risk difference (95% CI)	6.96 (-4.04, 17.96)	
P-value for Risk Difference	0.2132	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Skin and subcutaneous tissue disorders	42 (59.2%)	35 (49.3%)
Odds ratio (95% CI)	1.392 (0.691, 2.805)	
P-value for Odds Ratio	0.3526	
Relative Risk (95% CI)	1.16 (0.86, 1.56)	
P-value for Relative Risk	0.3217	
Heterogeneity p-value of RR	0.4581	
Risk difference (95% CI)	7.91 (-8.45, 24.27)	
P-value for Risk Difference	0.3407	
Rash	13 (18.3%)	6 (8.5%)
Odds ratio (95% CI)	2.067 (0.704, 6.070)	
P-value for Odds Ratio	0.1848	
Relative Risk (95% CI)	1.83 (0.73, 4.60)	
P-value for Relative Risk	0.1986	
Heterogeneity p-value of RR	0.6647	
Risk difference (95% CI)	6.08 (-5.87, 18.03)	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Rash		
P-value for Risk Difference	0.3164	
Rash maculo-papular	8 (11.3%)	2 (2.8%)
Odds ratio (95% CI)	3.467 (0.634, 18.961)	
P-value for Odds Ratio	0.1502	
Relative Risk (95% CI)	3.07 (0.67, 14.10)	
P-value for Relative Risk	0.1472	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.14 (-15.31, 27.59)	
P-value for Risk Difference	0.5724	
Metabolism and nutrition disorders	16 (22.5%)	4 (5.6%)
Odds ratio (95% CI)	4.490 (1.377, 14.647)	
P-value for Odds Ratio	0.0132	
Relative Risk (95% CI)	3.62 (1.25, 10.47)	
P-value for Relative Risk	0.0178	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Metabolism and nutrition disorders		
Heterogeneity p-value of RR	0.0828	
Risk difference (95% CI)	15.59 (2.99, 28.19)	
P-value for Risk Difference	0.0157	
Endocrine disorders	13 (18.3%)	2 (2.8%)
Odds ratio (95% CI)	8.489 (1.782, 40.437)	
P-value for Odds Ratio	0.0076	
Relative Risk (95% CI)	7.04 (1.62, 30.61)	
P-value for Relative Risk	0.0096	
Heterogeneity p-value of RR	0.3111	
Risk difference (95% CI)	17.21 (2.73, 31.70)	
P-value for Risk Difference	0.0202	
Hypothyroidism	6 (8.5%)	2 (2.8%)
Odds ratio (95% CI)	3.460 (0.639, 18.728)	
P-value for Odds Ratio	0.1484	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Age group 2: >=75

Primary System Organ Class Preferred Term	Cemiplimab (N=71)	Placebo (N=71)
Hypothyroidism		
Relative Risk (95% CI)	3.17 (0.64, 15.70)	
P-value for Relative Risk	0.1553	
Heterogeneity p-value of RR	0.8249	
Risk difference (95% CI)	8.04 (-4.30, 20.39)	
P-value for Risk Difference	0.1999	
Investigations	10 (14.1%)	8 (11.3%)
Odds ratio (95% CI)	1.270 (0.451, 3.572)	
P-value for Odds Ratio	0.6488	
Relative Risk (95% CI)	1.13 (0.47, 2.74)	
P-value for Relative Risk	0.7820	
Heterogeneity p-value of RR	0.2601	
Risk difference (95% CI)	5.46 (-7.06, 17.99)	
P-value for Risk Difference	0.3900	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Skin and subcutaneous tissue disorders	98 (57.3%)	72 (41.9%)
Odds ratio (95% CI)	1.898 (1.227, 2.935)	
P-value for Odds Ratio	0.0041	
Relative Risk (95% CI)	1.36 (1.10, 1.69)	
P-value for Relative Risk	0.0055	
Heterogeneity p-value of RR	0.4327	
Risk difference (95% CI)	15.71 (5.27, 26.15)	
P-value for Risk Difference	0.0033	
Rash	32 (18.7%)	15 (8.7%)
Odds ratio (95% CI)	2.317 (1.193, 4.500)	
P-value for Odds Ratio	0.0133	
Relative Risk (95% CI)	2.06 (1.16, 3.66)	
P-value for Relative Risk	0.0140	
Heterogeneity p-value of RR	0.3654	
Risk difference (95% CI)	7.55 (0.26, 14.84)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Rash		
P-value for Risk Difference	0.0423	
Rash maculo-papular	24 (14.0%)	11 (6.4%)
Odds ratio (95% CI)	2.475 (1.145, 5.347)	
P-value for Odds Ratio	0.0213	
Relative Risk (95% CI)	2.16 (1.10, 4.22)	
P-value for Relative Risk	0.0250	
Heterogeneity p-value of RR	0.5164	
Risk difference (95% CI)	8.45 (-1.10, 17.99)	
P-value for Risk Difference	0.0826	
Investigations	34 (19.9%)	23 (13.4%)
Odds ratio (95% CI)	1.635 (0.911, 2.934)	
P-value for Odds Ratio	0.0991	
Relative Risk (95% CI)	1.48 (0.91, 2.40)	
P-value for Relative Risk	0.1127	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Investigations		
Heterogeneity p-value of RR	0.3758	
Risk difference (95% CI)	8.19 (0.25, 16.12)	
P-value for Risk Difference	0.0432	
Endocrine disorders	29 (17.0%)	6 (3.5%)
Odds ratio (95% CI)	5.656 (2.272, 14.079)	
P-value for Odds Ratio	0.0002	
Relative Risk (95% CI)	4.86 (2.06, 11.46)	
P-value for Relative Risk	0.0003	
Heterogeneity p-value of RR	0.2121	
Risk difference (95% CI)	14.11 (7.16, 21.06)	
P-value for Risk Difference	<0.0001	
Hypothyroidism	21 (12.3%)	5 (2.9%)
Odds ratio (95% CI)	4.721 (1.723, 12.932)	
P-value for Odds Ratio	0.0026	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Hypothyroidism		
Relative Risk (95% CI)	4.23 (1.63, 10.98)	
P-value for Relative Risk	0.0032	
Heterogeneity p-value of RR	0.2125	
Risk difference (95% CI)	10.20 (2.99, 17.41)	
P-value for Risk Difference	0.0057	
Metabolism and nutrition disorders	28 (16.4%)	13 (7.6%)
Odds ratio (95% CI)	2.450 (1.211, 4.959)	
P-value for Odds Ratio	0.0129	
Relative Risk (95% CI)	2.19 (1.17, 4.07)	
P-value for Relative Risk	0.0138	
Heterogeneity p-value of RR	0.1362	
Risk difference (95% CI)	8.43 (0.76, 16.10)	
P-value for Risk Difference	0.0314	
Hepatobiliary disorders	11 (6.4%)	2 (1.2%)

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Male

Primary System Organ Class Preferred Term	Cemiplimab (N=171)	Placebo (N=172)
Hepatobiliary disorders		
Odds ratio (95% CI)	5.951 (1.289, 27.477)	
P-value for Odds Ratio	0.0225	
Relative Risk (95% CI)	5.64 (1.26, 25.21)	
P-value for Relative Risk	0.0237	
Heterogeneity p-value of RR	0.9936	
Risk difference (95% CI)	6.12 (-2.97, 15.21)	
P-value for Risk Difference	0.1864	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Skin and subcutaneous tissue disorders	17 (50.0%)	15 (46.9%)
Odds ratio (95% CI)	1.213 (0.439, 3.347)	
P-value for Odds Ratio	0.7053	
Relative Risk (95% CI)	1.11 (0.68, 1.82)	
P-value for Relative Risk	0.6668	
Heterogeneity p-value of RR	0.4327	
Risk difference (95% CI)	4.50 (-19.96, 28.96)	
P-value for Risk Difference	0.7143	
Rash	5 (14.7%)	4 (12.5%)
Odds ratio (95% CI)	1.074 (0.222, 5.191)	
P-value for Odds Ratio	0.9276	
Relative Risk (95% CI)	1.02 (0.32, 3.21)	
P-value for Relative Risk	0.9759	
Heterogeneity p-value of RR	0.3654	
Risk difference (95% CI)	3.91 (-25.63, 33.45)	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Rash		
P-value for Risk Difference	0.7924	
Rash maculo-papular	1 (2.9%)	1 (3.1%)
Odds ratio (95% CI)	0.989 (0.055, 17.785)	
P-value for Odds Ratio	0.9938	
Relative Risk (95% CI)	0.98 (0.06, 15.68)	
P-value for Relative Risk	0.9889	
Heterogeneity p-value of RR	0.5164	
Risk difference (95% CI)	0.04 (-47.09, 47.18)	
P-value for Risk Difference	0.9985	
Endocrine disorders	8 (23.5%)	4 (12.5%)
Odds ratio (95% CI)	2.424 (0.598, 9.827)	
P-value for Odds Ratio	0.2107	
Relative Risk (95% CI)	2.31 (0.74, 7.22)	
P-value for Relative Risk	0.1461	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Endocrine disorders		
Heterogeneity p-value of RR	0.2121	
Risk difference (95% CI)	9.61 (-14.61, 33.82)	
P-value for Risk Difference	0.4308	
Hypothyroidism	7 (20.6%)	4 (12.5%)
Odds ratio (95% CI)	1.895 (0.464, 7.738)	
P-value for Odds Ratio	0.3672	
Relative Risk (95% CI)	1.82 (0.56, 5.93)	
P-value for Relative Risk	0.3163	
Heterogeneity p-value of RR	0.2125	
Risk difference (95% CI)	6.37 (-17.28, 30.02)	
P-value for Risk Difference	0.5922	
Investigations	8 (23.5%)	3 (9.4%)
Odds ratio (95% CI)	2.677 (0.609, 11.764)	
P-value for Odds Ratio	0.1883	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Investigations		
Relative Risk (95% CI)	2.25 (0.62, 8.15)	
P-value for Relative Risk	0.2138	
Heterogeneity p-value of RR	0.3758	
Risk difference (95% CI)	13.24 (-4.85, 31.33)	
P-value for Risk Difference	0.1484	
Metabolism and nutrition disorders	3 (8.8%)	4 (12.5%)
Odds ratio (95% CI)	0.671 (0.122, 3.698)	
P-value for Odds Ratio	0.6418	
Relative Risk (95% CI)	0.70 (0.16, 2.94)	
P-value for Relative Risk	0.6172	
Heterogeneity p-value of RR	0.1362	
Risk difference (95% CI)	-4.09 (-29.07, 20.89)	
P-value for Risk Difference	0.7444	
Hepatobiliary disorders	0	0

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Gender group: Female

Primary System Organ Class Preferred Term	Cemiplimab (N=34)	Placebo (N=32)
Hepatobiliary disorders		
Odds ratio (95% CI)	1.000 (0.000, NE)	
P-value for Odds Ratio	1.0000	
Relative Risk (95% CI)	1.00 (0.00, NE)	
P-value for Relative Risk	1.0000	
Heterogeneity p-value of RR	0.9936	
Risk difference (95% CI)	0.00 (NE, NE)	
P-value for Risk Difference	NE	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Skin and subcutaneous tissue disorders	21 (56.8%)	13 (41.9%)
Odds ratio (95% CI)	1.880 (0.696, 5.082)	
P-value for Odds Ratio	0.2094	
Relative Risk (95% CI)	1.35 (0.81, 2.25)	
P-value for Relative Risk	0.2384	
Heterogeneity p-value of RR	0.9774	
Risk difference (95% CI)	15.99 (-8.45, 40.43)	
P-value for Risk Difference	0.1959	
Rash	9 (24.3%)	4 (12.9%)
Odds ratio (95% CI)	1.983 (0.519, 7.574)	
P-value for Odds Ratio	0.3111	
Relative Risk (95% CI)	1.83 (0.62, 5.36)	
P-value for Relative Risk	0.2668	
Heterogeneity p-value of RR	0.5034	
Risk difference (95% CI)	7.75 (-10.75, 26.25)	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Rash		
P-value for Risk Difference	0.4056	
Rash maculo-papular	7 (18.9%)	2 (6.5%)
Odds ratio (95% CI)	3.780 (0.694, 20.578)	
P-value for Odds Ratio	0.1219	
Relative Risk (95% CI)	3.17 (0.70, 14.46)	
P-value for Relative Risk	0.1335	
Heterogeneity p-value of RR	0.1897	
Risk difference (95% CI)	13.92 (-3.36, 31.21)	
P-value for Risk Difference	0.1124	
Investigations	11 (29.7%)	4 (12.9%)
Odds ratio (95% CI)	3.009 (0.821, 11.030)	
P-value for Odds Ratio	0.0952	
Relative Risk (95% CI)	2.37 (0.82, 6.83)	
P-value for Relative Risk	0.1081	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Investigations		
Heterogeneity p-value of RR	0.4655	
Risk difference (95% CI)	18.10 (-2.63, 38.83)	
P-value for Risk Difference	0.0859	
Metabolism and nutrition disorders	8 (21.6%)	4 (12.9%)
Odds ratio (95% CI)	1.777 (0.462, 6.829)	
P-value for Odds Ratio	0.3969	
Relative Risk (95% CI)	1.63 (0.53, 5.02)	
P-value for Relative Risk	0.3850	
Heterogeneity p-value of RR	0.6401	
Risk difference (95% CI)	7.23 (-11.34, 25.80)	
P-value for Risk Difference	0.4395	
Endocrine disorders	6 (16.2%)	1 (3.2%)
Odds ratio (95% CI)	6.462 (0.699, 59.772)	
P-value for Odds Ratio	0.0987	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): North America

Primary System Organ Class Preferred Term	Cemiplimab (N=37)	Placebo (N=31)
Endocrine disorders		
Relative Risk (95% CI)	5.44 (0.67, 44.20)	
P-value for Relative Risk	0.1114	
Heterogeneity p-value of RR	0.7067	
Risk difference (95% CI)	14.30 (-0.90, 29.49)	
P-value for Risk Difference	0.0647	
Hypothyroidism	3 (8.1%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	6.36 (0.34, 118.18)	
P-value for Relative Risk	0.1494	
Heterogeneity p-value of RR	0.3317	
Risk difference (95% CI)	9.09 (-29.32, 47.50)	
P-value for Risk Difference	0.6382	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Skin and subcutaneous tissue disorders	56 (64.4%)	43 (48.3%)
Odds ratio (95% CI)	1.974 (1.070, 3.642)	
P-value for Odds Ratio	0.0298	
Relative Risk (95% CI)	1.33 (1.01, 1.73)	
P-value for Relative Risk	0.0388	
Heterogeneity p-value of RR	0.9774	
Risk difference (95% CI)	16.42 (1.88, 30.96)	
P-value for Risk Difference	0.0271	
Rash	18 (20.7%)	12 (13.5%)
Odds ratio (95% CI)	1.691 (0.755, 3.789)	
P-value for Odds Ratio	0.2004	
Relative Risk (95% CI)	1.55 (0.79, 3.03)	
P-value for Relative Risk	0.2025	
Heterogeneity p-value of RR	0.5034	
Risk difference (95% CI)	7.29 (-3.84, 18.43)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Rash		
P-value for Risk Difference	0.1978	
Rash maculo-papular	15 (17.2%)	10 (11.2%)
Odds ratio (95% CI)	1.648 (0.691, 3.929)	
P-value for Odds Ratio	0.2581	
Relative Risk (95% CI)	1.54 (0.73, 3.25)	
P-value for Relative Risk	0.2601	
Heterogeneity p-value of RR	0.1897	
Risk difference (95% CI)	6.02 (-4.36, 16.40)	
P-value for Risk Difference	0.2542	
Metabolism and nutrition disorders	16 (18.4%)	7 (7.9%)
Odds ratio (95% CI)	2.687 (1.037, 6.963)	
P-value for Odds Ratio	0.0420	
Relative Risk (95% CI)	2.36 (1.02, 5.48)	
P-value for Relative Risk	0.0461	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Metabolism and nutrition disorders		
Heterogeneity p-value of RR	0.6401	
Risk difference (95% CI)	11.63 (0.66, 22.60)	
P-value for Risk Difference	0.0379	
Investigations	15 (17.2%)	8 (9.0%)
Odds ratio (95% CI)	2.074 (0.823, 5.223)	
P-value for Odds Ratio	0.1210	
Relative Risk (95% CI)	1.87 (0.83, 4.23)	
P-value for Relative Risk	0.1306	
Heterogeneity p-value of RR	0.4655	
Risk difference (95% CI)	8.53 (-1.33, 18.38)	
P-value for Risk Difference	0.0894	
Endocrine disorders	13 (14.9%)	5 (5.6%)
Odds ratio (95% CI)	2.971 (1.002, 8.808)	
P-value for Odds Ratio	0.0496	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Australia/New Zealand

Primary System Organ Class Preferred Term	Cemiplimab (N=87)	Placebo (N=89)
Endocrine disorders		
Relative Risk (95% CI)	2.68 (0.99, 7.27)	
P-value for Relative Risk	0.0522	
Heterogeneity p-value of RR	0.7067	
Risk difference (95% CI)	9.42 (0.44, 18.39)	
P-value for Risk Difference	0.0399	
Hypothyroidism	10 (11.5%)	5 (5.6%)
Odds ratio (95% CI)	2.176 (0.705, 6.712)	
P-value for Odds Ratio	0.1750	
Relative Risk (95% CI)	2.04 (0.72, 5.78)	
P-value for Relative Risk	0.1783	
Heterogeneity p-value of RR	0.3317	
Risk difference (95% CI)	5.99 (-2.29, 14.27)	
P-value for Risk Difference	0.1551	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Skin and subcutaneous tissue disorders	38 (46.9%)	31 (36.9%)
Odds ratio (95% CI)	1.509 (0.804, 2.832)	
P-value for Odds Ratio	0.1984	
Relative Risk (95% CI)	1.27 (0.88, 1.83)	
P-value for Relative Risk	0.1995	
Heterogeneity p-value of RR	0.9774	
Risk difference (95% CI)	9.99 (-5.19, 25.18)	
P-value for Risk Difference	0.1957	
Rash	10 (12.3%)	3 (3.6%)
Odds ratio (95% CI)	3.479 (0.897, 13.498)	
P-value for Odds Ratio	0.0712	
Relative Risk (95% CI)	3.13 (0.89, 10.98)	
P-value for Relative Risk	0.0745	
Heterogeneity p-value of RR	0.5034	
Risk difference (95% CI)	5.94 (-2.32, 14.21)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Rash		
P-value for Risk Difference	0.1575	
Rash maculo-papular	3 (3.7%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	3.85 (0.46, 32.36)	
P-value for Relative Risk	0.1816	
Heterogeneity p-value of RR	0.1897	
Risk difference (95% CI)	3.96 (NE, NE)	
P-value for Risk Difference	NE	
Endocrine disorders	18 (22.2%)	4 (4.8%)
Odds ratio (95% CI)	5.524 (1.759, 17.353)	
P-value for Odds Ratio	0.0037	
Relative Risk (95% CI)	4.52 (1.58, 12.90)	
P-value for Relative Risk	0.0051	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Endocrine disorders		
Heterogeneity p-value of RR	0.7067	
Risk difference (95% CI)	16.79 (6.29, 27.28)	
P-value for Risk Difference	0.0019	
Hypothyroidism	15 (18.5%)	4 (4.8%)
Odds ratio (95% CI)	4.314 (1.345, 13.838)	
P-value for Odds Ratio	0.0143	
Relative Risk (95% CI)	3.69 (1.27, 10.72)	
P-value for Relative Risk	0.0169	
Heterogeneity p-value of RR	0.3317	
Risk difference (95% CI)	12.22 (2.11, 22.33)	
P-value for Risk Difference	0.0181	
Investigations	16 (19.8%)	14 (16.7%)
Odds ratio (95% CI)	1.270 (0.569, 2.838)	
P-value for Odds Ratio	0.5574	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Geographic region group (EDC): Rest of World

Primary System Organ Class Preferred Term	Cemiplimab (N=81)	Placebo (N=84)
Investigations		
Relative Risk (95% CI)	1.20 (0.63, 2.31)	
P-value for Relative Risk	0.5802	
Heterogeneity p-value of RR	0.4655	
Risk difference (95% CI)	4.72 (-7.52, 16.95)	
P-value for Risk Difference	0.4478	
Metabolism and nutrition disorders	7 (8.6%)	6 (7.1%)
Odds ratio (95% CI)	1.344 (0.423, 4.267)	
P-value for Odds Ratio	0.6140	
Relative Risk (95% CI)	1.30 (0.45, 3.70)	
P-value for Relative Risk	0.6255	
Heterogeneity p-value of RR	0.6401	
Risk difference (95% CI)	3.11 (-7.43, 13.66)	
P-value for Risk Difference	0.5607	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Skin and subcutaneous tissue disorders	107 (57.5%)	80 (42.8%)
Odds ratio (95% CI)	1.880 (1.233, 2.865)	
P-value for Odds Ratio	0.0034	
Relative Risk (95% CI)	1.36 (1.11, 1.66)	
P-value for Relative Risk	0.0035	
Heterogeneity p-value of RR	0.3176	
Risk difference (95% CI)	15.20 (5.18, 25.23)	
P-value for Risk Difference	0.0031	
Rash	35 (18.8%)	17 (9.1%)
Odds ratio (95% CI)	2.231 (1.184, 4.205)	
P-value for Odds Ratio	0.0132	
Relative Risk (95% CI)	1.96 (1.15, 3.37)	
P-value for Relative Risk	0.0143	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	7.61 (0.89, 14.32)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Rash		
P-value for Risk Difference	0.0265	
Rash maculo-papular	24 (12.9%)	12 (6.4%)
Odds ratio (95% CI)	2.251 (1.068, 4.744)	
P-value for Odds Ratio	0.0331	
Relative Risk (95% CI)	2.00 (1.04, 3.85)	
P-value for Relative Risk	0.0372	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	7.40 (-1.59, 16.38)	
P-value for Risk Difference	0.1064	
Investigations	37 (19.9%)	21 (11.2%)
Odds ratio (95% CI)	1.979 (1.099, 3.563)	
P-value for Odds Ratio	0.0231	
Relative Risk (95% CI)	1.78 (1.08, 2.93)	
P-value for Relative Risk	0.0238	

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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Investigations		
Heterogeneity p-value of RR	0.2118	
Risk difference (95% CI)	8.32 (1.03, 15.62)	
P-value for Risk Difference	0.0255	
Endocrine disorders	33 (17.7%)	9 (4.8%)
Odds ratio (95% CI)	4.246 (1.952, 9.237)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	3.67 (1.80, 7.49)	
P-value for Relative Risk	0.0004	
Heterogeneity p-value of RR	0.9768	
Risk difference (95% CI)	12.56 (6.08, 19.03)	
P-value for Risk Difference	0.0002	
Hypothyroidism	26 (14.0%)	8 (4.3%)
Odds ratio (95% CI)	3.583 (1.556, 8.251)	
P-value for Odds Ratio	0.0028	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Hypothyroidism		
Relative Risk (95% CI)	3.19 (1.47, 6.88)	
P-value for Relative Risk	0.0033	
Heterogeneity p-value of RR	0.7638	
Risk difference (95% CI)	9.57 (2.60, 16.54)	
P-value for Risk Difference	0.0073	
Hyperthyroidism	11 (5.9%)	2 (1.1%)
Odds ratio (95% CI)	5.462 (1.173, 25.436)	
P-value for Odds Ratio	0.0306	
Relative Risk (95% CI)	5.18 (1.15, 23.36)	
P-value for Relative Risk	0.0324	
Heterogeneity p-value of RR	0.5437	
Risk difference (95% CI)	4.34 (-0.89, 9.58)	
P-value for Risk Difference	0.1038	
Metabolism and nutrition disorders	28 (15.1%)	14 (7.5%)

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Metabolism and nutrition disorders		
Odds ratio (95% CI)	2.246 (1.131, 4.461)	
P-value for Odds Ratio	0.0210	
Relative Risk (95% CI)	2.03 (1.10, 3.74)	
P-value for Relative Risk	0.0228	
Heterogeneity p-value of RR	0.1679	
Risk difference (95% CI)	7.96 (0.68, 15.25)	
P-value for Risk Difference	0.0323	
Hepatobiliary disorders	11 (5.9%)	1 (0.5%)
Odds ratio (95% CI)	13.200 (1.669, 104.384)	
P-value for Odds Ratio	0.0146	
Relative Risk (95% CI)	12.26 (1.59, 94.48)	
P-value for Relative Risk	0.0163	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	7.09 (-2.33, 16.52)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: White

Primary System Organ Class Preferred Term	Cemiplimab (N=186)	Placebo (N=187)
Hepatobiliary disorders		
P-value for Risk Difference	0.1396	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Skin and subcutaneous tissue disorders	8 (42.1%)	7 (41.2%)
Odds ratio (95% CI)	1.185 (0.260, 5.391)	
P-value for Odds Ratio	0.8209	
Relative Risk (95% CI)	1.06 (0.42, 2.67)	
P-value for Relative Risk	0.8923	
Heterogeneity p-value of RR	0.3176	
Risk difference (95% CI)	3.84 (-31.52, 39.21)	
P-value for Risk Difference	0.8260	
Rash	2 (10.5%)	2 (11.8%)
Odds ratio (95% CI)	0.853 (0.088, 8.293)	
P-value for Odds Ratio	0.8875	
Relative Risk (95% CI)	0.79 (0.10, 6.26)	
P-value for Relative Risk	0.8181	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	4.41 (-23.32, 32.14)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Rash		
P-value for Risk Difference	0.7479	
Rash maculo-papular	1 (5.3%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.00 (0.09, 43.22)	
P-value for Relative Risk	0.6564	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	7.74 (NE, NE)	
P-value for Risk Difference	NE	
Investigations	5 (26.3%)	5 (29.4%)
Odds ratio (95% CI)	0.564 (0.103, 3.091)	
P-value for Odds Ratio	0.4977	
Relative Risk (95% CI)	0.64 (0.19, 2.19)	
P-value for Relative Risk	0.4617	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Investigations		
Heterogeneity p-value of RR	0.2118	
Risk difference (95% CI)	-13.51 (-46.46, 19.44)	
P-value for Risk Difference	0.4093	
Endocrine disorders	4 (21.1%)	1 (5.9%)
Odds ratio (95% CI)	3.310 (0.247, 44.303)	
P-value for Odds Ratio	0.3540	
Relative Risk (95% CI)	2.85 (0.29, 28.44)	
P-value for Relative Risk	0.3602	
Heterogeneity p-value of RR	0.9768	
Risk difference (95% CI)	16.54 (-59.43, 92.50)	
P-value for Risk Difference	0.6601	
Hypothyroidism	2 (10.5%)	1 (5.9%)
Odds ratio (95% CI)	2.092 (0.133, 32.964)	
P-value for Odds Ratio	0.5889	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Hypothyroidism		
Relative Risk (95% CI)	1.90 (0.16, 21.93)	
P-value for Relative Risk	0.5971	
Heterogeneity p-value of RR	0.7638	
Risk difference (95% CI)	8.92 (-68.82, 86.67)	
P-value for Risk Difference	0.8165	
Hyperthyroidism	1 (5.3%)	0
Odds ratio (95% CI)	1.000 (0.000, NE)	
P-value for Odds Ratio	1.0000	
Relative Risk (95% CI)	1.00 (0.10, 9.61)	
P-value for Relative Risk	1.0000	
Heterogeneity p-value of RR	0.5437	
Risk difference (95% CI)	0.00 (NE, NE)	
P-value for Risk Difference	NE	
Metabolism and nutrition disorders	3 (15.8%)	3 (17.6%)

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Metabolism and nutrition disorders		
Odds ratio (95% CI)	0.314 (0.035, 2.846)	
P-value for Odds Ratio	0.2922	
Relative Risk (95% CI)	0.46 (0.09, 2.28)	
P-value for Relative Risk	0.3267	
Heterogeneity p-value of RR	0.1679	
Risk difference (95% CI)	-18.55 (-54.81, 17.71)	
P-value for Risk Difference	0.3047	
Hepatobiliary disorders	0	1 (5.9%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	1.00 (0.05, 18.57)	
P-value for Relative Risk	1.0000	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-6.88 (-147.69, 133.94)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Race: Non-white

Primary System Organ Class Preferred Term	Cemiplimab (N=19)	Placebo (N=17)
Hepatobiliary disorders		
P-value for Risk Difference	0.9213	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Skin and subcutaneous tissue disorders	92 (56.1%)	79 (45.1%)
Odds ratio (95% CI)	1.550 (1.004, 2.395)	
P-value for Odds Ratio	0.0482	
Relative Risk (95% CI)	1.24 (1.01, 1.53)	
P-value for Relative Risk	0.0447	
Heterogeneity p-value of RR	0.1124	
Risk difference (95% CI)	10.69 (0.16, 21.23)	
P-value for Risk Difference	0.0467	
Rash	26 (15.9%)	17 (9.7%)
Odds ratio (95% CI)	1.728 (0.888, 3.362)	
P-value for Odds Ratio	0.1068	
Relative Risk (95% CI)	1.58 (0.90, 2.79)	
P-value for Relative Risk	0.1130	
Heterogeneity p-value of RR	0.2473	
Risk difference (95% CI)	5.09 (-1.30, 11.49)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Rash		
P-value for Risk Difference	0.1184	
Rash maculo-papular	22 (13.4%)	11 (6.3%)
Odds ratio (95% CI)	2.289 (1.053, 4.974)	
P-value for Odds Ratio	0.0366	
Relative Risk (95% CI)	2.03 (1.03, 4.01)	
P-value for Relative Risk	0.0417	
Heterogeneity p-value of RR	0.9662	
Risk difference (95% CI)	7.60 (-1.82, 17.01)	
P-value for Risk Difference	0.1133	
Investigations	34 (20.7%)	23 (13.1%)
Odds ratio (95% CI)	1.731 (0.964, 3.107)	
P-value for Odds Ratio	0.0661	
Relative Risk (95% CI)	1.56 (0.96, 2.53)	
P-value for Relative Risk	0.0716	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Investigations		
Heterogeneity p-value of RR	0.7805	
Risk difference (95% CI)	7.90 (0.10, 15.70)	
P-value for Risk Difference	0.0471	
Endocrine disorders	29 (17.7%)	8 (4.6%)
Odds ratio (95% CI)	4.497 (1.983, 10.197)	
P-value for Odds Ratio	0.0003	
Relative Risk (95% CI)	3.88 (1.82, 8.26)	
P-value for Relative Risk	0.0005	
Heterogeneity p-value of RR	0.7356	
Risk difference (95% CI)	13.14 (6.50, 19.79)	
P-value for Risk Difference	0.0001	
Hypothyroidism	20 (12.2%)	7 (4.0%)
Odds ratio (95% CI)	3.407 (1.393, 8.334)	
P-value for Odds Ratio	0.0074	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Hypothyroidism		
Relative Risk (95% CI)	3.09 (1.34, 7.12)	
P-value for Relative Risk	0.0084	
Heterogeneity p-value of RR	0.9648	
Risk difference (95% CI)	8.49 (1.84, 15.13)	
P-value for Risk Difference	0.0125	
Metabolism and nutrition disorders	26 (15.9%)	17 (9.7%)
Odds ratio (95% CI)	1.726 (0.895, 3.330)	
P-value for Odds Ratio	0.1029	
Relative Risk (95% CI)	1.61 (0.91, 2.86)	
P-value for Relative Risk	0.1025	
Heterogeneity p-value of RR	0.0583	
Risk difference (95% CI)	5.64 (-1.54, 12.83)	
P-value for Risk Difference	0.1233	
Hepatobiliary disorders	11 (6.7%)	1 (0.6%)

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=164)	Placebo (N=175)
Hepatobiliary disorders		
Odds ratio (95% CI)	12.392 (1.569, 97.886)	
P-value for Odds Ratio	0.0171	
Relative Risk (95% CI)	11.62 (1.51, 89.72)	
P-value for Relative Risk	0.0188	
Heterogeneity p-value of RR	0.0244	
Risk difference (95% CI)	6.49 (-1.07, 14.06)	
P-value for Risk Difference	0.0921	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Skin and subcutaneous tissue disorders	23 (56.1%)	8 (27.6%)
Odds ratio (95% CI)	3.411 (1.196, 9.727)	
P-value for Odds Ratio	0.0224	
Relative Risk (95% CI)	2.06 (1.07, 3.99)	
P-value for Relative Risk	0.0319	
Heterogeneity p-value of RR	0.1124	
Risk difference (95% CI)	29.25 (6.12, 52.38)	
P-value for Risk Difference	0.0140	
Rash	11 (26.8%)	2 (6.9%)
Odds ratio (95% CI)	4.749 (0.919, 24.542)	
P-value for Odds Ratio	0.0627	
Relative Risk (95% CI)	3.75 (0.88, 15.94)	
P-value for Relative Risk	0.0729	
Heterogeneity p-value of RR	0.2473	
Risk difference (95% CI)	17.07 (-0.00, 34.15)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Rash		
P-value for Risk Difference	0.0501	
Rash maculo-papular	3 (7.3%)	1 (3.4%)
Odds ratio (95% CI)	2.470 (0.220, 27.704)	
P-value for Odds Ratio	0.4577	
Relative Risk (95% CI)	2.18 (0.24, 19.72)	
P-value for Relative Risk	0.4824	
Heterogeneity p-value of RR	0.9662	
Risk difference (95% CI)	4.30 (-26.09, 34.69)	
P-value for Risk Difference	0.7786	
Endocrine disorders	8 (19.5%)	2 (6.9%)
Odds ratio (95% CI)	3.636 (0.677, 19.545)	
P-value for Odds Ratio	0.1302	
Relative Risk (95% CI)	3.08 (0.70, 13.61)	
P-value for Relative Risk	0.1354	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Endocrine disorders		
Heterogeneity p-value of RR	0.7356	
Risk difference (95% CI)	13.10 (-6.25, 32.45)	
P-value for Risk Difference	0.1812	
Hypothyroidism	8 (19.5%)	2 (6.9%)
Odds ratio (95% CI)	3.636 (0.677, 19.545)	
P-value for Odds Ratio	0.1302	
Relative Risk (95% CI)	3.08 (0.70, 13.61)	
P-value for Relative Risk	0.1354	
Heterogeneity p-value of RR	0.9648	
Risk difference (95% CI)	13.10 (-6.25, 32.45)	
P-value for Risk Difference	0.1812	
Investigations	8 (19.5%)	3 (10.3%)
Odds ratio (95% CI)	2.131 (0.497, 9.145)	
P-value for Odds Ratio	0.3036	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Investigations		
Relative Risk (95% CI)	1.87 (0.53, 6.62)	
P-value for Relative Risk	0.3262	
Heterogeneity p-value of RR	0.7805	
Risk difference (95% CI)	11.61 (-5.60, 28.82)	
P-value for Risk Difference	0.1825	
Metabolism and nutrition disorders	5 (12.2%)	0
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	2.85 (0.54, 15.20)	
P-value for Relative Risk	0.1940	
Heterogeneity p-value of RR	0.0583	
Risk difference (95% CI)	NE (NE, NE)	
P-value for Risk Difference	NE	
Hepatobiliary disorders	0	1 (3.4%)

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Anatomic region of resected high-risk tumor (EDC): Non Head and Neck

Primary System Organ Class Preferred Term	Cemiplimab (N=41)	Placebo (N=29)
Hepatobiliary disorders		
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.25 (0.01, 5.88)	
P-value for Relative Risk	0.3580	
Heterogeneity p-value of RR	0.0244	
Risk difference (95% CI)	-4.36 (NE, NE)	
P-value for Risk Difference	NE	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Skin and subcutaneous tissue disorders	76 (58.5%)	57 (43.5%)
Odds ratio (95% CI)	1.905 (1.153, 3.145)	
P-value for Odds Ratio	0.0120	
Relative Risk (95% CI)	1.33 (1.05, 1.70)	
P-value for Relative Risk	0.0203	
Heterogeneity p-value of RR	0.9304	
Risk difference (95% CI)	15.73 (3.75, 27.72)	
P-value for Risk Difference	0.0103	
Rash	22 (16.9%)	13 (9.9%)
Odds ratio (95% CI)	1.777 (0.839, 3.767)	
P-value for Odds Ratio	0.1328	
Relative Risk (95% CI)	1.61 (0.85, 3.05)	
P-value for Relative Risk	0.1399	
Heterogeneity p-value of RR	0.5149	
Risk difference (95% CI)	5.89 (-1.60, 13.37)	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Rash		
P-value for Risk Difference	0.1230	
Rash maculo-papular	20 (15.4%)	8 (6.1%)
Odds ratio (95% CI)	3.048 (1.249, 7.434)	
P-value for Odds Ratio	0.0145	
Relative Risk (95% CI)	2.54 (1.18, 5.46)	
P-value for Relative Risk	0.0176	
Heterogeneity p-value of RR	0.3038	
Risk difference (95% CI)	10.22 (-2.16, 22.61)	
P-value for Risk Difference	0.1054	
Investigations	30 (23.1%)	17 (13.0%)
Odds ratio (95% CI)	1.995 (1.031, 3.860)	
P-value for Odds Ratio	0.0404	
Relative Risk (95% CI)	1.77 (1.03, 3.06)	
P-value for Relative Risk	0.0404	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Investigations		
Heterogeneity p-value of RR	0.4937	
Risk difference (95% CI)	9.82 (0.40, 19.24)	
P-value for Risk Difference	0.0412	
Endocrine disorders	26 (20.0%)	8 (6.1%)
Odds ratio (95% CI)	3.778 (1.628, 8.766)	
P-value for Odds Ratio	0.0021	
Relative Risk (95% CI)	3.23 (1.51, 6.91)	
P-value for Relative Risk	0.0026	
Heterogeneity p-value of RR	0.5405	
Risk difference (95% CI)	13.52 (5.22, 21.83)	
P-value for Risk Difference	0.0015	
Hypothyroidism	20 (15.4%)	7 (5.3%)
Odds ratio (95% CI)	3.116 (1.255, 7.739)	
P-value for Odds Ratio	0.0145	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 0

Primary System Organ Class Preferred Term	Cemiplimab (N=130)	Placebo (N=131)
Hypothyroidism		
Relative Risk (95% CI)	2.79 (1.22, 6.37)	
P-value for Relative Risk	0.0155	
Heterogeneity p-value of RR	0.7064	
Risk difference (95% CI)	9.31 (0.84, 17.78)	
P-value for Risk Difference	0.0314	
Metabolism and nutrition disorders	19 (14.6%)	8 (6.1%)
Odds ratio (95% CI)	2.981 (1.230, 7.226)	
P-value for Odds Ratio	0.0158	
Relative Risk (95% CI)	2.60 (1.19, 5.67)	
P-value for Relative Risk	0.0169	
Heterogeneity p-value of RR	0.2478	
Risk difference (95% CI)	9.29 (0.41, 18.17)	
P-value for Risk Difference	0.0405	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Skin and subcutaneous tissue disorders	39 (52.0%)	30 (41.1%)
Odds ratio (95% CI)	1.538 (0.785, 3.010)	
P-value for Odds Ratio	0.2076	
Relative Risk (95% CI)	1.32 (0.94, 1.85)	
P-value for Relative Risk	0.1118	
Heterogeneity p-value of RR	0.9304	
Risk difference (95% CI)	9.71 (-6.29, 25.71)	
P-value for Risk Difference	0.2323	
Rash	15 (20.0%)	6 (8.2%)
Odds ratio (95% CI)	2.723 (0.961, 7.716)	
P-value for Odds Ratio	0.0592	
Relative Risk (95% CI)	2.30 (0.95, 5.56)	
P-value for Relative Risk	0.0650	
Heterogeneity p-value of RR	0.5149	
Risk difference (95% CI)	8.50 (-4.02, 21.03)	

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For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Rash		
P-value for Risk Difference	0.1817	
Rash maculo-papular	5 (6.7%)	4 (5.5%)
Odds ratio (95% CI)	1.189 (0.291, 4.863)	
P-value for Odds Ratio	0.8080	
Relative Risk (95% CI)	1.16 (0.33, 4.07)	
P-value for Relative Risk	0.8136	
Heterogeneity p-value of RR	0.3038	
Risk difference (95% CI)	3.28 (-12.66, 19.21)	
P-value for Risk Difference	0.6850	
Investigations	12 (16.0%)	9 (12.3%)
Odds ratio (95% CI)	1.393 (0.535, 3.626)	
P-value for Odds Ratio	0.4947	
Relative Risk (95% CI)	1.29 (0.58, 2.86)	
P-value for Relative Risk	0.5284	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Investigations		
Heterogeneity p-value of RR	0.4937	
Risk difference (95% CI)	6.18 (-6.26, 18.63)	
P-value for Risk Difference	0.3276	
Metabolism and nutrition disorders	12 (16.0%)	9 (12.3%)
Odds ratio (95% CI)	1.237 (0.470, 3.256)	
P-value for Odds Ratio	0.6645	
Relative Risk (95% CI)	1.25 (0.57, 2.74)	
P-value for Relative Risk	0.5701	
Heterogeneity p-value of RR	0.2478	
Risk difference (95% CI)	0.41 (-10.74, 11.55)	
P-value for Risk Difference	0.9426	
Endocrine disorders	11 (14.7%)	2 (2.7%)
Odds ratio (95% CI)	6.464 (1.350, 30.962)	
P-value for Odds Ratio	0.0199	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

ECOG status: 1

Primary System Organ Class Preferred Term	Cemiplimab (N=75)	Placebo (N=73)
Endocrine disorders		
Relative Risk (95% CI)	5.67 (1.29, 24.99)	
P-value for Relative Risk	0.0220	
Heterogeneity p-value of RR	0.5405	
Risk difference (95% CI)	12.83 (-0.09, 25.75)	
P-value for Risk Difference	0.0516	
Hypothyroidism	8 (10.7%)	2 (2.7%)
Odds ratio (95% CI)	4.711 (0.937, 23.686)	
P-value for Odds Ratio	0.0599	
Relative Risk (95% CI)	4.27 (0.93, 19.58)	
P-value for Relative Risk	0.0612	
Heterogeneity p-value of RR	0.7064	
Risk difference (95% CI)	7.84 (-3.43, 19.11)	
P-value for Risk Difference	0.1711	

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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Skin and subcutaneous tissue disorders	72 (58.5%)	47 (40.5%)
Odds ratio (95% CI)	2.242 (1.312, 3.831)	
P-value for Odds Ratio	0.0033	
Relative Risk (95% CI)	1.47 (1.13, 1.90)	
P-value for Relative Risk	0.0040	
Heterogeneity p-value of RR	0.2545	
Risk difference (95% CI)	19.32 (7.01, 31.62)	
P-value for Risk Difference	0.0022	
Rash	20 (16.3%)	11 (9.5%)
Odds ratio (95% CI)	1.796 (0.804, 4.011)	
P-value for Odds Ratio	0.1524	
Relative Risk (95% CI)	1.67 (0.84, 3.32)	
P-value for Relative Risk	0.1403	
Heterogeneity p-value of RR	0.6693	
Risk difference (95% CI)	4.17 (-4.07, 12.41)	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Rash		
P-value for Risk Difference	0.3194	
Rash maculo-papular	18 (14.6%)	9 (7.8%)
Odds ratio (95% CI)	2.195 (0.920, 5.237)	
P-value for Odds Ratio	0.0762	
Relative Risk (95% CI)	1.94 (0.92, 4.09)	
P-value for Relative Risk	0.0835	
Heterogeneity p-value of RR	0.7947	
Risk difference (95% CI)	8.52 (-3.58, 20.62)	
P-value for Risk Difference	0.1667	
Investigations	25 (20.3%)	16 (13.8%)
Odds ratio (95% CI)	1.600 (0.795, 3.221)	
P-value for Odds Ratio	0.1872	
Relative Risk (95% CI)	1.42 (0.80, 2.52)	
P-value for Relative Risk	0.2326	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Investigations		
Heterogeneity p-value of RR	0.5669	
Risk difference (95% CI)	7.77 (-1.34, 16.88)	
P-value for Risk Difference	0.0943	
Metabolism and nutrition disorders	20 (16.3%)	9 (7.8%)
Odds ratio (95% CI)	2.382 (1.019, 5.568)	
P-value for Odds Ratio	0.0452	
Relative Risk (95% CI)	2.10 (1.00, 4.42)	
P-value for Relative Risk	0.0507	
Heterogeneity p-value of RR	0.4796	
Risk difference (95% CI)	8.52 (-1.07, 18.10)	
P-value for Risk Difference	0.0814	
Endocrine disorders	19 (15.4%)	4 (3.4%)
Odds ratio (95% CI)	5.207 (1.695, 15.991)	
P-value for Odds Ratio	0.0041	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=123)	Placebo (N=116)
Endocrine disorders		
Relative Risk (95% CI)	4.53 (1.58, 13.00)	
P-value for Relative Risk	0.0052	
Heterogeneity p-value of RR	0.6535	
Risk difference (95% CI)	12.81 (4.04, 21.59)	
P-value for Risk Difference	0.0044	
Hypothyroidism	14 (11.4%)	3 (2.6%)
Odds ratio (95% CI)	5.004 (1.376, 18.201)	
P-value for Odds Ratio	0.0147	
Relative Risk (95% CI)	4.46 (1.31, 15.17)	
P-value for Relative Risk	0.0169	
Heterogeneity p-value of RR	0.4705	
Risk difference (95% CI)	9.84 (1.24, 18.44)	
P-value for Risk Difference	0.0250	

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Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Skin and subcutaneous tissue disorders	43 (52.4%)	40 (45.5%)
Odds ratio (95% CI)	1.298 (0.699, 2.410)	
P-value for Odds Ratio	0.4058	
Relative Risk (95% CI)	1.18 (0.87, 1.59)	
P-value for Relative Risk	0.2907	
Heterogeneity p-value of RR	0.2545	
Risk difference (95% CI)	6.24 (-8.72, 21.19)	
P-value for Risk Difference	0.4114	
Rash	17 (20.7%)	8 (9.1%)
Odds ratio (95% CI)	2.499 (0.993, 6.287)	
P-value for Odds Ratio	0.0518	
Relative Risk (95% CI)	2.13 (0.97, 4.67)	
P-value for Relative Risk	0.0580	
Heterogeneity p-value of RR	0.6693	
Risk difference (95% CI)	10.24 (-0.42, 20.90)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Rash		
P-value for Risk Difference	0.0597	
Rash maculo-papular	7 (8.5%)	3 (3.4%)
Odds ratio (95% CI)	2.486 (0.586, 10.549)	
P-value for Odds Ratio	0.2152	
Relative Risk (95% CI)	2.22 (0.61, 8.12)	
P-value for Relative Risk	0.2268	
Heterogeneity p-value of RR	0.7947	
Risk difference (95% CI)	4.52 (-9.42, 18.45)	
P-value for Risk Difference	0.5231	
Endocrine disorders	18 (22.0%)	6 (6.8%)
Odds ratio (95% CI)	3.865 (1.427, 10.467)	
P-value for Odds Ratio	0.0081	
Relative Risk (95% CI)	3.12 (1.29, 7.55)	
P-value for Relative Risk	0.0117	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Endocrine disorders		
Heterogeneity p-value of RR	0.6535	
Risk difference (95% CI)	16.26 (4.57, 27.95)	
P-value for Risk Difference	0.0067	
Hypothyroidism	14 (17.1%)	6 (6.8%)
Odds ratio (95% CI)	2.813 (1.003, 7.886)	
P-value for Odds Ratio	0.0493	
Relative Risk (95% CI)	2.38 (0.96, 5.93)	
P-value for Relative Risk	0.0615	
Heterogeneity p-value of RR	0.4705	
Risk difference (95% CI)	11.33 (0.08, 22.57)	
P-value for Risk Difference	0.0484	
Investigations	17 (20.7%)	10 (11.4%)
Odds ratio (95% CI)	2.014 (0.852, 4.764)	
P-value for Odds Ratio	0.1101	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

High risk feature: Non-Nodal

Primary System Organ Class Preferred Term	Cemiplimab (N=82)	Placebo (N=88)
Investigations		
Relative Risk (95% CI)	1.82 (0.88, 3.75)	
P-value for Relative Risk	0.1046	
Heterogeneity p-value of RR	0.5669	
Risk difference (95% CI)	8.35 (-2.78, 19.48)	
P-value for Risk Difference	0.1404	
Metabolism and nutrition disorders	11 (13.4%)	8 (9.1%)
Odds ratio (95% CI)	1.518 (0.569, 4.051)	
P-value for Odds Ratio	0.4024	
Relative Risk (95% CI)	1.45 (0.61, 3.42)	
P-value for Relative Risk	0.3965	
Heterogeneity p-value of RR	0.4796	
Risk difference (95% CI)	5.04 (-5.81, 15.89)	
P-value for Risk Difference	0.3601	

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TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Skin and subcutaneous tissue disorders	86 (56.2%)	69 (45.4%)
Odds ratio (95% CI)	1.583 (0.999, 2.507)	
P-value for Odds Ratio	0.0504	
Relative Risk (95% CI)	1.23 (0.99, 1.54)	
P-value for Relative Risk	0.0648	
Heterogeneity p-value of RR	0.1012	
Risk difference (95% CI)	11.15 (0.02, 22.28)	
P-value for Risk Difference	0.0496	
Rash	26 (17.0%)	14 (9.2%)
Odds ratio (95% CI)	1.987 (0.981, 4.024)	
P-value for Odds Ratio	0.0566	
Relative Risk (95% CI)	1.80 (0.98, 3.31)	
P-value for Relative Risk	0.0569	
Heterogeneity p-value of RR	0.7951	
Risk difference (95% CI)	6.25 (-1.14, 13.64)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Rash		
P-value for Risk Difference	0.0970	
Rash maculo-papular	18 (11.8%)	11 (7.2%)
Odds ratio (95% CI)	1.765 (0.785, 3.968)	
P-value for Odds Ratio	0.1687	
Relative Risk (95% CI)	1.60 (0.79, 3.24)	
P-value for Relative Risk	0.1921	
Heterogeneity p-value of RR	0.1379	
Risk difference (95% CI)	4.87 (-5.23, 14.96)	
P-value for Risk Difference	0.3436	
Investigations	34 (22.2%)	19 (12.5%)
Odds ratio (95% CI)	2.037 (1.092, 3.800)	
P-value for Odds Ratio	0.0254	
Relative Risk (95% CI)	1.77 (1.06, 2.96)	
P-value for Relative Risk	0.0288	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Investigations		
Heterogeneity p-value of RR	0.4623	
Risk difference (95% CI)	10.32 (1.69, 18.95)	
P-value for Risk Difference	0.0192	
Endocrine disorders	29 (19.0%)	5 (3.3%)
Odds ratio (95% CI)	7.053 (2.625, 18.949)	
P-value for Odds Ratio	0.0001	
Relative Risk (95% CI)	5.82 (2.31, 14.66)	
P-value for Relative Risk	0.0002	
Heterogeneity p-value of RR	0.0404	
Risk difference (95% CI)	14.97 (7.81, 22.13)	
P-value for Risk Difference	<0.0001	
Hypothyroidism	21 (13.7%)	4 (2.6%)
Odds ratio (95% CI)	6.000 (1.983, 18.157)	
P-value for Odds Ratio	0.0016	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Hypothyroidism		
Relative Risk (95% CI)	5.19 (1.82, 14.78)	
P-value for Relative Risk	0.0021	
Heterogeneity p-value of RR	0.0708	
Risk difference (95% CI)	10.98 (3.61, 18.35)	
P-value for Risk Difference	0.0036	
Hyperthyroidism	10 (6.5%)	1 (0.7%)
Odds ratio (95% CI)	10.340 (1.291, 82.811)	
P-value for Odds Ratio	0.0279	
Relative Risk (95% CI)	9.73 (1.25, 75.69)	
P-value for Relative Risk	0.0299	
Heterogeneity p-value of RR	0.0424	
Risk difference (95% CI)	6.02 (-2.85, 14.88)	
P-value for Risk Difference	0.1826	
Metabolism and nutrition disorders	26 (17.0%)	11 (7.2%)

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Metabolism and nutrition disorders		
Odds ratio (95% CI)	2.751 (1.291, 5.864)	
P-value for Odds Ratio	0.0089	
Relative Risk (95% CI)	2.41 (1.24, 4.68)	
P-value for Relative Risk	0.0100	
Heterogeneity p-value of RR	0.0295	
Risk difference (95% CI)	9.16 (0.72, 17.60)	
P-value for Risk Difference	0.0336	
Hepatobiliary disorders	10 (6.5%)	1 (0.7%)
Odds ratio (95% CI)	10.989 (1.374, 87.884)	
P-value for Odds Ratio	0.0240	
Relative Risk (95% CI)	10.38 (1.33, 80.81)	
P-value for Relative Risk	0.0256	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	6.85 (-15.79, 29.49)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS>=1%

Primary System Organ Class Preferred Term	Cemiplimab (N=153)	Placebo (N=152)
Hepatobiliary disorders		
P-value for Risk Difference	0.5521	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Skin and subcutaneous tissue disorders	25 (62.5%)	15 (34.9%)
Odds ratio (95% CI)	3.191 (1.212, 8.399)	
P-value for Odds Ratio	0.0194	
Relative Risk (95% CI)	1.75 (1.09, 2.81)	
P-value for Relative Risk	0.0211	
Heterogeneity p-value of RR	0.1012	
Risk difference (95% CI)	24.60 (3.60, 45.61)	
P-value for Risk Difference	0.0223	
Rash	10 (25.0%)	5 (11.6%)
Odds ratio (95% CI)	2.492 (0.701, 8.854)	
P-value for Odds Ratio	0.1557	
Relative Risk (95% CI)	1.94 (0.74, 5.05)	
P-value for Relative Risk	0.1738	
Heterogeneity p-value of RR	0.7951	
Risk difference (95% CI)	10.65 (-10.33, 31.62)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Rash		
P-value for Risk Difference	0.3153	
Rash maculo-papular	6 (15.0%)	1 (2.3%)
Odds ratio (95% CI)	7.382 (0.761, 71.640)	
P-value for Odds Ratio	0.0838	
Relative Risk (95% CI)	5.89 (0.74, 46.74)	
P-value for Relative Risk	0.0924	
Heterogeneity p-value of RR	0.1379	
Risk difference (95% CI)	16.61 (-40.09, 73.31)	
P-value for Risk Difference	0.5613	
Endocrine disorders	4 (10.0%)	4 (9.3%)
Odds ratio (95% CI)	1.152 (0.254, 5.221)	
P-value for Odds Ratio	0.8530	
Relative Risk (95% CI)	1.16 (0.31, 4.33)	
P-value for Relative Risk	0.8243	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
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Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Endocrine disorders		
Heterogeneity p-value of RR	0.0404	
Risk difference (95% CI)	-0.12 (-15.73, 15.49)	
P-value for Risk Difference	0.9878	
Hypothyroidism	4 (10.0%)	4 (9.3%)
Odds ratio (95% CI)	1.152 (0.254, 5.221)	
P-value for Odds Ratio	0.8530	
Relative Risk (95% CI)	1.16 (0.31, 4.33)	
P-value for Relative Risk	0.8243	
Heterogeneity p-value of RR	0.0708	
Risk difference (95% CI)	-0.12 (-15.73, 15.49)	
P-value for Risk Difference	0.9878	
Hyperthyroidism	0	1 (2.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
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Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Hyperthyroidism		
Relative Risk (95% CI)	0.41 (0.02, 9.25)	
P-value for Relative Risk	0.5658	
Heterogeneity p-value of RR	0.0424	
Risk difference (95% CI)	-4.38 (-62.49, 53.73)	
P-value for Risk Difference	0.8811	
Investigations	4 (10.0%)	4 (9.3%)
Odds ratio (95% CI)	1.271 (0.280, 5.779)	
P-value for Odds Ratio	0.7532	
Relative Risk (95% CI)	1.21 (0.32, 4.53)	
P-value for Relative Risk	0.7729	
Heterogeneity p-value of RR	0.4623	
Risk difference (95% CI)	1.23 (-12.56, 15.03)	
P-value for Risk Difference	0.8590	
Metabolism and nutrition disorders	2 (5.0%)	5 (11.6%)

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Metabolism and nutrition disorders		
Odds ratio (95% CI)	0.315 (0.050, 1.979)	
P-value for Odds Ratio	0.2147	
Relative Risk (95% CI)	0.37 (0.08, 1.79)	
P-value for Relative Risk	0.2129	
Heterogeneity p-value of RR	0.0295	
Risk difference (95% CI)	-9.42 (-31.98, 13.14)	
P-value for Risk Difference	0.4083	
Hepatobiliary disorders	0	1 (2.3%)
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	0.41 (0.02, 9.25)	
P-value for Relative Risk	0.5658	
Heterogeneity p-value of RR	NE	
Risk difference (95% CI)	-4.38 (-62.49, 53.73)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

PD-L1 Protein Expression: TPS<1%

Primary System Organ Class Preferred Term	Cemiplimab (N=40)	Placebo (N=43)
Hepatobiliary disorders		
P-value for Risk Difference	0.8811	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Skin and subcutaneous tissue disorders	21 (55.3%)	21 (48.8%)
Odds ratio (95% CI)	1.303 (0.500, 3.399)	
P-value for Odds Ratio	0.5841	
Relative Risk (95% CI)	1.18 (0.80, 1.74)	
P-value for Relative Risk	0.4075	
Heterogeneity p-value of RR	0.6015	
Risk difference (95% CI)	5.67 (-15.63, 26.98)	
P-value for Risk Difference	0.5975	
Rash maculo-papular	7 (18.4%)	4 (9.3%)
Odds ratio (95% CI)	2.583 (0.594, 11.234)	
P-value for Odds Ratio	0.2026	
Relative Risk (95% CI)	1.96 (0.67, 5.73)	
P-value for Relative Risk	0.2175	
Heterogeneity p-value of RR	0.9842	
Risk difference (95% CI)	9.60 (-19.79, 38.98)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Rash maculo-papular		
P-value for Risk Difference	0.5174	
Rash	5 (13.2%)	2 (4.7%)
Odds ratio (95% CI)	2.932 (0.509, 16.892)	
P-value for Odds Ratio	0.2250	
Relative Risk (95% CI)	2.65 (0.54, 13.07)	
P-value for Relative Risk	0.2267	
Heterogeneity p-value of RR	0.5580	
Risk difference (95% CI)	10.90 (-10.22, 32.01)	
P-value for Risk Difference	0.3073	
Endocrine disorders	10 (26.3%)	2 (4.7%)
Odds ratio (95% CI)	7.306 (1.412, 37.793)	
P-value for Odds Ratio	0.0184	
Relative Risk (95% CI)	5.11 (1.16, 22.54)	
P-value for Relative Risk	0.0316	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Endocrine disorders		
Heterogeneity p-value of RR	0.5203	
Risk difference (95% CI)	25.59 (1.93, 49.25)	
P-value for Risk Difference	0.0344	
Hypothyroidism	8 (21.1%)	2 (4.7%)
Odds ratio (95% CI)	5.268 (0.994, 27.926)	
P-value for Odds Ratio	0.0508	
Relative Risk (95% CI)	4.01 (0.88, 18.33)	
P-value for Relative Risk	0.0727	
Heterogeneity p-value of RR	0.6244	
Risk difference (95% CI)	19.60 (-2.98, 42.18)	
P-value for Risk Difference	0.0879	
Investigations	8 (21.1%)	7 (16.3%)
Odds ratio (95% CI)	1.444 (0.455, 4.588)	
P-value for Odds Ratio	0.5284	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Investigations		
Relative Risk (95% CI)	1.34 (0.53, 3.39)	
P-value for Relative Risk	0.5259	
Heterogeneity p-value of RR	0.6497	
Risk difference (95% CI)	6.09 (-11.58, 23.76)	
P-value for Risk Difference	0.4946	
Metabolism and nutrition disorders	7 (18.4%)	4 (9.3%)
Odds ratio (95% CI)	2.384 (0.611, 9.299)	
P-value for Odds Ratio	0.2075	
Relative Risk (95% CI)	2.07 (0.65, 6.54)	
P-value for Relative Risk	0.2131	
Heterogeneity p-value of RR	0.8104	
Risk difference (95% CI)	9.38 (-9.69, 28.45)	
P-value for Risk Difference	0.3303	
Hepatobiliary disorders	1 (2.6%)	0

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W only

Primary System Organ Class Preferred Term	Cemiplimab (N=38)	Placebo (N=43)
Hepatobiliary disorders		
Odds ratio (95% CI)	NE (NE, NE)	
P-value for Odds Ratio	NE	
Relative Risk (95% CI)	4.00 (0.20, 82.01)	
P-value for Relative Risk	0.3390	
Heterogeneity p-value of RR	0.5210	
Risk difference (95% CI)	6.92 (-68.85, 82.69)	
P-value for Risk Difference	0.8562	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Skin and subcutaneous tissue disorders	94 (56.3%)	66 (41.0%)
Odds ratio (95% CI)	1.833 (1.172, 2.867)	
P-value for Odds Ratio	0.0081	
Relative Risk (95% CI)	1.34 (1.07, 1.69)	
P-value for Relative Risk	0.0108	
Heterogeneity p-value of RR	0.6015	
Risk difference (95% CI)	14.72 (4.01, 25.43)	
P-value for Risk Difference	0.0072	
Rash	32 (19.2%)	17 (10.6%)
Odds ratio (95% CI)	1.853 (0.964, 3.563)	
P-value for Odds Ratio	0.0644	
Relative Risk (95% CI)	1.65 (0.96, 2.83)	
P-value for Relative Risk	0.0704	
Heterogeneity p-value of RR	0.5580	
Risk difference (95% CI)	5.50 (-1.60, 12.60)	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Rash		
P-value for Risk Difference	0.1283	
Rash maculo-papular	18 (10.8%)	8 (5.0%)
Odds ratio (95% CI)	2.215 (0.913, 5.374)	
P-value for Odds Ratio	0.0783	
Relative Risk (95% CI)	2.02 (0.91, 4.50)	
P-value for Relative Risk	0.0838	
Heterogeneity p-value of RR	0.9842	
Risk difference (95% CI)	4.99 (-4.34, 14.32)	
P-value for Risk Difference	0.2931	
Investigations	34 (20.4%)	19 (11.8%)
Odds ratio (95% CI)	1.925 (1.037, 3.574)	
P-value for Odds Ratio	0.0382	
Relative Risk (95% CI)	1.70 (1.01, 2.86)	
P-value for Relative Risk	0.0443	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Investigations		
Heterogeneity p-value of RR	0.6497	
Risk difference (95% CI)	9.13 (1.37, 16.88)	
P-value for Risk Difference	0.0212	
Endocrine disorders	27 (16.2%)	8 (5.0%)
Odds ratio (95% CI)	3.798 (1.651, 8.735)	
P-value for Odds Ratio	0.0018	
Relative Risk (95% CI)	3.31 (1.55, 7.09)	
P-value for Relative Risk	0.0021	
Heterogeneity p-value of RR	0.5203	
Risk difference (95% CI)	10.58 (3.89, 17.27)	
P-value for Risk Difference	0.0020	
Hypothyroidism	20 (12.0%)	7 (4.3%)
Odds ratio (95% CI)	3.125 (1.268, 7.707)	
P-value for Odds Ratio	0.0135	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Hypothyroidism		
Relative Risk (95% CI)	2.83 (1.23, 6.51)	
P-value for Relative Risk	0.0148	
Heterogeneity p-value of RR	0.6244	
Risk difference (95% CI)	7.55 (0.64, 14.46)	
P-value for Risk Difference	0.0324	
Metabolism and nutrition disorders	24 (14.4%)	13 (8.1%)
Odds ratio (95% CI)	1.890 (0.916, 3.899)	
P-value for Odds Ratio	0.0849	
Relative Risk (95% CI)	1.74 (0.92, 3.31)	
P-value for Relative Risk	0.0891	
Heterogeneity p-value of RR	0.8104	
Risk difference (95% CI)	6.39 (-1.16, 13.95)	
P-value for Risk Difference	0.0967	
Hepatobiliary disorders	10 (6.0%)	2 (1.2%)

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.1.2.1 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Dosing Regimen: 350 mg Q3W + 700 mg Q6W

Primary System Organ Class Preferred Term	Cemiplimab (N=167)	Placebo (N=161)
Hepatobiliary disorders		
Odds ratio (95% CI)	5.331 (1.138, 24.981)	
P-value for Odds Ratio	0.0338	
Relative Risk (95% CI)	5.08 (1.12, 23.00)	
P-value for Relative Risk	0.0350	
Heterogeneity p-value of RR	0.5210	
Risk difference (95% CI)	5.68 (-2.33, 13.69)	
P-value for Risk Difference	0.1643	

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.5.2.1 Treatment-Emergent Adverse Events with Grade >=3 by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)

No record met criteria

Data cut-off as of April 07, 2025. All adverse events were coded using MedDRA Version 27.0.
TEAE: Treatment-emergent adverse event. A patient is counted only once for multiple occurrences within a system organ class/preferred term.
For SOCs, the table is sorted by decreasing frequency of all grades in the cemiplimab group. Within each SOC, PTs are sorted by decreasing frequency of all grades in the cemiplimab group.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).

Table 14.3.2.2.1 Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term (Part 1) by Subgroup
(Safety Analysis Set)

Primary System Organ Class Preferred Term	Cemiplimab (N=205)	Placebo (N=204)

No record met criteria

Data cut-off as of April 07, 2025.
TEAE: Treatment-emergent adverse event. All adverse events were coded using MedDRA Version 27.0.
A patient is counted only once for multiple occurrences within a system organ class/preferred term.
Odds ratio and relative risk and risk difference were derived from logistic regression, adjusting for the following stratification factors: high-risk tumor (HN vs non-HN; except when subgroup was high-risk tumor) and geographical region (North America vs Australia/New Zealand vs ROW; except when subgroup was geographical region).
Subgroup analyses were performed only when all of the following criteria were met: (1) each subgroup contained >=10 patients per treatment arm; (2) at least one subgroup in any treatment arm had >=10 events, and (3) the main analysis showed statistically significant relative risk ($p<0.05$).